

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levisse

**Form:** COHORT SELECTION

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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**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                        | 30 JUN 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:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** MAIN INFORMED CONSENT

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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**Informed Consent**

|    |              |  |
|----|--------------|--|
| 1. | Consent Was: | OBTAINED<br>Date Written Consent Obtained<br>Jul/30/2020 |
|----|--------------|--|

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

**Form Version:** 06-Jul-2020 21:55

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

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Demography**

|    |                                 |  |
|----|---------------------------------|--|
| 1. | Subject ID                      | [10011100]                                     |
| 2. | Birth Date:                     | (b) (6) /1951                                  |
| 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:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levisse

**Form:** DATE OF VISIT

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

| Date of Visit |                 |             |
|---------------|-----------------|-------------|
| 1.            | Date of Visit   | Jul/30/2020 |
| 2.            | Erroneous Visit |             |

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 17-Jul-2020 21:53**Site No:** 1001**Subject No:** 10011100**Generated By:** pfe.levissc**Form:** INCLUSION/EXCLUSION CRITERIA**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1001) NYU Langone Health**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[eCRF Audit Trail History](#)

Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclusion criteria (NO).

**Inclusion Criteria**

|     |                                     |  |
|-----|-------------------------------------|--|
| 1.a | Inclusion Number:                   | 1  |
|     | Criterion Description:              | Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage) |
|     | Criterion met?                      | YES  |
|     | Criterion ID: (For Pfizer use only) | IN01A00  |
| 1.b | Inclusion Number:                   | 2  |
|     | Criterion Description:              | Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures                  |
|     | Criterion met?                      | YES  |
|     | Criterion ID: (For Pfizer use only) | IN02A00  |
| 1.c | Inclusion Number:                   | 3  |
|     | Criterion Description:              | Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study                |
|     | Criterion met?                      | YES  |
|     | Criterion ID: (For Pfizer use only) | IN03A00  |
| 1.d | Inclusion Number:                   | 4  |
|     | Criterion Description:              | Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol                          |
|     | Criterion met?                      | YES  |
|     | Criterion ID: (For Pfizer use only) | IN04A00  |

**Exclusion Criteria**

|     |                                     |   |
|-----|-------------------------------------|---|
| 2.a | Exclusion Number:                   | 1   |
|     | Criterion Description:              | Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation |
|     | Criterion met?                      | NO  |
|     | Criterion ID: (For Pfizer use only) | EX01A00   |

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

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**Form:** INCLUSION/EXCLUSION CRITERIA

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

|     |                                     |  |
|-----|-------------------------------------|--|
| 2.b | Exclusion Number:                   | 2  |
|     | Criterion Description:              | Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)   |
|     | Criterion met?                      | NO   |
|     | Criterion ID: (For Pfizer use only) | EX02A00  |
| 2.c | Exclusion Number:                   | 3  |
|     | Criterion Description:              | History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s) |
|     | Criterion met?                      | NO   |
|     | Criterion ID: (For Pfizer use only) | EX03A00  |
| 2.d | Exclusion Number:                   | 4  |
|     | Criterion Description:              | Receipt of medications intended to prevent COVID-19  |
|     | Criterion met?                      | NO   |
|     | Criterion ID: (For Pfizer use only) | EX04A00  |
| 2.e | Exclusion Number:                   | 8  |
|     | Criterion Description:              | Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination                      |
|     | Criterion met?                      | NO   |
|     | Criterion ID: (For Pfizer use only) | EX08A00  |
| 2 f | Exclusion Number:                   | 10   |
|     | Criterion Description:              | Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection    |
|     | Criterion met?                      | NO   |
|     | Criterion ID: (For Pfizer use only) | EX10A00  |
| 2.g | Exclusion Number:                   | 11   |
|     | Criterion Description:              | Women who are pregnant or breastfeeding  |
|     | Criterion met?                      | NO   |
|     | Criterion ID: (For Pfizer use only) | EX11A00  |

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**Header Text:** c4591001

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

**Form Version:** 17-Jul-2020 21:53

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

|     |                                     |   |
|-----|-------------------------------------|---|
| 2.h | Exclusion Number:                   | 12  |
|     | Criterion Description:              | Previous vaccination with any coronavirus vaccine   |
|     | Criterion met?                      | NO  |
|     | Criterion ID: (For Pfizer use only) | EX12A00   |
| 2.i | Exclusion Number:                   | 13  |
|     | Criterion Description:              | Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids  |
|     | Criterion met?                      | NO  |
|     | Criterion ID: (For Pfizer use only) | EX13A01   |
| 2.j | Exclusion Number:                   | 15  |
|     | Criterion Description:              | Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study                                   |
|     | Criterion met?                      | NO  |
|     | Criterion ID: (For Pfizer use only) | EX14A01   |
| 2.k | Exclusion Number:                   | 16  |
|     | Criterion Description:              | Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation   |
|     | Criterion met?                      | NO  |
|     | Criterion ID: (For Pfizer use only) | EX15A01   |
| 2.l | Exclusion Number:                   | 17  |
|     | Criterion Description:              | Previous participation in other studies involving study intervention containing lipid nanoparticles   |
|     | Criterion met?                      | NO  |
|     | Criterion ID: (For Pfizer use only) | EX16A01   |
| 2.m | Exclusion Number:                   | 22  |
|     | Criterion Description:              | Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members |
|     | Criterion met?                      | NO  |
|     | Criterion ID: (For Pfizer use only) | EX21A01   |

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**Header Text:** c4591001

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

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Screening**

|    |   |             |
|----|---|-------------|
| 1. | Date of Completion/Discontinuation /Death | Jul/30/2020 |
| 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:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1001) NYU Langone Health

**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: | [dyslipidemia]       |
|     | Start Date:  | UNK/UNK/2000         |
|     | Ongoing:   | YES                  |
| 1.b | Line/MH Number:  | [2]                  |
|     | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [hypertension]       |
|     | Start Date:  | UNK/UNK/2000         |
|     | Ongoing:   | YES                  |
| 1.c | Line/MH Number:  | [3]                  |
|     | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [osteoarthritis]     |
|     | Start Date:  | UNK/UNK/2018         |
|     | Ongoing:   | YES                  |
| 1.d | Line/MH Number:  | [4]                  |
|     | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [seasonal allergies] |
|     | Start Date:  | UNK/UNK/2017         |
|     | Ongoing:   | YES                  |

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**Header Text:** c4591001

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

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** VITAL SIGNS - BASELINE

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

|    |                  |             |
|----|------------------|-------------|
| 1. | Date:            | Jul/30/2020 |
| 2. | Weight:          | [62.6]      |
| 3. | Unit:            | kg          |
| 4. | Height:          | [165.1]     |
| 5. | Unit:            | cm          |
| 6. | Body Mass Index: | [23.0]      |

**Vital Signs Details**

|     |                       |        |
|-----|-----------------------|--------|
| 7.a | Record Identifier:    | 1      |
|     | Temperature:          | [36.2] |
|     | Unit:                 | C      |
|     | Temperature Location: | EAR    |

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**Header Text:** c4591001

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

**Form Version:** 17-Jul-2020 21:53

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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**Lab Urinalysis**

|    |                                       |              |
|----|---------------------------------------|--------------|
| 1. | Lab Panel:                            | URINALYSIS   |
| 2. | Lab Sub-Panel:                        | PREGNANCY    |
| 3. | Collection Date:                      | Jul/30/2020  |
| 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:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** RANDOMIZATION

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition**

|    |                       |             |
|----|-----------------------|-------------|
| 1. | Randomization Date :  | Jul/30/2020 |
| 2. | Randomization Number: | [220395]    |
| 3. | Randomization Group:  | [ ]         |

**Header Text:** c4591001

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

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1001) NYU Langone Health

**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>Jul/30/2020 |
| 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 | [BMR2HW] |
| 5.b | Sample ID | [BMR2HX] |
| 5.c | Sample ID | [BP775T] |
| 5.d | Sample ID | [BP775V] |
| 5.e | Sample ID | [BP775W] |

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**Header Text:** c4591001

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

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

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

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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**Electronic Sample Tracking**

|    |  |   |
|----|--|---|
| 1. | Data Origin  | SITE                                      |
| 2. | Sample Type  | NASAL_SWAB                                |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Jul/30/2020 |
| 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 | [BP774W] |
|-----|-----------|----------|

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

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** VACCINATION

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

**Site Name:** (1001) NYU Langone Health

**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:   | Jul/30/2020 12:04                         |
| 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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**Visit:** V1\_DAY1\_VAX1\_L

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

|    |   |   |
|----|---|---|
| 1. | Select appropriate response - Reactogenicity diary collection | YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT |
|----|---|---|



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levisse

**Form:** DATE OF VISIT

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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**Date of Visit**

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

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

|     |   |                               |
|-----|---|-------------------------------|
| 1.  | Were medications to treat fever/pain given on the last day the Subject Diary was completed? | NO                            |
| 2.a | Symptom:  | FEVER                         |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | NO                            |
| 2.b | Symptom:  | FATIGUE                       |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | NO                            |
| 2.c | Symptom:  | HEADACHE                      |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | NO                            |
| 2.d | Symptom:  | CHILLS                        |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | NO                            |
| 2.e | Symptom:  | VOMITING                      |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | NO                            |
| 2.f | Symptom:  | DIARRHEA                      |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | NO                            |
| 2.g | Symptom:  | NEW OR WORSENERED MUSCLE PAIN |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | NO                            |

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**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

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|     |  |                             |
|-----|--|-----------------------------|
| 2.h | Symptom:   | NEW OR WORSENERD JOINT PAIN |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO                          |
| 3.  | Injection Site Location:   | DELTOID MUSCLE              |
| 4.  | Injection Site Body Side:  | LEFT                        |
| 5.a | Injection Site Reaction:   | REDNESS                     |
|     | Were injection site reactions present on the last day the Subject Diary was completed?   | NO                          |
| 5.b | Injection Site Reaction:   | SWELLING                    |
|     | Were injection site reactions present on the last day the Subject Diary was completed?   | NO                          |
| 5.c | Injection Site Reaction:   | PAIN AT INJECTION SITE      |
|     | Were injection site reactions present on the last day the Subject Diary was completed?   | NO                          |

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

|    |       |             |
|----|-------|-------------|
| 1. | Date: | Aug/18/2020 |
|----|-------|-------------|

**Vital Signs Details**

|     |                       |             |
|-----|-----------------------|-------------|
| 2.a | Record Identifier:    | 1           |
|     | Temperature:          | [36.9]      |
|     | Unit:                 | C           |
|     | Temperature Location: | ORAL CAVITY |

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**Visit:** V2\_VAX2\_L

**Form Version:** 17-Jul-2020 21:53

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1001) NYU Langone Health

**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:                      | Aug/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                      |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

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

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

**Site Name:** (1001) NYU Langone Health

**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>Aug/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 | [BP76H3] |
|-----|-----------|----------|

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** VACCINATION

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

**Site Name:** (1001) NYU Langone Health

**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:   | Aug/18/2020 11:19                         |
| 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                                       |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

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

**Form:** DATE OF VISIT

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

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

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[eCRF Audit Trail History](#)

**Date of Visit**

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



**Header Text:** c4591001

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

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

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

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

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

|     |   |                               |
|-----|---|-------------------------------|
| 1.  | Were medications to treat fever/pain given on the last day the Subject Diary was completed? | NO                            |
| 2.a | Symptom:  | FEVER                         |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | NO                            |
| 2.b | Symptom:  | FATIGUE                       |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | NO                            |
| 2.c | Symptom:  | HEADACHE                      |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | NO                            |
| 2.d | Symptom:  | CHILLS                        |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | NO                            |
| 2.e | Symptom:  | VOMITING                      |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | NO                            |
| 2.f | Symptom:  | DIARRHEA                      |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | NO                            |
| 2.g | Symptom:  | NEW OR WORSENERED MUSCLE PAIN |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | NO                            |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

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

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

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

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

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

|     |  |                             |
|-----|--|-----------------------------|
| 2.h | Symptom:   | NEW OR WORSENERD JOINT PAIN |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO                          |
| 3.  | Injection Site Location:   | DELTOID MUSCLE              |
| 4.  | Injection Site Body Side:  | LEFT                        |
| 5.a | Injection Site Reaction:   | REDNESS                     |
|     | Were injection site reactions present on the last day the Subject Diary was completed?   | NO                          |
| 5.b | Injection Site Reaction:   | SWELLING                    |
|     | Were injection site reactions present on the last day the Subject Diary was completed?   | NO                          |
| 5.c | Injection Site Reaction:   | PAIN AT INJECTION SITE      |
|     | Were injection site reactions present on the last day the Subject Diary was completed?   | NO                          |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levissc

**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>Sep/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 | [BNW7KF] |
| 5.b | Sample ID | [BNW7KN] |
| 5.c | Sample ID | [BNW7KP] |
| 5.d | Sample ID | [BP76RT] |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET

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

**Form Status:** Not Started

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levisse

**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:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**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:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**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:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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

**Form Status:** Not Started

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**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:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levisse

**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:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**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:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levisse

**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 **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY Visit

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

**Form Status:** Not Started

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**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:** Unplanned 1 - Unscheduled Visit on  
Aug/31/2020

**Form:** DATE OF VISIT

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

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

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Aug/31/2020 |
| 2. | Erroneous Visit |             |

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Aug/31/2020

**Form:** UNPLANNED VISIT

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

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

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Unplanned Assessments**

|    |             |                 |
|----|-------------|-----------------|
| 1. | Assessments | CONTACT OUTCOME |
|----|-------------|-----------------|

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Aug/31/2020

**Form:** CONTACT OUTCOME - UNPLANNED

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

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

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levissc

**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>Aug/31/2020<br><br>Contact Outcome:<br>VISIT ARRANGED |
| 3. | Comments:         | [ ]  |

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Aug/31/2020

**Form:** VITAL SIGNS - TEMP

**Form Version:** 21-Aug-2020 02:51

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

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Vital Signs**

|    |       |             |
|----|-------|-------------|
| 1. | Date: | Aug/31/2020 |
|----|-------|-------------|

**Vital Signs Details**

|     |                       |             |
|-----|-----------------------|-------------|
| 2.a | Record Identifier:    | 1           |
|     | Temperature:          | [36.9]      |
|     | Unit:                 | C           |
|     | Temperature Location: | ORAL CAVITY |

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Aug/31/2020

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION -  
SYSTEMIC EVENT

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Unplanned Assessment Of Local Reaction**

|    |                           |                |
|----|---------------------------|----------------|
| 1. | Date of Assessment:       | Aug/31/2020    |
| 2. | Injection Site Location   | DELTOID MUSCLE |
| 3. | Injection Site Body Side: | LEFT           |

**Reaction**

|     |                                  |          |
|-----|----------------------------------|----------|
| 4.a | Reaction:                        | REDNESS  |
|     | Reaction Present:                | YES      |
|     | Maximum Diameter (cm):           | [4.0]    |
|     | Minimum Diameter (cm):           | [2.0]    |
|     | Meets Grade 4 Reaction Criteria: | NO       |
| 4.b | Reaction:                        | SWELLING |
|     | Reaction Present:                | NO       |

**Symptom**

|     |                  |                        |
|-----|------------------|------------------------|
| 5.a | Symptom:         | PAIN AT INJECTION SITE |
|     | Symptom Present: | NO                     |
| 5.b | Symptom:         | FATIGUE/TIREDNESS      |
|     | Symptom Present: | NO                     |
| 5.c | Symptom:         | HEADACHE               |
|     | Symptom Present: | NO                     |
| 5.d | Symptom:         | VOMITING               |
|     | Symptom Present: | NO                     |
| 5.e | Symptom:         | DIARRHEA               |
|     | Symptom Present: | NO                     |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)



**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Aug/31/2020

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

|     |                  |                               |
|-----|------------------|-------------------------------|
| 5.f | Symptom:         | NEW OR WORSENERED MUSCLE PAIN |
|     | Symptom Present: | NO                            |
| 5.g | Symptom:         | NEW OR WORSENERED JOINT PAIN  |
|     | Symptom Present: | NO                            |
| 5.h | Symptom:         | CHILLS                        |
|     | Symptom Present: | NO                            |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levisse

**Form:** DISPOSITION - TREATMENT

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Treatment**

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

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** DISPOSITION - FOLLOW-UP

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

[Form Comments](#)

[eCRF Audit Trail History](#)

**Disposition - Follow-Up**

|    |   |                          |                          |
|----|---|--------------------------|--------------------------|
| 1. | Date of Completion/Discontinuation /Death : | Not Done<br>_____<br>//  | <a href="#">Comments</a> |
| 2. | Phase of Disposition:                       | Not Done<br>_____        | <a href="#">Comments</a> |
| 3. | Status:                                     | Not Done<br>_____        | <a href="#">Comments</a> |
| 4. | Specify Status:                             | Not Done<br>_____<br>[ ] | <a href="#">Comments</a> |

**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:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levisse

**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:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**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: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levisse

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

| #          | Category      | AE Identifier | Adverse Event  | Start Date             | Is the Adverse Event Still Ongoing              | Form Instance                   |
|------------|---------------|---------------|--|------------------------|---|---------------------------------|
| 1. DELETED | ADVERSE EVENT | 1             | macular rash on neck   | Aug/10/2020<br>UNK:UNK | NO<br>End Date Time:<br><br>Aug/25/2020 UNK:UNK | <a href="#">Repeating Pages</a> |
| 2. DELETED | ADVERSE EVENT | 2             | Dermatitis with red patch on left abdomen                      | Aug/10/2020<br>UNK:UNK | NO<br>End Date Time:<br><br>Sep/9/2020 UNK:UNK  | <a href="#">Repeating Pages</a> |
| 3. DELETED | ADVERSE EVENT | 3             | Dermatitis with red patch on right breast                      | Aug/10/2020<br>UNK:UNK | NO<br>End Date Time:<br><br>Sep/9/2020 UNK:UNK  | <a href="#">Repeating Pages</a> |
| 4. DELETED | ADVERSE EVENT | 4             | Dermatitis with red patch from left areola extending laterally | Aug/10/2020<br>UNK:UNK | NO<br>End Date Time:<br><br>Sep/9/2020 UNK:UNK  | <a href="#">Repeating Pages</a> |
| 5.         | ADVERSE EVENT | 5             | Dermatitis of trunk  | Aug/25/2020<br>UNK:UNK | NO<br>End Date Time:<br><br>Sep/3/2020 UNK:UNK  | <a href="#">Repeating Pages</a> |
| 6.         | ADVERSE EVENT | 6             | poison ivy   | Aug/11/2020<br>UNK:UNK | NO<br>End Date Time:<br><br>Aug/31/2020 UNK:UNK | <a href="#">Repeating Pages</a> |
| 7.         | ADVERSE EVENT | 7             | R 5th metatarsal fracture                                      | Dec/12/2020<br>UNK:UNK | YES   | <a href="#">Repeating Pages</a> |
| 8.         | ADVERSE EVENT | 8             | L radial head fracture   | Dec/12/2020<br>UNK:UNK | YES   | <a href="#">Repeating Pages</a> |

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**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**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                   |
|-----|---------------|---------------|-------------------------------|---------------------|---|---------------------------------|
| 9.  | ADVERSE EVENT | 9             | R pinky finger trigger finger | Jan/1/2021 UNK:UNK  | YES   | <a href="#">Repeating Pages</a> |
| 10. | ADVERSE EVENT | 10            | fall                          | Dec/12/2020 UNK:UNK | NO<br>End Date Time:<br><br>Dec/12/2020 UNK:UNK | <a href="#">Repeating Pages</a> |

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1001

Subject No: 10011100

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted, Locked, Frozen

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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**Adverse Event Report**

|     |   |   |
|-----|---|---|
| 1.  | Category:   | ADVERSE EVENT   |
| 2.  | AE ID:  | [+]   |
| 3.  | Adverse Event:<br>(If possible specify diagnosis, not individual symptoms)  | [macular rash on neck]  |
| 4.  | Start Date Time:  | Aug/10/2020 UNK:UNK   |
| 5.  | Is the adverse event still ongoing?   | NO<br>End Date Time:<br>Aug/25/2020 UNK:UNK   |
| 6.  | Toxicity Grade:   | 2   |
| 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:   | NOT RELATED<br>If Not Related to study treatment(s), this event is due to:<br>OTHER<br>If Other, specify:<br>[poison ivy] |
| 10. | Latest Action Taken with Study Treatment:   | NOT APPLICABLE  |

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

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**Adverse Event Report**

|     |   |  |
|-----|---|--|
| 1.  | Category:   | ADVERSE EVENT  |
| 2.  | AE ID:  | [2]  |
| 3.  | Adverse Event:<br>(If possible specify diagnosis, not individual symptoms)  | [Dermatitis with red patch on left abdomen]  |
| 4.  | Start Date Time:  | Aug/10/2020 UNK:UNK  |
| 5.  | Is the adverse event still ongoing?   | NO<br>End Date Time:<br>Sep/9/2020 UNK:UNK   |
| 6.  | Toxicity Grade:   | +  |
| 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:   | NOT RELATED<br>If Not Related to study treatment(s), this event is due to:<br>OTHER<br>If Other, specify:<br>[Unspecified] |
| 10. | Latest Action Taken with Study Treatment:   | NOT APPLICABLE   |

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

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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)  | [ <del>Dermatitis with red patch on right breast</del> ]   |
| 4.  | Start Date Time:  | <del>Aug/10/2020 UNK:UNK</del>   |
| 5.  | Is the adverse event still ongoing?   | NO<br>End Date Time:<br><del>Sep/9/2020 UNK:UNK</del>  |
| 6.  | Toxicity Grade:   | +  |
| 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:   | NOT RELATED<br>If Not Related to study treatment(s), this event is due to:<br>OTHER<br>If Other, specify:<br>[Unspecified non-allergy] |
| 10. | Latest Action Taken with Study Treatment:   | NOT APPLICABLE   |

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

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**Adverse Event Report**

|     |   |  |
|-----|---|--|
| 1.  | Category:   | ADVERSE EVENT  |
| 2.  | AE ID:  | [4]  |
| 3.  | Adverse Event:<br>(If possible specify diagnosis, not individual symptoms)  | <del>[Dermatitis with red patch from left areola extending laterally]</del>  |
| 4.  | Start Date Time:  | <del>Aug/10/2020 UNK:UNK</del>   |
| 5.  | Is the adverse event still ongoing?   | NO<br><del>End Date Time:<br/>Sep/9/2020 UNK:UNK</del>   |
| 6.  | Toxicity Grade:   | +  |
| 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:   | <del>NOT RELATED</del><br>If Not Related to study treatment(s), this event is due to:<br>OTHER<br>If Other, specify:<br><del>[unspecified non-allergic reaction]</del> |
| 10. | Latest Action Taken with Study Treatment:   | NOT APPLICABLE   |

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

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**Adverse Event Report**

|     |   |   |
|-----|---|---|
| 1.  | Category:   | ADVERSE EVENT   |
| 2.  | AE ID:  | [5]   |
| 3.  | Adverse Event:<br>(If possible specify diagnosis, not individual symptoms)  | [Dermatitis of trunk]   |
| 4.  | Start Date Time:  | Aug/25/2020 UNK:UNK   |
| 5.  | Is the adverse event still ongoing?   | NO<br>End Date Time:<br>Sep/3/2020 UNK:UNK  |
| 6.  | Toxicity Grade:   | 2   |
| 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:   | NOT RELATED<br>If Not Related to study treatment(s), this event is due to:<br>OTHER<br>If Other, specify:<br>[poison ivy] |
| 10. | Latest Action Taken with Study Treatment:   | NOT APPLICABLE  |
| 11. | Was a Concomitant Medication given?   | YES   |

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|     |  |                    |
|-----|--|--------------------|
| 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: For Pfizer Use Only                          | [ ]                |

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**Adverse Event Report**

|     |   |   |
|-----|---|---|
| 1.  | Category:   | ADVERSE EVENT   |
| 2.  | AE ID:  | [6]   |
| 3.  | Adverse Event:<br>(If possible specify diagnosis, not individual symptoms)  | [poison ivy]  |
| 4.  | Start Date Time:  | Aug/11/2020 UNK:UNK   |
| 5.  | Is the adverse event still ongoing?   | NO<br>End Date Time:<br>Aug/31/2020 UNK:UNK   |
| 6.  | Toxicity Grade:   | 2   |
| 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:   | NOT RELATED<br>If Not Related to study treatment(s), this event is due to:<br>OTHER<br>If Other, specify:<br>[exposure to poison ivy] |
| 10. | Latest Action Taken with Study Treatment:   | NOT APPLICABLE  |
| 11. | Was a Concomitant Medication given?   | YES   |

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|     |  |                    |
|-----|--|--------------------|
| 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: For Pfizer Use Only                          | [ ]                |

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**Adverse Event Report**

|     |   |   |
|-----|---|---|
| 1.  | Category:   | ADVERSE EVENT   |
| 2.  | AE ID:  | [7]   |
| 3.  | Adverse Event:<br>(If possible specify diagnosis, not individual symptoms)  | [R 5th metatarsal fracture]   |
| 4.  | Start Date Time:  | Dec/12/2020 UNK:UNK   |
| 5.  | Is the adverse event still ongoing?   | YES   |
| 6.  | Toxicity Grade:   | 2   |
| 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). | YES<br><br>Is this serious event associated with congenital anomaly or birth defect?<br>NO<br><br>Did this serious event result in death?<br>NO<br><br>Did this serious event require or prolong hospitalization?<br>YES<br><br>Did this serious event result in persistent or significant disability/incapacity?<br>NO<br><br>Is this serious event life threatening?<br>NO<br><br>Other medically important serious event<br>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:   | NOT RELATED<br><br>If Not Related to study treatment(s), this event is due to:<br>OTHER<br><br>If Other, specify:<br>[Participant tripped and fell down]  |
| 10. | Latest Action Taken with Study Treatment:   | NOT APPLICABLE  |

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|     |  |                      |
|-----|--|----------------------|
| 11. | Was a Concomitant Medication given?  | YES                  |
| 12. | Was a Non-Drug Treatment given?  | YES                  |
| 13. | What was the outcome of this adverse event?:                               | RECOVERING/RESOLVING |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO                   |
| 15. | Serious Adverse Event Number: For Pfizer Use Only                          | [2021139022]         |

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**Adverse Event Report**

|     |   |   |
|-----|---|---|
| 1.  | Category:   | ADVERSE EVENT   |
| 2.  | AE ID:  | [8]   |
| 3.  | Adverse Event:<br>(If possible specify diagnosis, not individual symptoms)  | [L radial head fracture]  |
| 4.  | Start Date Time:  | Dec/12/2020 UNK:UNK   |
| 5.  | Is the adverse event still ongoing?   | YES   |
| 6.  | Toxicity Grade:   | 2   |
| 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). | YES<br><br>Is this serious event associated with congenital anomaly or birth defect?<br>NO<br><br>Did this serious event result in death?<br>NO<br><br>Did this serious event require or prolong hospitalization?<br>YES<br><br>Did this serious event result in persistent or significant disability/incapacity?<br>NO<br><br>Is this serious event life threatening?<br>NO<br><br>Other medically important serious event<br>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:   | NOT RELATED<br>If Not Related to study treatment(s), this event is due to:<br>OTHER<br>If Other, specify:<br>[Participant tripped and fell down]  |
| 10. | Latest Action Taken with Study Treatment:   | NOT APPLICABLE  |

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**Subject No:** 10011100

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**Form Status:** Data Complete

**Site Name:** (1001) NYU Langone Health

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|     |  |                      |
|-----|--|----------------------|
| 11. | Was a Concomitant Medication given?  | YES                  |
| 12. | Was a Non-Drug Treatment given?  | YES                  |
| 13. | What was the outcome of this adverse event?:                               | RECOVERING/RESOLVING |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO                   |
| 15. | Serious Adverse Event Number: For Pfizer Use Only                          | [2021139022]         |

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**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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**Adverse Event Report**

|     |   |  |
|-----|---|--|
| 1.  | Category:   | ADVERSE EVENT  |
| 2.  | AE ID:  | [9]  |
| 3.  | Adverse Event:<br>(If possible specify diagnosis, not individual symptoms)  | [R pinky finger trigger finger]  |
| 4.  | Start Date Time:  | Jan/1/2021 UNK:UNK   |
| 5.  | Is the adverse event still ongoing?   | YES  |
| 6.  | Toxicity Grade:   | 2  |
| 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:   | NOT RELATED<br>If Not Related to study treatment(s), this event is due to:<br>OTHER<br>If Other, specify:<br>[R pinky finger trigger finger] |
| 10. | Latest Action Taken with Study Treatment:   | NOT APPLICABLE   |
| 11. | Was a Concomitant Medication given?   | NO   |
| 12. | Was a Non-Drug Treatment given?   | YES  |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

|     |  |                            |
|-----|--|----------------------------|
| 13. | What was the outcome of this adverse event?:                               | NOT RECOVERED/NOT RESOLVED |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO                         |
| 15. | Serious Adverse Event Number: For Pfizer Use Only                          | [ ]                        |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Queries

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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**Adverse Event Report**

|    |   |  |
|----|---|--|
| 1. | Category:   | ADVERSE EVENT  |
| 2. | AE ID:  | [10]   |
| 3. | Adverse Event:<br>(If possible specify diagnosis, not individual symptoms)  | [fall]   |
| 4. | Start Date Time:  | Dec/12/2020 UNK:UNK  |
| 5. | Is the adverse event still ongoing?   | NO<br>End Date Time:<br>Dec/12/2020 UNK:UNK  |
| 6. | Toxicity Grade:   | 2  |
| 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). | YES<br><br>Is this serious event associated with congenital anomaly or birth defect?<br>NO<br><br>Did this serious event result in death?<br>NO<br><br>Did this serious event require or prolong hospitalization?<br>YES<br><br>Did this serious event result in persistent or significant disability/incapacity?<br>YES<br><br>Is this serious event life threatening?<br>NO<br><br>Other medically important serious event<br>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:   | NOT RELATED<br>If Not Related to study treatment(s), this event is due to:<br>OTHER<br>If Other, specify:<br>[fall]  |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Queries

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

|     |  |                      |
|-----|--|----------------------|
| 10. | Latest Action Taken with Study Treatment:                                  | NOT APPLICABLE       |
| 11. | Was a Concomitant Medication given?  | NO                   |
| 12. | Was a Non-Drug Treatment given?  | NO                   |
| 13. | What was the outcome of this adverse event?:                               | RECOVERING/RESOLVING |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO                   |
| 15. | Serious Adverse Event Number: For Pfizer Use Only                          | [ ]                  |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

| #  | Category | Medication Error | Start Date | Is the medication error Still On going | 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:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1001) NYU Langone Health

**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: For Pfizer Use Only                             | [ ] |

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**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levisc

**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:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**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:   | //  |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**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:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1001) NYU Langone Health

**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 Pre-specified:  |     |
| 4.  | Medication:<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?  |     |

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**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levisse

**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:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1001) NYU Langone Health

**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:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levisse

**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:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1001) NYU Langone Health

**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 Vaccination - Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levisse

**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:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**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: |     |

**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:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**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:   |     |



**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**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? |     |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (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:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levissc

**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:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Contact Outcome**

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

**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:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Jan/15/2021 |
| 2. | Erroneous Visit |             |

**Header Text:** c4591001

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

**Form:** FURTHER VACCINATION CONFIRMATION

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

**Form Status:** Data Complete, Frozen

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**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:** Disposition - Unscheduled

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levisse

**Form:** TREATMENT UNBLINDED

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Treatment Unblinded**

|    |                                |   |
|----|--------------------------------|---|
| 1. | Date Treatment Unblinded :     | Jan/15/2021                                   |
| 2. | Primary Reason for Unblinding: | ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION |

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** WITHDRAWAL OF CONSENT

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

**Form Status:** Not Started

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Withdrawal Of Consent**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED

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

**Form Status:** Not Started

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levissc

**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:** V101\_VAX3

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levisse

**Form:** DATE OF VISIT

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Jan/20/2021 |
| 2. | Erroneous Visit |             |

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** INFORMED CONSENT - FURTHER VACCINATION

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

**Site Name:** (1001) NYU Langone Health

**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>Jan/20/2021 |
|----|--------------|--|

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levissc

**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:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

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

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

**Site Name:** (1001) NYU Langone Health

**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 : | Jan/20/2021        |
| 2. | Phase of Disposition:                       | REPEAT SCREENING 1 |
| 3. | Status:                                     | COMPLETED          |
| 4. | Specify Status:                             | [ ]                |

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

[Form Comments](#)  
[eCRF Audit Trail History](#)

**Lab Urinalysis**

|    |                                       |                          |                          |
|----|---------------------------------------|--------------------------|--------------------------|
| 1. | Lab Panel:                            | Not Done<br>_____        | <a href="#">Comments</a> |
| 2. | Lab Sub-Panel:                        | Not Done<br>_____        | <a href="#">Comments</a> |
| 3. | Collection Date:                      | Not Done<br>_____<br>//  | <a href="#">Comments</a> |
| 4. | Laboratory Name and Address (Derived) | Not Done<br>_____<br>[ ] | <a href="#">Comments</a> |
| 5. | Specimen Type:                        | Not Done<br>_____        | <a href="#">Comments</a> |

**Lab Result**

|     |             |  |                          |
|-----|-------------|--|--------------------------|
| 6.a | Sponsor ID: | Not Done<br>_____<br>[ ]                           | <a href="#">Comments</a> |
|     | Test:       | Not Done<br>_____<br>Choriogonadotropin Beta_PX113 |                          |
|     | Result:     | Not Done<br>_____                                  | <a href="#">Comments</a> |
|     | Not Done:   | Not Done<br>_____                                  | <a href="#">Comments</a> |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1001) NYU Langone Health

**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>Jan/20/2021 |
| 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 | [BP27DN] |
| 5.b | Sample ID | [BNW7R0] |
| 5.c | Sample ID | [BNW7NP] |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

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

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

**Site Name:** (1001) NYU Langone Health

**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/20/2021 |
| 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 | [BP27DL] |
|-----|-----------|----------|

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** VACCINATION

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

**Site Name:** (1001) NYU Langone Health

**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/20/2021 12:15 |
| 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               |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)



**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levisse

**Form:** DATE OF VISIT

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

**Site Name:** (1001) NYU Langone Health

**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:** V102\_VAX4

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Version:** 14-Jan-2021 02:21

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

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Lab Urinalysis**

|    |                                       |                               |                          |
|----|---------------------------------------|-------------------------------|--------------------------|
| 1. | Lab Panel:                            |                               |                          |
| 2. | Lab Sub-Panel:                        |                               |                          |
| 3. | Collection Date:                      | Not Applicable<br>_____<br>// | <a href="#">Comments</a> |
| 4. | Laboratory Name and Address (Derived) | [ ]                           |                          |
| 5. | Specimen Type:                        |                               |                          |

**Lab Result**

|     |             |                                |                          |
|-----|-------------|--------------------------------|--------------------------|
| 6.a | Sponsor ID: | Not Applicable<br>_____<br>[ ] | <a href="#">Comments</a> |
|     | Test:       | Choriogonadotropin Beta_PX113  |                          |
|     | Result:     | Not Applicable<br>_____        | <a href="#">Comments</a> |
|     | Not Done:   | Not Applicable<br>_____        | <a href="#">Comments</a> |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

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

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

**Site Name:** (1001) NYU Langone Health

**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>Feb/8/2021 |
| 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 | [BP27FN] |
|-----|-----------|----------|

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** VACCINATION

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

**Site Name:** (1001) NYU Langone Health

**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:   | Feb/8/2021 12:21 |
| 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              |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levisse

**Form:** DATE OF VISIT

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |                 |
|----|-----------------|-----------------|
| 1. | Date of Visit   | Mar/8/2021      |
| 2. | Erroneous Visit | ERRONEOUS VISIT |

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** CONTACT OUTCOME

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

**Site Name:** (1001) NYU Langone Health

**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>Mar/8/2021 |
| 3. | Comments:         | [ ]                                   |

**Header Text:** c4591001

**Visit:** V104\_MONTH6

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1001) NYU Langone Health

**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:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1001) NYU Langone Health

**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:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levisse

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1001) NYU Langone Health

**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:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1001) NYU Langone Health

**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:** 20-Feb-2021 02:26

**Form Status:** Not Started

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**Disposition - Treatment**

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

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levisse

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1001) NYU Langone Health

**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 | Sep/22/2020 |

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[eCRF Audit Trail History](#)

**Casebook Signature Form**

|    |                    |                                      |
|----|--------------------|--------------------------------------|
| 1. | Casebook Signature | <a href="#">Click Here to Enable</a> |
|----|--------------------|--------------------------------------|

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levisse

**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
- CRF\_Sign\_1

| Name | Signature<br>Meaning | Date | Type | Action |
|------|----------------------|------|------|--------|
|------|----------------------|------|------|--------|

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** DISPOSITION - FOLLOW-UP - Comments

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

[Back to Form](#)

| Item | Date   | User                    | Comment  |
|------|--|-------------------------|----------|
| Form | Feb-19-2021 16:50:32 (UTC-05:00) Eastern Time<br>(US & Canada) | Nazia Ria<br>(pfe nria) | Not Done |

**Header Text:** c4591001

**Visit:** Follow-Up

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** DISPOSITION - FOLLOW-UP - Comments

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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| Item | Date  | User                    | Comment  |
|------|---|-------------------------|----------|
| 1    | Feb-19-2021 16:50:32 (UTC-05:00) Eastern Time (US & Canada) | Nazia Ria<br>(pfe nria) | Not Done |



**Header Text:** c4591001

**Visit:** Follow-Up

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** DISPOSITION - FOLLOW-UP - Comments

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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| Item | Date  | User                    | Comment  |
|------|---|-------------------------|----------|
| 2    | Feb-19-2021 16:50:32 (UTC-05:00) Eastern Time (US & Canada) | Nazia Ria<br>(pfe nria) | Not Done |

**Header Text:** c4591001

**Visit:** Follow-Up

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** DISPOSITION - FOLLOW-UP - Comments

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

[Back to Form](#)

| Item | Date  | User                    | Comment  |
|------|---|-------------------------|----------|
| 3    | Feb-19-2021 16:50:32 (UTC-05:00) Eastern Time (US & Canada) | Nazia Ria<br>(pfe nria) | Not Done |

**Header Text:** c4591001

**Visit:** Follow-Up

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** DISPOSITION - FOLLOW-UP - Comments

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

[Back to Form](#)

| Item | Date  | User                    | Comment  |
|------|---|-------------------------|----------|
| 4    | Feb-19-2021 16:50:32 (UTC-05:00) Eastern Time (US & Canada) | Nazia Ria<br>(pfe nria) | Not Done |

**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:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[Back to Form](#)

| Item | Date   | User                    | Comment        |
|------|--|-------------------------|----------------|
| Form | Jan-21-2021 11:56:44 (UTC-05:00) Eastern Time<br>(US & Canada) | Nazia Ria<br>(pfe nria) | Not Applicable |

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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| Item | Date   | User                       | Comment  |
|------|--|----------------------------|----------|
| Form | Feb-01-2021 15:21:55 (UTC-05:00) Eastern Time<br>(US & Canada) | Sara Hyman<br>(pfe.shyman) | Not Done |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

[Back to Form](#)

| Item | Date  | User                    | Comment  |
|------|---|-------------------------|----------|
| 1    | Feb-01-2021 15:21:55 (UTC-05:00) Eastern Time (US & Canada) | Sara Hyman (pfe.shyman) | Not Done |

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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| Item | Date  | User                       | Comment  |
|------|---|----------------------------|----------|
| 2    | Feb-01-2021 15:21:55 (UTC-05:00) Eastern Time (US & Canada) | Sara Hyman<br>(pfe.shyman) | Not Done |

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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| Item | Date  | User                      | Comment        |
|------|---|---------------------------|----------------|
| 3    | Feb-01-2021 15:21:55 (UTC-05:00) Eastern Time (US & Canada) | Sara Hyman (pfe.shyman)   | Not Done       |
| 3    | Jan-26-2021 13:46:00 (UTC-05:00) Eastern Time (US & Canada) | Gali Moritz (pfe.gmoritz) | Not Done       |
| 3    | Jan-21-2021 11:57:08 (UTC-05:00) Eastern Time (US & Canada) | Nazia Ria (pfe.nria)      | Not Applicable |



**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

[Back to Form](#)

| Item | Date  | User                       | Comment  |
|------|---|----------------------------|----------|
| 4    | Feb-01-2021 15:21:55 (UTC-05:00) Eastern Time (US & Canada) | Sara Hyman<br>(pfe.shyman) | Not Done |

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

[Back to Form](#)

| Item | Date  | User                    | Comment  |
|------|---|-------------------------|----------|
| 5    | Feb-01-2021 15:21:55 (UTC-05:00) Eastern Time (US & Canada) | Sara Hyman (pfe.shyman) | Not Done |

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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| Item | Date  | User                       | Comment  |
|------|---|----------------------------|----------|
| 6.a  | Feb-01-2021 15:21:55 (UTC-05:00) Eastern Time (US & Canada) | Sara Hyman<br>(pfe.shyman) | Not Done |

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

[Back to Form](#)

| Item | Date  | User                    | Comment        |
|------|---|-------------------------|----------------|
| 6.a  | Feb-01-2021 15:21:55 (UTC-05:00) Eastern Time (US & Canada) | Sara Hyman (pfe.shyman) | Not Done       |
| 6.a  | Jan-22-2021 12:10:14 (UTC-05:00) Eastern Time (US & Canada) | Nazia Ria (pfe.nria)    | Not Applicable |

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

[Back to Form](#)

| Item | Date  | User                    | Comment        |
|------|---|-------------------------|----------------|
| 6.a  | Feb-01-2021 15:21:55 (UTC-05:00) Eastern Time (US & Canada) | Sara Hyman (pfe.shyman) | Not Done       |
| 6.a  | Jan-22-2021 12:10:36 (UTC-05:00) Eastern Time (US & Canada) | Nazia Ria (pfe.nria)    | Not Applicable |

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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| Item | Date  | User                    | Comment        |
|------|---|-------------------------|----------------|
| 3    | Feb-08-2021 17:07:32 (UTC-05:00) Eastern Time (US & Canada) | Nazia Ria<br>(pfe nria) | Not Applicable |

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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| Item | Date  | User                    | Comment        |
|------|---|-------------------------|----------------|
| 6.a  | Feb-08-2021 17:07:50 (UTC-05:00) Eastern Time (US & Canada) | Nazia Ria<br>(pfe nria) | Not Applicable |

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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| Item | Date  | User                    | Comment        |
|------|---|-------------------------|----------------|
| 6.a  | Feb-08-2021 17:07:50 (UTC-05:00) Eastern Time (US & Canada) | Nazia Ria<br>(pfe nria) | Not Applicable |



**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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| Item | Date  | User                    | Comment        |
|------|---|-------------------------|----------------|
| 6.a  | Feb-08-2021 17:07:50 (UTC-05:00) Eastern Time (US & Canada) | Nazia Ria<br>(pfe nria) | 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, Verified

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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

- CRF\_Sign
- CRF\_Sign\_1

| Name        | Signature Meaning | Date  | Type | Action                            |
|-------------|-------------------|---|------|-----------------------------------|
| Gali Moritz | N/A               | Jan-20-2021 15:43:08 (UTC-05:00) Eastern Time (US & Canada) |      | Edit - All signatures invalidated |

**Affidavit:**

N/A

|               |          |   |      |        |
|---------------|----------|---|------|--------|
| Mark Mulligan | Approved | Oct-11-2020 20:22:34 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |
|---------------|----------|---|------|--------|

**Affidavit:**

By my dated signature below, I, MarkMulligan, 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.

|             |     |   |  |                                   |
|-------------|-----|---|--|-----------------------------------|
| Gali Moritz | N/A | Oct-08-2020 10:22:34 (UTC-05:00) Eastern Time (US & Canada) |  | Edit - All signatures invalidated |
|-------------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|               |          |   |      |        |
|---------------|----------|---|------|--------|
| Vanessa Raabe | Approved | Sep-23-2020 17:03:19 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |
|---------------|----------|---|------|--------|

**Affidavit:**

By my dated signature below, I, VanessaRaabe, 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.

|            |     |   |  |                                   |
|------------|-----|---|--|-----------------------------------|
| Sara Hyman | N/A | Sep-22-2020 16:00:06 (UTC-05:00) Eastern Time (US & Canada) |  | Edit - All signatures invalidated |
|------------|-----|---|--|-----------------------------------|

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (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, Verified

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Affidavit:**

N/A

|               |          |  |      |        |
|---------------|----------|--|------|--------|
| Vanessa Raabe | Approved | Sep-16-2020 16:07:40 (UTC-05:00) Eastern Time<br>(US & Canada) | BOOK | Signed |
|---------------|----------|--|------|--------|

**Affidavit:**

By my dated signature below, I, VanessaRaabe, 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.

|             |     |  |  |                                   |
|-------------|-----|--|--|-----------------------------------|
| Akeem Moore | N/A | Sep-16-2020 13:15:22 (UTC-05:00) Eastern Time<br>(US & Canada) |  | Edit - All signatures invalidated |
|-------------|-----|--|--|-----------------------------------|

**Affidavit:**

N/A

|               |          |  |      |        |
|---------------|----------|--|------|--------|
| Mark Mulligan | Approved | Sep-11-2020 11:45:59 (UTC-05:00) Eastern Time<br>(US & Canada) | BOOK | Signed |
|---------------|----------|--|------|--------|

**Affidavit:**

By my dated signature below, I, MarkMulligan, 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.

|             |     |  |  |                                   |
|-------------|-----|--|--|-----------------------------------|
| Akeem Moore | N/A | Sep-08-2020 19:12:59 (UTC-05:00) Eastern Time<br>(US & Canada) |  | Edit - All signatures invalidated |
|-------------|-----|--|--|-----------------------------------|

**Affidavit:**

N/A

|               |          |  |      |        |
|---------------|----------|--|------|--------|
| Mark Mulligan | Approved | Sep-03-2020 17:57:30 (UTC-05:00) Eastern Time<br>(US & Canada) | BOOK | Signed |
|---------------|----------|--|------|--------|

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (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, Verified

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Affidavit:**

By my dated signature below, I, MarkMulligan, 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.

|             |     |   |  |                                   |
|-------------|-----|---|--|-----------------------------------|
| Akeem Moore | N/A | Sep-03-2020 13:40:23 (UTC-05:00) Eastern Time (US & Canada) |  | Edit - All signatures invalidated |
|-------------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|               |          |   |      |        |
|---------------|----------|---|------|--------|
| Mark Mulligan | Approved | Sep-01-2020 13:21:11 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |
|---------------|----------|---|------|--------|

**Affidavit:**

By my dated signature below, I, MarkMulligan, 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.

|             |     |   |  |                                   |
|-------------|-----|---|--|-----------------------------------|
| Akeem Moore | N/A | Aug-31-2020 16:20:59 (UTC-05:00) Eastern Time (US & Canada) |  | Edit - All signatures invalidated |
|-------------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|               |          |   |      |        |
|---------------|----------|---|------|--------|
| Mark Mulligan | Approved | Aug-27-2020 09:46:17 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |
|---------------|----------|---|------|--------|

**Affidavit:**

By my dated signature below, I, MarkMulligan, 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.

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levisse

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

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

**Site Name:** (1001) NYU Langone Health

**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        |
|---|-----------------|----------------------------|-----------------------------------|---------------|
| Jul-30-2020 12:35:14<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>30 JUN 2020 | Initial Entry |

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

| Date  | Location        | User                       | Value                                 | Reason        |
|---|-----------------|----------------------------|---------------------------------------|---------------|
| Jul-30-2020 12:35:14<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>STAGE 3 COHORTS | Initial Entry |

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

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

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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*I. Consent Was:*

| Date  | Location        | User                       | Value  | Reason        |
|---|-----------------|----------------------------|--|---------------|
| Jul-30-2020 12:35:25<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>OBTAINED<br>Date Written Consent Obtained<br><br>Jul/30/2020 | Initial Entry |

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1001

Subject No: 10011100

Generated By: pfe.levissc

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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**1. Subject ID**

| Date  | Location        | User                       | Value                          | Reason   |
|---|-----------------|----------------------------|--------------------------------|--|
| Jul-30-2020 12:35:51<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)  | Query 1: Closed                | Close Auto Query   |
| Jul-30-2020 12:35:51<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>10011100 | Transcription Error                                      |
| Jul-30-2020 12:35:36<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)  | Query 1: Opened                | Subject ID is expected to be in 8 digits. Please review. |
| Jul-30-2020 12:35:09<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc)    | <b>Data Entry:</b><br>1100     | Item copied from previous form                           |

**2. Birth Date:**

| Date  | Location        | User                    | Value                               | Reason           |
|---|-----------------|-------------------------|-------------------------------------|------------------|
| Jul-30-2020 12:35:07<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>(b) (6) /1951 | Enrollment Entry |

**3. Sex:**

| Date  | Location        | User                       | Value                        | Reason        |
|---|-----------------|----------------------------|------------------------------|---------------|
| Jul-30-2020 12:35:36<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>FEMALE | Initial Entry |

**4. Ethnicity:**

| Date  | Location        | User                       | Value  | Reason        |
|---|-----------------|----------------------------|--|---------------|
| Jul-30-2020 12:35:36<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN | Initial Entry |

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

| Date                 | Location        | User       | Value              | Reason        |
|----------------------|-----------------|------------|--------------------|---------------|
| Jul-30-2020 12:35:36 | ACV0PFEINFP6000 | Sara Hyman | <b>Data Entry:</b> | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

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

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

|   |  |              |       |  |
|---|--|--------------|-------|--|
| (UTC-05:00) Eastern Time<br>(US & Canada) |  | (pfe.shyman) | WHITE |  |
|---|--|--------------|-------|--|



**Header Text:** c4591001

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

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levisse

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

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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*I. Date of Visit*

| <b>Date</b>   | <b>Location</b> | <b>User</b>                | <b>Value</b>                      | <b>Reason</b> |
|---|-----------------|----------------------------|-----------------------------------|---------------|
| Jul-30-2020 12:36:03<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>Jul/30/2020 | Initial Entry |

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 17-Jul-2020 21:53

Site No: 1001

Subject No: 10011100

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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I.a

| Date  | Location        | User                       | Value   | Reason        |
|---|-----------------|----------------------------|---|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br><b>Inclusion Number:</b><br><b>Criterion Description:</b> Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)<br><b>Criterion met?:</b><br><b>Criterion ID:</b> IN01A00<br><b>Use only:</b> (For Pfizer use only): | Initial Entry |

I.a Inclusion Number:

| Date  | Location        | User                       | Value                   | Reason        |
|---|-----------------|----------------------------|-------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>1 | Initial Entry |

I.a Criterion Description:

| Date  | Location        | User                       | Value  | Reason        |
|---|-----------------|----------------------------|--|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage) | Initial Entry |

I.a Criterion met?

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

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

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

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

**Form Version:** 17-Jul-2020 21:53

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

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

|   |                 |                            |                           |               |
|---|-----------------|----------------------------|---------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>YES | Initial Entry |
|---|-----------------|----------------------------|---------------------------|---------------|

**1.a Criterion ID: (For Pfizer use only)**

| Date  | Location        | User                       | Value                         | Reason        |
|---|-----------------|----------------------------|-------------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>IN01A00 | Initial Entry |

**1.b**

| Date  | Location        | User                       | Value   | Reason        |
|---|-----------------|----------------------------|---|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br><b>Inclusion Number:</b><br><b>Criterion Description:</b> Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures<br><b>Criterion met?:</b><br><b>Criterion ID:</b> IN02A00<br><b>(For Pfizer use only):</b><br>: | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levissc

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

**I.b Inclusion Number:**

| Date  | Location        | User                       | Value                   | Reason        |
|---|-----------------|----------------------------|-------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>2 | Initial Entry |

**I.b Criterion Description:**

| Date  | Location        | User                       | Value  | Reason        |
|---|-----------------|----------------------------|--|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>Participants who are willing and able to comply with all scheduled visits , vaccination plan, laboratory tests, lifestyle considerations, and other study procedures | Initial Entry |

**I.b Criterion met?**

| Date  | Location        | User                       | Value                     | Reason        |
|---|-----------------|----------------------------|---------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>YES | Initial Entry |

**I.b Criterion ID: (For Pfizer use only)**

| Date  | Location        | User                       | Value                         | Reason        |
|---|-----------------|----------------------------|-------------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>IN02A00 | Initial Entry |

**I.c**

| Date  | Location        | User                       | Value   | Reason        |
|---|-----------------|----------------------------|---|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br><b>Inclusion Number:</b><br><b>Criteria:</b> Healthy participants who are determined by medical history, physical examination , and clinical judgment of the investigator to be eligible for inclusion in the study | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 17-Jul-2020 21:53

Site No: 1001

Subject No: 10011100

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | <b>Criteria on met ?:</b><br><b>Criteria on ID: (For Pfizer use only):</b><br>IN03A00 |  |
|--|--|--|---|--|

**I.c Inclusion Number:**

| Date  | Location        | User                       | Value                   | Reason        |
|---|-----------------|----------------------------|-------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>3 | Initial Entry |

**I.c Criterion Description:**

| Date  | Location        | User                       | Value   | Reason        |
|---|-----------------|----------------------------|---|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study | Initial Entry |

**I.c Criterion met?**

| Date  | Location        | User                       | Value                     | Reason        |
|---|-----------------|----------------------------|---------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>YES | Initial Entry |

**I.c Criterion ID: (For Pfizer use only)**

| Date  | Location        | User                       | Value                         | Reason        |
|---|-----------------|----------------------------|-------------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>IN03A00 | Initial Entry |

**I.d**

| Date                 | Location        | User       | Value              | Reason        |
|----------------------|-----------------|------------|--------------------|---------------|
| Jul-30-2020 12:36:24 | ACV0PFEINFP6000 | Sara Hyman | <b>Data Entry:</b> | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

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

**Form Version:** 17-Jul-2020 21:53

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

|   |  |              |  |  |
|---|--|--------------|--|--|
| (UTC-05:00) Eastern Time<br>(US & Canada) |  | (pfe.shyman) | <b>Inclusion Number:</b> 4<br><b>Criteria Description:</b> Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol<br><b>Criteria met?:</b> YES<br><b>Criteria ID: (For Printer use only):</b> IN04A00 |  |
|---|--|--------------|--|--|

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levissc

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

**I.d Inclusion Number:**

| Date  | Location        | User                       | Value                   | Reason        |
|---|-----------------|----------------------------|-------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>4 | Initial Entry |

**I.d Criterion Description:**

| Date  | Location        | User                       | Value  | Reason        |
|---|-----------------|----------------------------|--|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>Capable of giving personal signed in formed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol | Initial Entry |

**I.d Criterion met?**

| Date  | Location        | User                       | Value                     | Reason        |
|---|-----------------|----------------------------|---------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>YES | Initial Entry |

**I.d Criterion ID: (For Pfizer use only)**

| Date  | Location        | User                       | Value                         | Reason        |
|---|-----------------|----------------------------|-------------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>IN04A00 | Initial Entry |

**2.a**

| Date  | Location        | User                       | Value   | Reason        |
|---|-----------------|----------------------------|---|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br><b>Exclusion Number:</b><br><b>Criterion Description:</b> Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 17-Jul-2020 21:53

Site No: 1001

Subject No: 10011100

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | <b>Criteria NO on met ?:</b><br><b>Criteria EX01A00 on ID: (For Pfizer use only):</b> |  |
|--|--|--|---|--|

**2.a Exclusion Number:**

| Date  | Location        | User                       | Value                   | Reason        |
|---|-----------------|----------------------------|-------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>1 | Initial Entry |

**2.a Criterion Description:**

| Date  | Location        | User                       | Value   | Reason        |
|---|-----------------|----------------------------|---|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation | Initial Entry |

**2.a Criterion met?**

| Date  | Location        | User                       | Value                    | Reason        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.a Criterion ID: (For Pfizer use only)**

| Date  | Location        | User                       | Value                         | Reason        |
|---|-----------------|----------------------------|-------------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>EX01A00 | Initial Entry |

**2.b**

| Date                 | Location        | User       | Value              | Reason        |
|----------------------|-----------------|------------|--------------------|---------------|
| Jul-30-2020 12:36:24 | ACV0PFEINFP6000 | Sara Hyman | <b>Data Entry:</b> | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 17-Jul-2020 21:53

Site No: 1001

Subject No: 10011100

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

|   |  |              |   |  |
|---|--|--------------|---|--|
| (UTC-05:00) Eastern Time<br>(US & Canada) |  | (pfe.shyman) | <b>Exclusion Number:</b><br><b>Criterion Description:</b><br>Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)<br><b>Criterion met?:</b><br>NO<br><b>Criterion ID: (For Pfizer use only):</b><br>EX02A00 |  |
|---|--|--------------|---|--|

**2.b Exclusion Number:**

| Date  | Location        | User                       | Value                   | Reason        |
|---|-----------------|----------------------------|-------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>2 | Initial Entry |

**2.b Criterion Description:**

| Date  | Location        | User                       | Value  | Reason        |
|---|-----------------|----------------------------|--|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV) | Initial Entry |

**2.b Criterion met?**

| Date  | Location        | User                       | Value                    | Reason        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.b Criterion ID: (For Pfizer use only)**

| Date  | Location        | User                       | Value                         | Reason        |
|---|-----------------|----------------------------|-------------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>EX02A00 | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

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

**Form Version:** 17-Jul-2020 21:53

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

2.c

| Date  | Location        | User                       | Value   | Reason        |
|---|-----------------|----------------------------|---|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br><b>Exclusion Number:</b><br>3<br><b>Criterion Description:</b><br>History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)<br><b>Criterion met?:</b><br>NO<br><b>Criterion ID:</b><br>EX03A00<br>(For Pfizer use only): | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levissc

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

2.c Exclusion Number:

| Date  | Location        | User                       | Value                   | Reason        |
|---|-----------------|----------------------------|-------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>3 | Initial Entry |

2.c Criterion Description:

| Date  | Location        | User                       | Value  | Reason        |
|---|-----------------|----------------------------|--|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>History of severe adverse reaction as<br>sociated with a vaccine and/or sever<br>e allergic reaction (eg, anaphylaxis) t<br>o any component of the study interv<br>ention(s) | Initial Entry |

2.c Criterion met?

| Date  | Location        | User                       | Value                    | Reason        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>NO | Initial Entry |

2.c Criterion ID: (For Pfizer use only)

| Date  | Location        | User                       | Value                         | Reason        |
|---|-----------------|----------------------------|-------------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>EX03A00 | Initial Entry |

2.d

| Date  | Location        | User                       | Value   | Reason        |
|---|-----------------|----------------------------|---|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br><b>Exclusion Nu 4</b><br><b>umber:</b><br><b>Criterion Des</b> Receipt of medicati<br><b>cription:</b> ons intended to prev<br>ent COVID-19<br><b>Criterion met</b> NO<br><b>?:</b><br><b>Criterion ID:</b> EX04A00<br><b>(For Pfizer us</b><br><b>e only):</b> | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.lewissc

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

2.d Exclusion Number:

| Date  | Location        | User                       | Value                   | Reason        |
|---|-----------------|----------------------------|-------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>4 | Initial Entry |

2.d Criterion Description:

| Date  | Location        | User                       | Value   | Reason        |
|---|-----------------|----------------------------|---|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>Receipt of medications intended to p<br>revent COVID-19 | Initial Entry |

2.d Criterion met?

| Date  | Location        | User                       | Value                    | Reason        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>NO | Initial Entry |

2.d Criterion ID: (For Pfizer use only)

| Date  | Location        | User                       | Value                         | Reason        |
|---|-----------------|----------------------------|-------------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>EX04A00 | Initial Entry |

2.e

| Date  | Location        | User                       | Value   | Reason        |
|---|-----------------|----------------------------|---|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br><b>Exclusi 8</b><br><b>on Nu</b><br><b>mber:</b><br><b>Criteria</b> Immunocompromised indi<br><b>on Desc</b> viduals with known or sus<br><b>ription:</b> pected immunodeficiency,<br>as determined by history a<br>nd/or laboratory/physical e<br>xamination<br><b>Criteria</b> NO<br><b>on met</b><br><b>?:</b> | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 17-Jul-2020 21:53

Site No: 1001

Subject No: 10011100

Generated By: pfe.lewissc

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | Criteria ID: (For Pfizer use only): EX08A00 |  |
|--|--|--|---|--|

2.e Exclusion Number:

| Date  | Location        | User                       | Value            | Reason        |
|---|-----------------|----------------------------|------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | Data Entry:<br>8 | Initial Entry |

2.e Criterion Description:

| Date  | Location        | User                       | Value  | Reason        |
|---|-----------------|----------------------------|--|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | Data Entry:<br>Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination | Initial Entry |

2.e Criterion met?

| Date  | Location        | User                       | Value             | Reason        |
|---|-----------------|----------------------------|-------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | Data Entry:<br>NO | Initial Entry |

2.e Criterion ID: (For Pfizer use only)

| Date  | Location        | User                       | Value                  | Reason        |
|---|-----------------|----------------------------|------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | Data Entry:<br>EX08A00 | Initial Entry |

2.f

| Date  | Location        | User                       | Value                               | Reason        |
|---|-----------------|----------------------------|-------------------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | Data Entry:<br>Exclusion Number: 10 | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 17-Jul-2020 21:53

Site No: 1001

Subject No: 10011100

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <b>Criterion Description:</b><br>Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection<br><br><b>Criterion met?:</b><br>NO<br><br><b>Criterion ID:<br/>(For Pfizer use only):</b><br>EX10A00 |  |
|--|--|--|--|--|

**2.f Exclusion Number:**

| Date  | Location        | User                       | Value                    | Reason        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>10 | Initial Entry |

**2.f Criterion Description:**

| Date  | Location        | User                       | Value   | Reason        |
|---|-----------------|----------------------------|---|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection | Initial Entry |

**2.f Criterion met?**

| Date  | Location        | User                       | Value                    | Reason        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.f Criterion ID: (For Pfizer use only)**

| Date  | Location        | User                       | Value                         | Reason        |
|---|-----------------|----------------------------|-------------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>EX10A00 | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 17-Jul-2020 21:53

Site No: 1001

Subject No: 10011100

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

2.g

| Date  | Location        | User                       | Value   | Reason        |
|---|-----------------|----------------------------|---|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>Exclusion Num 11<br>ber:<br>Criterion Descr Women who are p<br>ption: regnant or breastfe<br>eding<br>Criterion met?: NO<br>Criterion ID: ( EX11A00<br>For Pfizer use<br>only): | Initial Entry |

2.g Exclusion Number:

| Date  | Location        | User                       | Value                    | Reason        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>11 | Initial Entry |

2.g Criterion Description:

| Date  | Location        | User                       | Value   | Reason        |
|---|-----------------|----------------------------|---|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>Women who are pregnant or breastfe<br>eding | Initial Entry |

2.g Criterion met?

| Date  | Location        | User                       | Value                    | Reason        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>NO | Initial Entry |

2.g Criterion ID: (For Pfizer use only)

| Date  | Location        | User                       | Value                         | Reason        |
|---|-----------------|----------------------------|-------------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>EX11A00 | Initial Entry |

2.h

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

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.lewissc

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

|   |                 |                            |  |               |
|---|-----------------|----------------------------|--|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br><b>Exclusion Number:</b> 12<br><b>Criterion Description:</b> Previous vaccination with any coronavirus vaccine<br><b>Criterion met?:</b> NO<br><b>Criterion ID:</b> EX12A00<br><b>(For Pfizer use only):</b> | Initial Entry |
|---|-----------------|----------------------------|--|---------------|

**2.h Exclusion Number:**

| Date  | Location        | User                       | Value                    | Reason        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>12 | Initial Entry |

**2.h Criterion Description:**

| Date  | Location        | User                       | Value   | Reason        |
|---|-----------------|----------------------------|---|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>Previous vaccination with any coronavirus vaccine | Initial Entry |

**2.h Criterion met?**

| Date  | Location        | User                       | Value                    | Reason        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.h Criterion ID: (For Pfizer use only)**

| Date  | Location        | User                       | Value                         | Reason        |
|---|-----------------|----------------------------|-------------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>EX12A00 | Initial Entry |

**2.i**

| Date   | Location        | User                       | Value                                     | Reason        |
|--|-----------------|----------------------------|---|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br><b>Exclusion</b> 13 | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 17-Jul-2020 21:53

Site No: 1001

Subject No: 10011100

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

|               |  |  |   |  |
|---------------|--|--|---|--|
| (US & Canada) |  |  | <b>n Number:</b><br><b>Criterion Description:</b> Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids<br><b>Criterion met?:</b><br><b>Criterion ID: (For Pfizer use only):</b> EX13A01 |  |
|---------------|--|--|---|--|

**2.i Exclusion Number:**

| Date  | Location        | User                    | Value                 | Reason        |
|---|-----------------|-------------------------|-----------------------|---------------|
| Jul-30-2020 12:36:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Sara Hyman (pfe.shyman) | <b>Data Entry:</b> 13 | Initial Entry |

**2.i Criterion Description:**

| Date  | Location        | User                    | Value   | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Jul-30-2020 12:36:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Sara Hyman (pfe.shyman) | <b>Data Entry:</b> Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids | Initial Entry |

**2.i Criterion met?**

| Date  | Location        | User                    | Value                 | Reason        |
|---|-----------------|-------------------------|-----------------------|---------------|
| Jul-30-2020 12:36:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Sara Hyman (pfe.shyman) | <b>Data Entry:</b> NO | Initial Entry |

**2.i Criterion ID: (For Pfizer use only)**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Jul-30-2020 12:36:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Sara Hyman (pfe.shyman) | <b>Data Entry:</b> EX13A01 | Initial Entry |

**2.j**

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

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

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

**Form Version:** 17-Jul-2020 21:53

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

|   |                 |                            |  |               |
|---|-----------------|----------------------------|--|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br><b>Exclusion Number:</b> 15<br><b>Criterion Description:</b> Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt through out the study<br><b>Criterion met?:</b> NO<br><b>Criterion ID:</b> EX14A01<br><b>(For Printer use only):</b> | Initial Entry |
|---|-----------------|----------------------------|--|---------------|

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 17-Jul-2020 21:53

Site No: 1001

Subject No: 10011100

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

**2.j Exclusion Number:**

| Date  | Location        | User                       | Value                    | Reason        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>15 | Initial Entry |

**2.j Criterion Description:**

| Date  | Location        | User                       | Value   | Reason        |
|---|-----------------|----------------------------|---|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study | Initial Entry |

**2.j Criterion met?**

| Date  | Location        | User                       | Value                    | Reason        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.j Criterion ID: (For Pfizer use only)**

| Date  | Location        | User                       | Value                         | Reason        |
|---|-----------------|----------------------------|-------------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>EX14A01 | Initial Entry |

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 17-Jul-2020 21:53

Site No: 1001

Subject No: 10011100

Generated By: pfe.lewissc

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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2.k

| Date  | Location        | User                       | Value  | Reason        |
|---|-----------------|----------------------------|--|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br><b>Exclusion Number:</b> 16<br><b>Criterion Description:</b> Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation<br><b>Criterion met?:</b> NO<br><b>Criterion ID: (For Pfizer use only):</b> EX15A01 | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 17-Jul-2020 21:53

Site No: 1001

Subject No: 10011100

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

**2.k Exclusion Number:**

| Date  | Location        | User                       | Value                    | Reason        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>16 | Initial Entry |

**2.k Criterion Description:**

| Date  | Location        | User                       | Value   | Reason        |
|---|-----------------|----------------------------|---|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation | Initial Entry |

**2.k Criterion met?**

| Date  | Location        | User                       | Value                    | Reason        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.k Criterion ID: (For Pfizer use only)**

| Date  | Location        | User                       | Value                         | Reason        |
|---|-----------------|----------------------------|-------------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>EX15A01 | Initial Entry |

**2.l**

| Date  | Location        | User                       | Value   | Reason        |
|---|-----------------|----------------------------|---|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br><b>Exclusion 17</b><br><b>Number:</b><br><b>Criterion</b> Previous participation in<br><b>Descripti</b> other studies involving s<br><b>on:</b> tudy intervention containi<br>ning lipid nanoparticles<br><b>Criterion</b> NO<br><b>met?:</b> | Initial Entry |

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levissc

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

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | <b>Criterion ID: (For Pfizer use only):</b> EX16A01 |  |
|--|--|--|---|--|

**2.l Exclusion Number:**

| Date  | Location        | User                       | Value                    | Reason        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>17 | Initial Entry |

**2.l Criterion Description:**

| Date  | Location        | User                       | Value   | Reason        |
|---|-----------------|----------------------------|---|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>Previous participation in other studies involving study intervention containing lipid nanoparticles | Initial Entry |

**2.l Criterion met?**

| Date  | Location        | User                       | Value                    | Reason        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.l Criterion ID: (For Pfizer use only)**

| Date  | Location        | User                       | Value                         | Reason        |
|---|-----------------|----------------------------|-------------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>EX16A01 | Initial Entry |

**2.m**

| Date  | Location        | User                       | Value  | Reason        |
|---|-----------------|----------------------------|--|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>Exclus 22<br>ion Number: | Initial Entry |

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**Header Text:** c4591001

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

**Form Version:** 17-Jul-2020 21:53

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <p><b>Criteria</b> Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members</p> <p><b>Criteria NO on met?:</b></p> <p><b>Criteria EX21A01 on ID: (For Pfizer use only):</b></p> |  |
|--|--|--|--|--|

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Header Text: c4591001

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Site No: 1001

Subject No: 10011100

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

**2.m Exclusion Number:**

| Date  | Location        | User                       | Value                    | Reason        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>22 | Initial Entry |

**2.m Criterion Description:**

| Date  | Location        | User                       | Value   | Reason        |
|---|-----------------|----------------------------|---|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members | Initial Entry |

**2.m Criterion met?**

| Date  | Location        | User                       | Value                    | Reason        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.m Criterion ID: (For Pfizer use only)**

| Date  | Location        | User                       | Value                         | Reason        |
|---|-----------------|----------------------------|-------------------------------|---------------|
| Jul-30-2020 12:36:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>EX21A01 | Initial Entry |

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**Header Text:** c4591001

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

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

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

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

**Site Name:** (1001) NYU Langone Health

**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        |
|---|-----------------|----------------------------|-----------------------------------|---------------|
| Jul-30-2020 12:36:38<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>Jul/30/2020 | Initial Entry |

**2. Phase of Disposition:**

| Date  | Location        | User                    | Value                           | Reason        |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Jul-30-2020 12:36:38<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SCREENING | Initial Entry |

**3. Status:**

| Date  | Location        | User                       | Value                           | Reason        |
|---|-----------------|----------------------------|---------------------------------|---------------|
| Jul-30-2020 12:36:38<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>COMPLETED | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1001

Subject No: 10011100

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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*I.a*

| Date  | Location        | User                       | Value   | Reason              |
|---|-----------------|----------------------------|---|---------------------|
| Aug-03-2020 19:30:50<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Mahnoor Ali<br>(pfe.mali1) | <b>Data Entry:</b><br><b>Line/MH Number:</b> 1<br><b>Medical History Term:</b> dyslipidemia<br><b>Start Date:</b> UNK/UNK/2000<br><b>Ongoing:</b> YES | Changed Information |
| Jul-30-2020 15:23:28<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc)    | <b>Data Entry:</b><br><b>Line/MH Number:</b> 1<br><b>Medical History Term:</b> dyslipidemia<br><b>Start Date:</b> UNK/UNK/2000<br><b>Ongoing:</b> YES | Initial Entry       |

*I.a Line/MH Number:*

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Jul-30-2020 15:23:28<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>1 | Initial Entry |

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

| Date  | Location        | User                              | Value                              | Reason   |
|---|-----------------|-----------------------------------|------------------------------------|--|
| Aug-04-2020 11:23:40<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Kiran Potdar<br>(pfe.potdak02)    | Query 1: Closed                    | Response satisfies query                           |
| Aug-03-2020 19:30:50<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)         | Query 1: Answered                  | Changed Information                                |
| Aug-03-2020 19:30:50<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Mahnoor Ali<br>(pfe.mali1)        | <b>Data Entry:</b><br>dyslipidemia | Changed Information                                |
| Aug-03-2020 16:02:19<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Jeffrey Signora<br>(pfe.signoj01) | Query 1: Opened                    | DM QUERY: A trailing space is identified. To avoid |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1001

Subject No: 10011100

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

|  |                 |                            |                                    |  |
|--|-----------------|----------------------------|------------------------------------|--|
|  |                 |                            |                                    | processing errors, please remove the identified character by deleting the entry and re-entering the data (without using copy and paste). |
| Jul-30-2020 15:23:28<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>dyslipidemia | Initial Entry  |

**I.a Start Date:**

| Date   | Location        | User                       | Value                              | Reason        |
|--|-----------------|----------------------------|------------------------------------|---------------|
| Jul-30-2020 15:23:28<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>UNK/UNK/2000 | Initial Entry |

**I.a Ongoing:**

| Date   | Location        | User                       | Value                     | Reason        |
|--|-----------------|----------------------------|---------------------------|---------------|
| Jul-30-2020 15:23:28<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>YES | Initial Entry |

**I.b**

| Date   | Location        | User                       | Value   | Reason              |
|--|-----------------|----------------------------|---|---------------------|
| Aug-03-2020 19:31:00<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Mahnoor Ali<br>(pfe.mali1) | <b>Data Entry:</b><br><b>Line/MH Number:</b> 2<br><b>Medical History Term:</b> hypertension<br><b>Start Date:</b> UNK/UNK/2000<br><b>Ongoing:</b> YES | Changed Information |
| Jul-30-2020 15:23:53<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc)    | <b>Data Entry:</b><br><b>Line/MH Number:</b> 2<br><b>Medical History Term:</b> hypertension<br><b>Start Date:</b> UNK/UNK/2000<br><b>Ongoing:</b> YES | Initial Entry       |

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levissc

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

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

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Jul-30-2020 15:23:53<br>(UTC-05:00) Eastern Time<br>(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  |
|---|-----------------|-----------------------------------|------------------------------------|---|
| Aug-04-2020 11:23:40<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Kiran Potdar<br>(pfe.potdak02)    | Query 1: Closed                    | Response satisfies query  |
| Aug-03-2020 19:31:00<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)         | Query 1: Answered                  | Changed Information   |
| Aug-03-2020 19:31:00<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Mahnoor Ali<br>(pfe.mali1)        | <b>Data Entry:</b><br>hypertension | Changed Information   |
| Aug-03-2020 16:02:30<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Jeffrey Signora<br>(pfe.signoj01) | Query 1: Opened                    | DM QUERY: A trailing space is identified. To avoid processing errors, please remove the identified character by deleting the entry and re-entering the data (without using copy and paste). |
| Jul-30-2020 15:23:53<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman)        | <b>Data Entry:</b><br>hypertension | Initial Entry   |

**I.b Start Date:**

| Date  | Location        | User                       | Value                              | Reason        |
|---|-----------------|----------------------------|------------------------------------|---------------|
| Jul-30-2020 15:23:53<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>UNK/UNK/2000 | Initial Entry |

**I.b Ongoing:**

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

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

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

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

|   |                 |                            |                           |               |
|---|-----------------|----------------------------|---------------------------|---------------|
| Jul-30-2020 15:23:53<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>YES | Initial Entry |
|---|-----------------|----------------------------|---------------------------|---------------|

*I.c*

| Date  | Location        | User                          | Value   | Reason              |
|---|-----------------|-------------------------------|---|---------------------|
| Aug-03-2020 19:31:06<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Mahnoor<br>Ali<br>(pfe.mali1) | <b>Data Entry:</b><br><b>Line/MH Number:</b> 3<br><b>Medical History Term:</b> osteoarthritis<br><b>Start Date:</b> UNK/UNK/2018<br><b>Ongoing:</b> YES | Changed Information |
| Jul-30-2020 15:24:20<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc)       | <b>Data Entry:</b><br><b>Line/MH Number:</b> 3<br><b>Medical History Term:</b> osteoarthritis<br><b>Start Date:</b> UNK/UNK/2018<br><b>Ongoing:</b> YES | Initial Entry       |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levissc

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

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

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Jul-30-2020 15:24:20<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>3 | Initial Entry |

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

| Date  | Location        | User                              | Value                                | Reason  |
|---|-----------------|-----------------------------------|--------------------------------------|---|
| Aug-04-2020 11:23:40<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Kiran Potdar<br>(pfe.potdak02)    | Query 1: Closed                      | Response satisfies query  |
| Aug-03-2020 19:31:06<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)         | Query 1: Answered                    | Changed Information   |
| Aug-03-2020 19:31:06<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Mahnoor Ali<br>(pfe.mali1)        | <b>Data Entry:</b><br>osteoarthritis | Changed Information   |
| Aug-03-2020 16:02:42<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Jeffrey Signora<br>(pfe.signoj01) | Query 1: Opened                      | DM QUERY: A trailing space is identified. To avoid processing errors, please remove the identified character by deleting the entry and re-entering the data (without using copy and paste). |
| Jul-30-2020 15:24:20<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman)        | <b>Data Entry:</b><br>osteoarthritis | Initial Entry   |

**I.c Start Date:**

| Date  | Location        | User                       | Value                              | Reason        |
|---|-----------------|----------------------------|------------------------------------|---------------|
| Jul-30-2020 15:24:20<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>UNK/UNK/2018 | Initial Entry |

**I.c Ongoing:**

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

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

|   |                 |                            |                           |               |
|---|-----------------|----------------------------|---------------------------|---------------|
| Jul-30-2020 15:24:20<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>YES | Initial Entry |
|---|-----------------|----------------------------|---------------------------|---------------|

*I.d*

| Date  | Location        | User                          | Value   | Reason              |
|---|-----------------|-------------------------------|---|---------------------|
| Aug-03-2020 19:31:13<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Mahnoor<br>Ali<br>(pfe.mali1) | <b>Data Entry:</b><br><b>Line/MH Number:</b> 4<br><b>Medical History Term:</b> seasonal allergies<br><b>Start Date:</b> UNK/UNK/2017<br><b>Ongoing:</b> YES | Changed Information |
| Jul-30-2020 15:24:44<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc)       | <b>Data Entry:</b><br><b>Line/MH Number:</b> 4<br><b>Medical History Term:</b> seasonal allergies<br><b>Start Date:</b> UNK/UNK/2017<br><b>Ongoing:</b> YES | Initial Entry       |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levissc

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

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

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Jul-30-2020 15:24:44<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>4 | Initial Entry |

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

| Date  | Location        | User                              | Value                                    | Reason  |
|---|-----------------|-----------------------------------|--|---|
| Aug-04-2020 11:23:40<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Kiran Potdar<br>(pfe.potdak02)    | Query 1: Closed                          | Response satisfies query  |
| Aug-03-2020 19:31:13<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)         | Query 1: Answered                        | Changed Information   |
| Aug-03-2020 19:31:13<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Mahnoor Ali<br>(pfe.mali1)        | <b>Data Entry:</b><br>seasonal allergies | Changed Information   |
| Aug-03-2020 16:02:56<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Jeffrey Signora<br>(pfe.signoj01) | Query 1: Opened                          | DM QUERY: A trailing space is identified. To avoid processing errors, please remove the identified character by deleting the entry and re-entering the data (without using copy and paste). |
| Jul-30-2020 15:24:44<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman)        | <b>Data Entry:</b><br>seasonal allergies | Initial Entry   |

**I.d Start Date:**

| Date  | Location        | User                       | Value                              | Reason        |
|---|-----------------|----------------------------|------------------------------------|---------------|
| Jul-30-2020 15:24:44<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>UNK/UNK/2017 | Initial Entry |

**I.d Ongoing:**

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

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

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

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

|   |                 |                            |                           |               |
|---|-----------------|----------------------------|---------------------------|---------------|
| Jul-30-2020 15:24:44<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>YES | Initial Entry |
|---|-----------------|----------------------------|---------------------------|---------------|

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 17-Jul-2020 21:54

Site No: 1001

Subject No: 10011100

Generated By: pfe.levissc

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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**1. Date:**

| Date  | Location        | User                       | Value                             | Reason        |
|---|-----------------|----------------------------|-----------------------------------|---------------|
| Jul-30-2020 15:25:53<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>Jul/30/2020 | Initial Entry |

**2. Weight:**

| Date  | Location        | User                       | Value                      | Reason        |
|---|-----------------|----------------------------|----------------------------|---------------|
| Jul-30-2020 15:25:53<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>62.6 | Initial Entry |

**3. Unit:**

| Date  | Location        | User                       | Value                    | Reason        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Jul-30-2020 15:25:53<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>kg | Initial Entry |

**4. Height:**

| Date  | Location        | User                       | Value                       | Reason        |
|---|-----------------|----------------------------|-----------------------------|---------------|
| Jul-30-2020 15:25:53<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>165.1 | Initial Entry |

**5. Unit:**

| Date  | Location        | User                       | Value                    | Reason        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Jul-30-2020 15:25:53<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>cm | Initial Entry |

**6. Body Mass Index:**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Jul-30-2020 15:25:53<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>23.0 | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 17-Jul-2020 21:54

Site No: 1001

Subject No: 10011100

Generated By: pfe.levissc

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

7.a

| Date  | Location        | User                       | Value   | Reason        |
|---|-----------------|----------------------------|---|---------------|
| Jul-30-2020 15:25:53<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br><b>Record Identifier::</b> 1<br><b>Temperature:</b> 36.2<br><b>Temperature Unit:</b> C<br><b>Temperature Location::</b> EAR | Initial Entry |

7.a Record Identifier:

| Date  | Location        | User                       | Value                   | Reason        |
|---|-----------------|----------------------------|-------------------------|---------------|
| Jul-30-2020 15:25:53<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>1 | Initial Entry |

7.a Temperature:

| Date  | Location        | User                       | Value                      | Reason        |
|---|-----------------|----------------------------|----------------------------|---------------|
| Jul-30-2020 15:25:53<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>36.2 | Initial Entry |

7.a Unit:

| Date  | Location        | User                       | Value                   | Reason        |
|---|-----------------|----------------------------|-------------------------|---------------|
| Jul-30-2020 15:25:53<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>C | Initial Entry |

7.a Temperature Location:

| Date  | Location        | User                       | Value                     | Reason        |
|---|-----------------|----------------------------|---------------------------|---------------|
| Jul-30-2020 15:25:53<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>EAR | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

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        |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Jul-30-2020 15:26:31<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>URINALYSIS | Initial Entry |

**2. Lab Sub-Panel:**

| Date  | Location        | User                    | Value                           | Reason        |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Jul-30-2020 15:26:31<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>PREGNANCY | Initial Entry |

**3. Collection Date:**

| Date  | Location        | User                       | Value                             | Reason        |
|---|-----------------|----------------------------|-----------------------------------|---------------|
| Jul-30-2020 15:26:31<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>Jul/30/2020 | Initial Entry |

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

| Date  | Location        | User                    | Value                            | Reason        |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Jul-30-2020 15:26:31<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>STUDY SITE | Initial Entry |

**5. Specimen Type:**

| Date  | Location        | User                    | Value                       | Reason        |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Jul-30-2020 15:26:31<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>URINE | Initial Entry |

**6.a**

| Date  | Location        | User                    | Value   | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Jul-30-2020 15:26:31<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Sponsor-Defined Identifier: 113 | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

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

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

**Form Version:** 17-Jul-2020 21:53

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

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | <b>Test::</b> Choriogonadotropin Beta_PX113 |  |
|  |  |  | <b>Result::</b>                             |  |
|  |  |  | <b>Not Done::</b> NOT DONE                  |  |

**6.a Sponsor ID:**

| Date  | Location        | User                    | Value                     | Reason        |
|---|-----------------|-------------------------|---------------------------|---------------|
| Jul-30-2020 15:26:31<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>113 | Initial Entry |

**6.a Test:**

| Date  | Location        | User                       | Value   | Reason        |
|---|-----------------|----------------------------|---|---------------|
| Jul-30-2020 15:26:31<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>Choriogonadotropin Beta_PX113 | Initial Entry |

**6.a Not Done:**

| Date  | Location        | User                       | Value                          | Reason        |
|---|-----------------|----------------------------|--------------------------------|---------------|
| Jul-30-2020 15:26:31<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>NOT DONE | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

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

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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**1. Randomization Date :**

| Date  | Location        | User                       | Value                             | Reason        |
|---|-----------------|----------------------------|-----------------------------------|---------------|
| Jul-30-2020 12:36:59<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>Jul/30/2020 | Initial Entry |

**2. Randomization Number:**

| Date  | Location        | User                       | Value                        | Reason              |
|---|-----------------|----------------------------|------------------------------|---------------------|
| Jul-30-2020 16:03:47<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>220395 | Transcription Error |
| Jul-30-2020 12:36:59<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b>           | Initial Entry       |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

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        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Jul-30-2020 12:37:08<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date  | Location        | User                    | Value                       | Reason        |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Jul-30-2020 12:37:08<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SERUM | Initial Entry |

**3. Sample Collected?**

| Date  | Location        | User                       | Value   | Reason   |
|---|-----------------|----------------------------|---|--|
| Jul-30-2020 16:54:11<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)  | Query 1: Deleted  | Close Auto Query   |
| Jul-30-2020 12:37:08<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)  | Query 1: Candidate  | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Jul-30-2020 12:37:08<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Jul/30/2020 | Initial Entry  |

**5.a**

| Date  | Location        | User                       | Value  | Reason        |
|---|-----------------|----------------------------|--|---------------|
| Jul-30-2020 16:54:11<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br><b>Sample ID:</b> BMR2HW | Initial Entry |

**5.a Sample ID**

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

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levisse

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

|   |                 |                            |                              |               |
|---|-----------------|----------------------------|------------------------------|---------------|
| Jul-30-2020 16:54:11<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>BMR2HW | Initial Entry |
|---|-----------------|----------------------------|------------------------------|---------------|

5.b

| Date  | Location        | User                       | Value  | Reason        |
|---|-----------------|----------------------------|--|---------------|
| Jul-30-2020 16:54:17<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br><b>Sample ID:</b> BMR2HX | Initial Entry |

5.b Sample ID

| Date  | Location        | User                       | Value                        | Reason        |
|---|-----------------|----------------------------|------------------------------|---------------|
| Jul-30-2020 16:54:17<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>BMR2HX | Initial Entry |

5.c

| Date  | Location        | User                       | Value  | Reason        |
|---|-----------------|----------------------------|--|---------------|
| Jul-30-2020 18:29:09<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br><b>Sample ID:</b> BP775T | Initial Entry |

5.c Sample ID

| Date  | Location        | User                       | Value                        | Reason        |
|---|-----------------|----------------------------|------------------------------|---------------|
| Jul-30-2020 18:29:09<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>BP775T | Initial Entry |

5.d

| Date  | Location        | User                       | Value  | Reason        |
|---|-----------------|----------------------------|--|---------------|
| Jul-30-2020 18:29:16<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br><b>Sample ID:</b> BP775V | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)



**Header Text:** c4591001

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

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

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

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

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**5.d Sample ID**

| Date  | Location        | User                       | Value                        | Reason        |
|---|-----------------|----------------------------|------------------------------|---------------|
| Jul-30-2020 18:29:16<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>BP775V | Initial Entry |

**5.e**

| Date  | Location        | User                       | Value  | Reason        |
|---|-----------------|----------------------------|--|---------------|
| Jul-30-2020 18:29:21<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br><b>Sample ID:</b> BP775W | Initial Entry |

**5.e Sample ID**

| Date  | Location        | User                       | Value                        | Reason        |
|---|-----------------|----------------------------|------------------------------|---------------|
| Jul-30-2020 18:29:21<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>BP775W | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1001**Site Name:** (1001) NYU Langone Health**Subject No:** 10011100**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        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Jul-30-2020 12:37:16<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date  | Location        | User                    | Value                            | Reason        |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Jul-30-2020 12:37:16<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB | Initial Entry |

**3. Sample Collected?**

| Date  | Location        | User                       | Value   | Reason  |
|---|-----------------|----------------------------|---|---|
| Jul-30-2020 16:43:25<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)  | Query 1: Deleted  | Close Auto Query  |
| Jul-30-2020 12:37:16<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)  | Query 1: Candidate  | 'Sample Collected?'<br>is Yes, however no<br>barcodes are entered.<br>Please review and<br>correct as<br>appropriate. |
| Jul-30-2020 12:37:16<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Jul/30/2020 | Initial Entry   |

**5.a**

| Date  | Location        | User                       | Value  | Reason        |
|---|-----------------|----------------------------|--|---------------|
| Jul-30-2020 16:43:25<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br><b>Sample ID:</b> BP774W | Initial Entry |

**5.a Sample ID**

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

**Header Text:** c4591001

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

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

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

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

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

|   |                 |                            |                              |               |
|---|-----------------|----------------------------|------------------------------|---------------|
| Jul-30-2020 16:43:25<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>BP774W | Initial Entry |
|---|-----------------|----------------------------|------------------------------|---------------|

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1001

Subject No: 10011100

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

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        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Jul-30-2020 12:37:36<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>NO | Initial Entry |

**2. Treatment Name**

| Date  | Location        | User                    | Value                                 | Reason        |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Jul-30-2020 12:37:36<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>BLINDED THERAPY | Initial Entry |

**3. Formulation:**

| Date  | Location        | User                    | Value                           | Reason        |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Jul-30-2020 12:37:36<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INJECTION | Initial Entry |

**4. Dose Date Time:**

| Date  | Location        | User                       | Value                                   | Reason        |
|---|-----------------|----------------------------|---|---------------|
| Jul-30-2020 12:37:36<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>Jul/30/2020 12:04 | Initial Entry |

**5. Anatomical Location:**

| Date  | Location        | User                    | Value                                | Reason        |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Jul-30-2020 12:37:36<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>DELTOID MUSCLE | Initial Entry |

**6. Body Side:**

| Date  | Location        | User                       | Value                      | Reason        |
|---|-----------------|----------------------------|----------------------------|---------------|
| Jul-30-2020 12:37:36<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>LEFT | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

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

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

**7. Route:**

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Jul-30-2020 12:37:36<br>(UTC-05:00) Eastern Time<br>(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        |
|---|-----------------|-------------------------|---|---------------|
| Jul-30-2020 12:37:36<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>THE PROTOCOL SPECIFIED OBS<br>ERVATION 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        |
|---|-----------------|----------------------------|---------------------------|---------------|
| Jul-30-2020 12:37:36<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

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

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

**Site Name:** (1001) NYU Langone Health

**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        |
|---|-----------------|----------------------------|---|---------------|
| Jul-30-2020 12:37:41<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT | Initial Entry |

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levisse

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

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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*I. Date of Visit*

| <b>Date</b>   | <b>Location</b> | <b>User</b>                     | <b>Value</b>                      | <b>Reason</b> |
|---|-----------------|---------------------------------|-----------------------------------|---------------|
| Aug-18-2020 13:21:32<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>Aug/18/2020 | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levissc

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

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*1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?*

| Date  | Location        | User                            | Value                    | Reason        |
|---|-----------------|---------------------------------|--------------------------|---------------|
| Aug-18-2020 13:22:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NO | Initial Entry |

*2.a*

| Date  | Location        | User                            | Value   | Reason        |
|---|-----------------|---------------------------------|---|---------------|
| Aug-18-2020 13:22:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br><b>Symptom::</b><br>FE<br>VE<br>R<br><b>Were fever or systemic symp<br/>toms present on the last day t<br/>he Subject Diary was comple<br/>ted?:</b> NO | Initial Entry |

*2.a Symptom:*

| Date  | Location        | User                            | Value                       | Reason        |
|---|-----------------|---------------------------------|-----------------------------|---------------|
| Aug-18-2020 13:22:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>FEVER | Initial Entry |

*2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?*

| Date  | Location        | User                            | Value                    | Reason        |
|---|-----------------|---------------------------------|--------------------------|---------------|
| Aug-18-2020 13:22:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NO | Initial Entry |

*2.b*

| Date  | Location        | User                            | Value   | Reason        |
|---|-----------------|---------------------------------|---|---------------|
| Aug-18-2020 13:22:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br><b>Symptom::</b><br>FAT<br>IG<br>UE | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)



Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levissc

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

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | Were fever or systemic symptoms present on the last day the Subject Diary was completed?: |  |
|--|--|--|---|--|

2.b Symptom:

| Date  | Location        | User                            | Value                         | Reason        |
|---|-----------------|---------------------------------|-------------------------------|---------------|
| Aug-18-2020 13:22:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <u>Data Entry:</u><br>FATIGUE | Initial Entry |

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date  | Location        | User                            | Value                    | Reason        |
|---|-----------------|---------------------------------|--------------------------|---------------|
| Aug-18-2020 13:22:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <u>Data Entry:</u><br>NO | Initial Entry |

2.c

| Date  | Location        | User                            | Value   | Reason        |
|---|-----------------|---------------------------------|---|---------------|
| Aug-18-2020 13:22:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <u>Data Entry:</u><br><u>Symptom::</u> HEADACHE<br><br>Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO | Initial Entry |

2.c Symptom:

| Date  | Location        | User                            | Value                          | Reason        |
|---|-----------------|---------------------------------|--------------------------------|---------------|
| Aug-18-2020 13:22:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <u>Data Entry:</u><br>HEADACHE | Initial Entry |

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date  | Location        | User                            | Value                    | Reason        |
|---|-----------------|---------------------------------|--------------------------|---------------|
| Aug-18-2020 13:22:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <u>Data Entry:</u><br>NO | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levisse

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

2.d

| Date  | Location        | User                            | Value  | Reason        |
|---|-----------------|---------------------------------|--|---------------|
| Aug-18-2020 13:22:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br><b>Symptom::</b> CH<br>ILL<br>S<br><b>Were fever or systemic symp</b> NO<br><b>toms present on the last day</b><br><b>the Subject Diary was compl</b><br><b>eted?:</b> | Initial Entry |

2.d Symptom:

| Date  | Location        | User                            | Value                        | Reason        |
|---|-----------------|---------------------------------|------------------------------|---------------|
| Aug-18-2020 13:22:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>CHILLS | Initial Entry |

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date  | Location        | User                            | Value                    | Reason        |
|---|-----------------|---------------------------------|--------------------------|---------------|
| Aug-18-2020 13:22:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NO | Initial Entry |

2.e

| Date  | Location        | User                            | Value   | Reason        |
|---|-----------------|---------------------------------|---|---------------|
| Aug-18-2020 13:22:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br><b>Symptom::</b> VO<br>MIT<br>ING<br><b>Were fever or systemic sym</b> NO<br><b>ptoms present on the last d</b><br><b>ay the Subject Diary was co</b><br><b>mpleted?:</b> | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levisse

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

**2.e Symptom:**

| Date  | Location        | User                            | Value                          | Reason        |
|---|-----------------|---------------------------------|--------------------------------|---------------|
| Aug-18-2020 13:22:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>VOMITING | Initial Entry |

**2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

| Date  | Location        | User                            | Value                    | Reason        |
|---|-----------------|---------------------------------|--------------------------|---------------|
| Aug-18-2020 13:22:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.f**

| Date  | Location        | User                            | Value  | Reason        |
|---|-----------------|---------------------------------|--|---------------|
| Aug-18-2020 13:22:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br><b>Symptom:</b> DIA<br>RR<br>HE<br>A<br><br><b>Were fever or systemic sym<br/>ptoms present on the last da<br/>y the Subject Diary was co<br/>mpleted?:</b> NO | Initial Entry |

**2.f Symptom:**

| Date  | Location        | User                            | Value                          | Reason        |
|---|-----------------|---------------------------------|--------------------------------|---------------|
| Aug-18-2020 13:22:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>DIARRHEA | Initial Entry |

**2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

| Date  | Location        | User                            | Value                    | Reason        |
|---|-----------------|---------------------------------|--------------------------|---------------|
| Aug-18-2020 13:22:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.g**

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

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.lewissc

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

|   |                 |                                 |   |               |
|---|-----------------|---------------------------------|---|---------------|
| Aug-18-2020 13:22:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br><b>Symptom::</b> NEW OR<br>WORSE<br>NED MUSC<br>LE PAIN<br><br>Were fever or systemi NO<br>c symptoms present o<br>n the last day the Subj<br>ect Diary was complet<br>ed?: | Initial Entry |
|---|-----------------|---------------------------------|---|---------------|

**2.g Symptom:**

| Date  | Location        | User                            | Value  | Reason        |
|---|-----------------|---------------------------------|--|---------------|
| Aug-18-2020 13:22:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NEW OR WORSE<br>NED MUSCLE<br>PAIN | Initial Entry |

**2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

| Date  | Location        | User                            | Value                    | Reason        |
|---|-----------------|---------------------------------|--------------------------|---------------|
| Aug-18-2020 13:22:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.h**

| Date  | Location        | User                            | Value  | Reason        |
|---|-----------------|---------------------------------|--|---------------|
| Aug-18-2020 13:22:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br><b>Symptom::</b> NEW OR<br>WORSE<br>NED JOIN<br>T PAIN<br><br>Were fever or systemic NO<br>symptoms present on t<br>he last day the Subject<br>Diary was completed?<br>: | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levissc

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

**2.h Symptom:**

| Date  | Location        | User                            | Value   | Reason        |
|---|-----------------|---------------------------------|---|---------------|
| Aug-18-2020 13:22:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NEW OR WORSENERD JOINT PAI<br>N | Initial Entry |

**2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

| Date  | Location        | User                            | Value                    | Reason        |
|---|-----------------|---------------------------------|--------------------------|---------------|
| Aug-18-2020 13:22:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NO | Initial Entry |

**3. Injection Site Location:**

| Date  | Location        | User                    | Value                                | Reason        |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Aug-18-2020 13:22:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>DELTOID MUSCLE | Initial Entry |

**4. Injection Site Body Side:**

| Date  | Location        | User                            | Value                      | Reason        |
|---|-----------------|---------------------------------|----------------------------|---------------|
| Aug-18-2020 13:22:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>LEFT | Initial Entry |

**5.a**

| Date  | Location        | User                            | Value  | Reason        |
|---|-----------------|---------------------------------|--|---------------|
| Aug-18-2020 13:22:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>Injection Site Reaction:: RE<br>DN<br>ESS<br><br>Were injection site reactions NO<br>present on the last day the S<br>ubject Diary was completed<br>?: | Initial Entry |

**5.a Injection Site Reaction:**

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

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - eCRF Audit Trail History**Form Version:** 17-Jul-2020 21:54**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1001**Site Name:** (1001) NYU Langone Health**Subject No:** 10011100**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04

|   |                 |                                 |                               |               |
|---|-----------------|---------------------------------|-------------------------------|---------------|
| Aug-18-2020 13:22:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>REDNESS | Initial Entry |
|---|-----------------|---------------------------------|-------------------------------|---------------|

**5.a Were injection site reactions present on the last day the Subject Diary was completed?**

| Date  | Location        | User                            | Value                    | Reason        |
|---|-----------------|---------------------------------|--------------------------|---------------|
| Aug-18-2020 13:22:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NO | Initial Entry |

**5.b**

| Date  | Location        | User                            | Value   | Reason        |
|---|-----------------|---------------------------------|---|---------------|
| Aug-18-2020 13:22:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br><b>Injection Site Reaction::</b> SWE<br>LLI<br>NG<br><br><b>Were injection site reaction NO<br/>s present on the last day th<br/>e Subject Diary was comple<br/>ted?:</b> | Initial Entry |

**5.b Injection Site Reaction:**

| Date  | Location        | User                            | Value                          | Reason        |
|---|-----------------|---------------------------------|--------------------------------|---------------|
| Aug-18-2020 13:22:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>SWELLING | Initial Entry |

**5.b Were injection site reactions present on the last day the Subject Diary was completed?**

| Date  | Location        | User                            | Value                    | Reason        |
|---|-----------------|---------------------------------|--------------------------|---------------|
| Aug-18-2020 13:22:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NO | Initial Entry |

**5.c**

| Date  | Location        | User                            | Value  | Reason        |
|---|-----------------|---------------------------------|--|---------------|
| Aug-18-2020 13:22:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br><b>Injection Site Reaction::</b> PAIN A<br>T INJE<br>CTION | Initial Entry |

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - eCRF Audit Trail History

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

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

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

|  |  |  |      |  |
|--|--|--|------|--|
|  |  |  | SITE |  |
| <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> |  |  |      |  |
|  |  |  | NO   |  |

**5.c Injection Site Reaction:**

| Date  | Location        | User                            | Value  | Reason        |
|---|-----------------|---------------------------------|--|---------------|
| Aug-18-2020 13:22:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>PAIN AT INJECTION SITE | Initial Entry |

**5.c Were injection site reactions present on the last day the Subject Diary was completed?:**

| Date  | Location        | User                            | Value                    | Reason        |
|---|-----------------|---------------------------------|--------------------------|---------------|
| Aug-18-2020 13:22:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 30-Jul-2020 21:28**Site No:** 1001**Subject No:** 10011100**Generated By:** pfe.levissc**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1001) NYU Langone Health**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Date:**

| Date  | Location        | User                            | Value                             | Reason        |
|---|-----------------|---------------------------------|-----------------------------------|---------------|
| Aug-18-2020 13:22:49<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>Aug/18/2020 | Initial Entry |

**2.a**

| Date  | Location        | User                            | Value  | Reason              |
|---|-----------------|---------------------------------|--|---------------------|
| Oct-08-2020 10:22:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Gali Moritz<br>(pfe.gmoritz)    | <b>Data Entry:</b><br><b>Record Identifier::</b> 1<br><b>Temperature:</b> 36.9<br><b>Temperature Unit:</b> C<br><b>Temperature Locat ion::</b> ORAL CAVI<br>TY | Transcription Error |
| Aug-18-2020 13:23:38<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br><b>Record Identifier::</b> 1<br><b>Temperature:</b> 36.9<br><b>Temperature Unit:</b> C<br><b>Temperature Location::</b> EAR              | Changed Information |
| Aug-18-2020 13:22:49<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br><b>Record Identifier::</b> 1<br><b>Temperature:</b> 36.9<br><b>Temperature Unit:</b> C<br><b>Temperature Locat ion::</b> ORAL CAVI<br>TY | Initial Entry       |

**2.a Record Identifier:**

| Date  | Location        | User                            | Value                   | Reason        |
|---|-----------------|---------------------------------|-------------------------|---------------|
| Aug-18-2020 13:22:49<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>1 | Initial Entry |

**2.a Temperature:**

| Date   | Location        | User           | Value                      | Reason        |
|--|-----------------|----------------|----------------------------|---------------|
| Aug-18-2020 13:22:49<br>(UTC-05:00) Eastern Time | ACV0PFEINFP6000 | Akeem<br>Moore | <b>Data Entry:</b><br>36.9 | Initial Entry |



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 30-Jul-2020 21:28

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

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

|               |  |               |  |
|---------------|--|---------------|--|
| (US & Canada) |  | (pfe.amoore1) |  |
|---------------|--|---------------|--|

**2.a Unit:**

| Date  | Location        | User                            | Value                   | Reason        |
|---|-----------------|---------------------------------|-------------------------|---------------|
| Aug-18-2020 13:22:49<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>C | Initial Entry |

**2.a Temperature Location:**

| Date  | Location        | User                            | Value                             | Reason              |
|---|-----------------|---------------------------------|-----------------------------------|---------------------|
| Oct-08-2020 10:22:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Gali Moritz<br>(pfe.gmoritz)    | <b>Data Entry:</b><br>ORAL CAVITY | Transcription Error |
| Aug-18-2020 13:23:38<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>EAR         | Changed Information |
| Aug-18-2020 13:22:49<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>ORAL CAVITY | Initial Entry       |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

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        |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Aug-18-2020 13:31:01<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>URINALYSIS | Initial Entry |

**2. Lab Sub-Panel:**

| Date  | Location        | User                    | Value                           | Reason        |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Aug-18-2020 13:31:01<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>PREGNANCY | Initial Entry |

**3. Collection Date:**

| Date  | Location        | User                            | Value                             | Reason        |
|---|-----------------|---------------------------------|-----------------------------------|---------------|
| Aug-18-2020 13:31:01<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>Aug/18/2020 | Initial Entry |

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

| Date  | Location        | User                    | Value                            | Reason        |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Aug-18-2020 13:31:01<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>STUDY SITE | Initial Entry |

**5. Specimen Type:**

| Date  | Location        | User                    | Value                       | Reason        |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Aug-18-2020 13:31:01<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>URINE | Initial Entry |

**6.a**

| Date  | Location        | User                    | Value   | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Aug-18-2020 13:31:01<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Sponsor-Define 113<br>d Identifier: | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 17-Jul-2020 21:53

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

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <b>Test::</b> Choriogonadotropin Beta_PX113<br><b>Result::</b><br><b>Not Done::</b> NOT DONE |  |
|--|--|--|--|--|

**6.a Sponsor ID:**

| Date  | Location        | User                    | Value                     | Reason        |
|---|-----------------|-------------------------|---------------------------|---------------|
| Aug-18-2020 13:31:01<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>113 | Initial Entry |

**6.a Test:**

| Date  | Location        | User                            | Value   | Reason        |
|---|-----------------|---------------------------------|---|---------------|
| Aug-18-2020 13:31:01<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>Choriogonadotropin Beta_PX113 | Initial Entry |

**6.a Not Done:**

| Date  | Location        | User                            | Value                          | Reason        |
|---|-----------------|---------------------------------|--------------------------------|---------------|
| Aug-18-2020 13:31:01<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NOT DONE | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

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        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Aug-19-2020 11:45:08<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date  | Location        | User                    | Value                            | Reason        |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Aug-19-2020 11:45:08<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB | Initial Entry |

**3. Sample Collected?**

| Date  | Location        | User                                | Value   | Reason                              |
|---|-----------------|-------------------------------------|---|-------------------------------------|
| Aug-20-2020 04:51:20<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sanjay Mishra<br>(pfe.mishrs01)     | Query 1: Closed   | Response satisfies<br>query         |
| Aug-19-2020 11:45:08<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)           | Query 1: Answered   | Initial Entry                       |
| Aug-19-2020 11:45:08<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman)          | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Aug/18/2020 | Initial Entry                       |
| Aug-19-2020 11:21:17<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Saumitra<br>Dubey<br>(pfe.dubeys27) | Query 1: Opened   | Please provide the<br>missing data. |

**5.a**

| Date  | Location        | User                       | Value                                   | Reason        |
|---|-----------------|----------------------------|---|---------------|
| Aug-18-2020 15:46:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>Sample ID: BP76H3 | Initial Entry |

**5.a Sample ID**

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

| Date  | Location        | User                       | Value                        | Reason        |
|---|-----------------|----------------------------|------------------------------|---------------|
| Aug-18-2020 15:46:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <u>Data Entry:</u><br>BP76H3 | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1001

Subject No: 10011100

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

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        |
|---|-----------------|---------------------------------|--------------------------|---------------|
| Aug-18-2020 13:31:45<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NO | Initial Entry |

**2. Treatment Name**

| Date  | Location        | User                    | Value                                 | Reason        |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Aug-18-2020 13:31:45<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>BLINDED THERAPY | Initial Entry |

**3. Formulation:**

| Date  | Location        | User                    | Value                           | Reason        |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Aug-18-2020 13:31:45<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INJECTION | Initial Entry |

**4. Dose Date Time:**

| Date  | Location        | User                            | Value                                   | Reason        |
|---|-----------------|---------------------------------|---|---------------|
| Aug-18-2020 13:31:45<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>Aug/18/2020 11:19 | Initial Entry |

**5. Anatomical Location:**

| Date  | Location        | User                    | Value                                | Reason        |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Aug-18-2020 13:31:45<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>DELTOID MUSCLE | Initial Entry |

**6. Body Side:**

| Date  | Location        | User                            | Value                      | Reason        |
|---|-----------------|---------------------------------|----------------------------|---------------|
| Aug-18-2020 13:31:45<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>LEFT | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

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

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

**7. Route:**

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Aug-18-2020 13:31:45<br>(UTC-05:00) Eastern Time<br>(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        |
|---|-----------------|-------------------------|---|---------------|
| Aug-18-2020 13:31:45<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>THE PROTOCOL SPECIFIED OBS<br>ERVATION 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        |
|---|-----------------|---------------------------------|---------------------------|---------------|
| Aug-18-2020 13:31:45<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levisse

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

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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*I. Date of Visit*

| <b>Date</b>   | <b>Location</b> | <b>User</b>                | <b>Value</b>                      | <b>Reason</b> |
|---|-----------------|----------------------------|-----------------------------------|---------------|
| Sep-22-2020 16:00:06<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>Sep/22/2020 | Initial Entry |



Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levissc

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

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**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

| Date  | Location        | User                       | Value                    | Reason        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Sep-22-2020 16:00:37<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.a**

| Date  | Location        | User                       | Value   | Reason        |
|---|-----------------|----------------------------|---|---------------|
| Sep-22-2020 16:00:37<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br><b>Symptom::</b> FE<br>VE<br>R<br><br><b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO | Initial Entry |

**2.a Symptom:**

| Date  | Location        | User                       | Value                       | Reason        |
|---|-----------------|----------------------------|-----------------------------|---------------|
| Sep-22-2020 16:00:37<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>FEVER | Initial Entry |

**2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

| Date  | Location        | User                       | Value                    | Reason        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Sep-22-2020 16:00:37<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.b**

| Date  | Location        | User                       | Value  | Reason        |
|---|-----------------|----------------------------|--|---------------|
| Sep-22-2020 16:00:37<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br><b>Symptom::</b> FAT<br>IG<br>UE | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levissc

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

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | Were fever or systemic symptoms present on the last day the Subject Diary was completed?: |  |
|--|--|--|---|--|

2.b Symptom:

| Date  | Location        | User                       | Value                         | Reason        |
|---|-----------------|----------------------------|-------------------------------|---------------|
| Sep-22-2020 16:00:37<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <u>Data Entry:</u><br>FATIGUE | Initial Entry |

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date  | Location        | User                       | Value                    | Reason        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Sep-22-2020 16:00:37<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <u>Data Entry:</u><br>NO | Initial Entry |

2.c

| Date  | Location        | User                       | Value   | Reason        |
|---|-----------------|----------------------------|---|---------------|
| Sep-22-2020 16:00:37<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <u>Data Entry:</u><br><u>Symptom::</u> HEA<br>DAC<br>HE<br><br>Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO | Initial Entry |

2.c Symptom:

| Date  | Location        | User                       | Value                          | Reason        |
|---|-----------------|----------------------------|--------------------------------|---------------|
| Sep-22-2020 16:00:37<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <u>Data Entry:</u><br>HEADACHE | Initial Entry |

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date  | Location        | User                       | Value                    | Reason        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Sep-22-2020 16:00:37<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <u>Data Entry:</u><br>NO | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levisse

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

2.d

| Date  | Location        | User                       | Value  | Reason        |
|---|-----------------|----------------------------|--|---------------|
| Sep-22-2020 16:00:37<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br><b>Symptom::</b> CH<br>ILL<br>S<br><br><b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO | Initial Entry |

2.d Symptom:

| Date  | Location        | User                       | Value                        | Reason        |
|---|-----------------|----------------------------|------------------------------|---------------|
| Sep-22-2020 16:00:37<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>CHILLS | Initial Entry |

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date  | Location        | User                       | Value                    | Reason        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Sep-22-2020 16:00:37<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>NO | Initial Entry |

2.e

| Date  | Location        | User                       | Value  | Reason        |
|---|-----------------|----------------------------|--|---------------|
| Sep-22-2020 16:00:37<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br><b>Symptom::</b> VO<br>MIT<br>ING<br><br><b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levisse

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

2.e Symptom:

| Date  | Location        | User                       | Value                          | Reason        |
|---|-----------------|----------------------------|--------------------------------|---------------|
| Sep-22-2020 16:00:37<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>VOMITING | Initial Entry |

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date  | Location        | User                       | Value                    | Reason        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Sep-22-2020 16:00:37<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>NO | Initial Entry |

2.f

| Date  | Location        | User                       | Value   | Reason        |
|---|-----------------|----------------------------|---|---------------|
| Sep-22-2020 16:00:37<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br><b>Symptom::</b> DIA<br>RR<br>HE<br>A<br><br><b>Were fever or systemic sym<br/>ptoms present on the last da<br/>y the Subject Diary was com<br/>pleted?:</b> NO | Initial Entry |

2.f Symptom:

| Date  | Location        | User                       | Value                          | Reason        |
|---|-----------------|----------------------------|--------------------------------|---------------|
| Sep-22-2020 16:00:37<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>DIARRHEA | Initial Entry |

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date  | Location        | User                       | Value                    | Reason        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Sep-22-2020 16:00:37<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>NO | Initial Entry |

2.g

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

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levissc

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

|   |                 |                            |  |               |
|---|-----------------|----------------------------|--|---------------|
| Sep-22-2020 16:00:37<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br><b>Symptom::</b> NEW OR WORSE<br>ED MUSC<br>LE PAIN<br><br><b>Were fever or systemi<br/>c symptoms present o<br/>n the last day the Subj<br/>ect Diary was complet<br/>ed?:</b> NO | Initial Entry |
|---|-----------------|----------------------------|--|---------------|

**2.g Symptom:**

| Date  | Location        | User                       | Value   | Reason        |
|---|-----------------|----------------------------|---|---------------|
| Sep-22-2020 16:00:37<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>NEW OR WORSE<br>NED MUSCLE P<br>AIN | Initial Entry |

**2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

| Date  | Location        | User                       | Value                    | Reason        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Sep-22-2020 16:00:37<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.h**

| Date  | Location        | User                       | Value   | Reason        |
|---|-----------------|----------------------------|---|---------------|
| Sep-22-2020 16:00:37<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br><b>Symptom::</b> NEW OR<br>WORSE<br>ED JOIN<br>T PAIN<br><br><b>Were fever or systemic<br/>symptoms present on t<br/>he last day the Subject<br/>Diary was completed?:</b> NO | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levissc

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

**2.h Symptom:**

| Date  | Location        | User                       | Value   | Reason        |
|---|-----------------|----------------------------|---|---------------|
| Sep-22-2020 16:00:37<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>NEW OR WORSENERD JOINT PAI<br>N | Initial Entry |

**2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

| Date  | Location        | User                       | Value                    | Reason        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Sep-22-2020 16:00:37<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>NO | Initial Entry |

**3. Injection Site Location:**

| Date  | Location        | User                    | Value                                | Reason        |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Sep-22-2020 16:00:37<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>DELTOID MUSCLE | Initial Entry |

**4. Injection Site Body Side:**

| Date  | Location        | User                       | Value                      | Reason        |
|---|-----------------|----------------------------|----------------------------|---------------|
| Sep-22-2020 16:00:37<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>LEFT | Initial Entry |

**5.a**

| Date  | Location        | User                       | Value   | Reason        |
|---|-----------------|----------------------------|---|---------------|
| Sep-22-2020 16:00:37<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br><b>Injection Site Reaction::</b> RE<br>DN<br>ESS<br><b>Were injection site reactions</b> NO<br><b>present on the last day the S</b><br><b>ubject Diary was completed</b><br><b>?:</b> | Initial Entry |

**5.a Injection Site Reaction:**

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

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001  
**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History  
**Form Version:** 17-Jul-2020 21:54 **Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1001 **Site Name:** (1001) NYU Langone Health  
**Subject No:** 10011100 **Subject Initials:** ---  
**Generated By:** pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:04

|   |                 |                            |                               |               |
|---|-----------------|----------------------------|-------------------------------|---------------|
| Sep-22-2020 16:00:37<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>REDNESS | Initial Entry |
|---|-----------------|----------------------------|-------------------------------|---------------|

**5.a Were injection site reactions present on the last day the Subject Diary was completed?**

| Date  | Location        | User                       | Value                    | Reason        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Sep-22-2020 16:00:37<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>NO | Initial Entry |

**5.b**

| Date  | Location        | User                       | Value  | Reason        |
|---|-----------------|----------------------------|--|---------------|
| Sep-22-2020 16:00:37<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br><b>Injection Site Reaction::</b> SWE<br>LLI<br>NG<br><b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO | Initial Entry |

**5.b Injection Site Reaction:**

| Date  | Location        | User                       | Value                          | Reason        |
|---|-----------------|----------------------------|--------------------------------|---------------|
| Sep-22-2020 16:00:37<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>SWELLING | Initial Entry |

**5.b Were injection site reactions present on the last day the Subject Diary was completed?**

| Date  | Location        | User                       | Value                    | Reason        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Sep-22-2020 16:00:37<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>NO | Initial Entry |

**5.c**

| Date  | Location        | User                       | Value   | Reason        |
|---|-----------------|----------------------------|---|---------------|
| Sep-22-2020 16:00:37<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br><b>Injection Site Reaction::</b> PAIN AT INJECTION SITE | Initial Entry |

**Header Text:** c4591001

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

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

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

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

|  |  |  |    |  |
|--|--|--|----|--|
|  |  |  | TE |  |
| <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> |  |  |    |  |

**5.c Injection Site Reaction:**

| Date  | Location        | User                       | Value  | Reason        |
|---|-----------------|----------------------------|--|---------------|
| Sep-22-2020 16:00:37<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>PAIN AT INJECTION SITE | Initial Entry |

**5.c Were injection site reactions present on the last day the Subject Diary was completed?**

| Date  | Location        | User                       | Value                    | Reason        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Sep-22-2020 16:00:37<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)



Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

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        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Sep-22-2020 16:49:06<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date  | Location        | User                    | Value                       | Reason        |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Sep-22-2020 16:49:06<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SERUM | Initial Entry |

**3. Sample Collected?**

| Date  | Location        | User                       | Value   | Reason   |
|---|-----------------|----------------------------|---|--|
| Sep-22-2020 16:49:15<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)  | Query 1: Deleted  | Close Auto Query   |
| Sep-22-2020 16:49:06<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)  | Query 1: Candidate  | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Sep-22-2020 16:49:06<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Sep/22/2020 | Initial Entry  |

**5.a**

| Date  | Location        | User                       | Value  | Reason        |
|---|-----------------|----------------------------|--|---------------|
| Sep-22-2020 16:49:15<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br><b>Sample ID:</b> BNW7KF | Initial Entry |

**5.a Sample ID**

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

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

|   |                 |                            |                              |               |
|---|-----------------|----------------------------|------------------------------|---------------|
| Sep-22-2020 16:49:15<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>BNW7KF | Initial Entry |
|---|-----------------|----------------------------|------------------------------|---------------|

**5.b**

| Date  | Location        | User                       | Value  | Reason        |
|---|-----------------|----------------------------|--|---------------|
| Sep-22-2020 16:49:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br><b>Sample ID:</b> BNW7KN | Initial Entry |

**5.b Sample ID**

| Date  | Location        | User                       | Value                        | Reason        |
|---|-----------------|----------------------------|------------------------------|---------------|
| Sep-22-2020 16:49:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>BNW7KN | Initial Entry |

**5.c**

| Date  | Location        | User                       | Value  | Reason        |
|---|-----------------|----------------------------|--|---------------|
| Sep-22-2020 16:49:39<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br><b>Sample ID:</b> BNW7KP | Initial Entry |

**5.c Sample ID**

| Date  | Location        | User                       | Value                        | Reason        |
|---|-----------------|----------------------------|------------------------------|---------------|
| Sep-22-2020 16:49:39<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>BNW7KP | Initial Entry |

**5.d**

| Date  | Location        | User                       | Value  | Reason        |
|---|-----------------|----------------------------|--|---------------|
| Sep-22-2020 16:51:14<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br><b>Sample ID:</b> BP76RT | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**5.d Sample ID**

| Date  | Location        | User                       | Value                        | Reason        |
|---|-----------------|----------------------------|------------------------------|---------------|
| Sep-22-2020 16:51:14<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>BP76RT | Initial Entry |

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Aug/31/2020

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

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

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

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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*1. Date of Visit*

| <b>Date</b>   | <b>Location</b> | <b>User</b>                     | <b>Value</b>                      | <b>Reason</b> |
|---|-----------------|---------------------------------|-----------------------------------|---------------|
| Sep-03-2020 13:48:32<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>Aug/31/2020 | Initial Entry |

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Aug/31/2020

**Form:** UNPLANNED VISIT - eCRF Audit Trail History

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

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

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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*I. Assessments*

| Date  | Location        | User                         | Value                                 | Reason   |
|---|-----------------|------------------------------|---------------------------------------|--|
| Sep-03-2020 13:49:16<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)    | Query 1: Deleted                      | Close Auto Query   |
| Sep-03-2020 13:48:38<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)    | Query 1: Candidate                    | 'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate. |
| Sep-03-2020 13:48:38<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>CONTACT OUTCOME | Initial Entry  |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Aug/31/2020

**Form:** CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

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

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

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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**1. Contact Type:**

| Date  | Location        | User                    | Value                                 | Reason        |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Sep-03-2020 13:49:16<br>(UTC-05:00) Eastern Time<br>(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  |
|---|-----------------|------------------------------|--|---|
| Sep-03-2020 13:52:11<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)    | Query 2: Closed  | Close Auto Query  |
| Sep-03-2020 13:52:11<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>YES<br>Date of Contact:<br><br>Aug/31/2020<br><br>Contact Outcome:<br><br>VISIT ARRANGED | Transcription Error   |
| Sep-03-2020 13:51:53<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)    | Query 2: Opened  | Date of Contact 28/Aug/2020 is not equal to the Date of Visit 31/Aug/2020 within same unplanned visit. Please review and update as appropriate. |
| Sep-03-2020 13:51:53<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>YES<br>Date of Contact:<br><br>Aug/28/2020<br><br>Contact Outcome:<br><br>VISIT ARRANGED | Transcription Error   |
| Sep-03-2020 13:50:34<br>(UTC-05:00) Eastern                       | ACV0PFEINFP6000 | auto query<br>(autoquery)    | Query 1: Deleted   | Close Auto Query  |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Aug/31/2020

**Form:** CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

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

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

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

| Time (US & Canada)  |                 |                              |  |  |
|---|-----------------|------------------------------|--|--|
| Sep-03-2020 13:49:16<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)    | Query 1: Candidate   | Contact Outcome' is selected as 'VISIT ARRANGED' but no 'VITAL SIGNS' and/or 'UNPLANNED ASSESSMENT OF LOCAL REACTION' form(s) is/are entered. Please review and update as appropriate. |
| Sep-03-2020 13:49:16<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Akeem Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>YES<br>Date of Contact:<br>Aug/31/2020<br>Contact Outcome:<br>VISIT ARRANGED | Initial Entry  |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Aug/31/2020

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levissc

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

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**1. Date:**

| Date  | Location        | User                            | Value                             | Reason        |
|---|-----------------|---------------------------------|-----------------------------------|---------------|
| Sep-03-2020 13:49:49<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>Aug/31/2020 | Initial Entry |

**2.a**

| Date  | Location        | User                            | Value   | Reason        |
|---|-----------------|---------------------------------|---|---------------|
| Sep-03-2020 13:49:49<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br><b>Record Identifier::</b> 1<br><b>Temperature:</b> 36.9<br><b>Temperature Unit:</b> C<br><b>Temperature Location::</b> ORAL CAVITY | Initial Entry |

**2.a Record Identifier:**

| Date  | Location        | User                            | Value                   | Reason        |
|---|-----------------|---------------------------------|-------------------------|---------------|
| Sep-03-2020 13:49:49<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>1 | Initial Entry |

**2.a Temperature:**

| Date  | Location        | User                            | Value                      | Reason        |
|---|-----------------|---------------------------------|----------------------------|---------------|
| Sep-03-2020 13:49:49<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>36.9 | Initial Entry |

**2.a Unit:**

| Date  | Location        | User                            | Value                   | Reason        |
|---|-----------------|---------------------------------|-------------------------|---------------|
| Sep-03-2020 13:49:49<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>C | Initial Entry |

**2.a Temperature Location:**

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

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)



**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Aug/31/2020

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

**Form Version:** 21-Aug-2020 02:51

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

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

|   |                 |                                 |                                   |               |
|---|-----------------|---------------------------------|-----------------------------------|---------------|
| Sep-03-2020 13:49:49<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>ORAL CAVITY | Initial Entry |
|---|-----------------|---------------------------------|-----------------------------------|---------------|

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001**Visit:** Unplanned 1 - Unscheduled Visit on Aug/31/2020**Form Version:** 21-Aug-2020 02:49**Site No:** 1001**Subject No:** 10011100**Generated By:** pfe.levissc**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1001) NYU Langone Health**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Date of Assessment:**

| Date  | Location        | User                            | Value                             | Reason  |
|---|-----------------|---------------------------------|-----------------------------------|---|
| Oct-13-2020 08:27:45<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Luke Cunliffe<br>(pfe.cunlil01) | Query 1: Closed                   | Response satisfies query.   |
| Oct-12-2020 13:45:42<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman)      | Query 1: Answered                 | This was related to the poison ivy.   |
| Oct-12-2020 12:31:08<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Luke Cunliffe<br>(pfe.cunlil01) | Query 1: Opened                   | ClinQuery: No redness was noted in the participant's ed diary, please confirm if the redness was isolated at the injection site or whether this is related to the AE of poison ivy. If this is an injection site reaction, please add as a separate AE. |
| Sep-03-2020 13:50:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem Moore<br>(pfe.amoore1)    | <b>Data Entry:</b><br>Aug/31/2020 | Initial Entry   |

**2. Injection Site Location**

| Date  | Location        | User                    | Value                                | Reason        |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Sep-03-2020 13:50:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>DELTOID MUSCLE | Initial Entry |

**3. Injection Site Body Side:**

| Date  | Location        | User                         | Value                      | Reason        |
|---|-----------------|------------------------------|----------------------------|---------------|
| Sep-03-2020 13:50:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>LEFT | Initial Entry |

**4.a**

**Header Text:** c4591001**Visit:** Unplanned 1 - Unscheduled Visit on Aug/31/2020**Form Version:** 21-Aug-2020 02:49**Site No:** 1001**Subject No:** 10011100**Generated By:** pfe.levissc**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1001) NYU Langone Health**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

| Date  | Location        | User                            | Value  | Reason        |
|---|-----------------|---------------------------------|--|---------------|
| Sep-03-2020 13:50:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br><b>Reaction::</b> REDNESS<br><b>Reaction P</b> YES<br><b>resent::</b> <i>Maximum Diameter (cm):</i><br><br>4.0<br><br><i>Minimum Diameter (cm):</i><br><br>2.0<br><br>Meets Grade 4 Reaction Criteria:<br><br>NO | Initial Entry |

**4.a Reaction:**

| Date  | Location        | User                            | Value                         | Reason        |
|---|-----------------|---------------------------------|-------------------------------|---------------|
| Sep-03-2020 13:50:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>REDNESS | Initial Entry |

**4.a Reaction Present:**

| Date  | Location        | User                            | Value   | Reason        |
|---|-----------------|---------------------------------|---|---------------|
| Sep-03-2020 13:50:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>YES<br><i>Maximum Diameter (cm):</i><br><br>4.0<br><br><i>Minimum Diameter (cm):</i><br><br>2.0<br><br>Meets Grade 4 Reaction Criteria:<br><br>NO | Initial Entry |

**4.b**

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

**Header Text:** c4591001**Visit:** Unplanned 1 - Unscheduled Visit on  
Aug/31/2020**Form Version:** 21-Aug-2020 02:49**Site No:** 1001**Subject No:** 10011100**Generated By:** pfe.levissc**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION -  
SYSTEMIC EVENT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1001) NYU Langone Health**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

|   |                 |                                 |  |               |
|---|-----------------|---------------------------------|--|---------------|
| Sep-03-2020 13:50:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br><b>Reaction::</b> SWELLING<br><b>Reaction Present::</b> NO | Initial Entry |
|---|-----------------|---------------------------------|--|---------------|

**4.b Reaction:**

| Date  | Location        | User                            | Value                          | Reason        |
|---|-----------------|---------------------------------|--------------------------------|---------------|
| Sep-03-2020 13:50:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>SWELLING | Initial Entry |

**4.b Reaction Present:**

| Date  | Location        | User                            | Value                    | Reason        |
|---|-----------------|---------------------------------|--------------------------|---------------|
| Sep-03-2020 13:50:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NO | Initial Entry |

**5.a**

| Date  | Location        | User                            | Value   | Reason        |
|---|-----------------|---------------------------------|---|---------------|
| Sep-03-2020 13:50:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br><b>Symptom::</b> PAIN AT INJECTI<br>ON SITE<br><b>Symptom Pre NO</b><br><b>sent::</b> | Initial Entry |

**5.a Symptom:**

| Date  | Location        | User                            | Value  | Reason        |
|---|-----------------|---------------------------------|--|---------------|
| Sep-03-2020 13:50:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>PAIN AT INJECTION SITE | Initial Entry |

**5.a Symptom Present:**

| Date  | Location        | User                            | Value                    | Reason        |
|---|-----------------|---------------------------------|--------------------------|---------------|
| Sep-03-2020 13:50:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NO | Initial Entry |

**5.b**

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

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Aug/31/2020

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levissc

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

|   |                 |                                 |   |               |
|---|-----------------|---------------------------------|---|---------------|
| Sep-03-2020 13:50:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br><b>Symptom::</b> FATIGUE/TIRED<br>NESS<br><b>Symptom Present::</b> NO | Initial Entry |
|---|-----------------|---------------------------------|---|---------------|

5.b Symptom:

| Date  | Location        | User                            | Value                                   | Reason        |
|---|-----------------|---------------------------------|---|---------------|
| Sep-03-2020 13:50:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>FATIGUE/TIREDNESS | Initial Entry |

5.b Symptom Present:

| Date  | Location        | User                            | Value                    | Reason        |
|---|-----------------|---------------------------------|--------------------------|---------------|
| Sep-03-2020 13:50:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NO | Initial Entry |

5.c

| Date  | Location        | User                            | Value  | Reason        |
|---|-----------------|---------------------------------|--|---------------|
| Sep-03-2020 13:50:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br><b>Symptom::</b> HEADACHE<br><b>Symptom Present::</b> NO | Initial Entry |

5.c Symptom:

| Date  | Location        | User                            | Value                          | Reason        |
|---|-----------------|---------------------------------|--------------------------------|---------------|
| Sep-03-2020 13:50:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>HEADACHE | Initial Entry |

5.c Symptom Present:

| Date  | Location        | User                            | Value                    | Reason        |
|---|-----------------|---------------------------------|--------------------------|---------------|
| Sep-03-2020 13:50:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NO | Initial Entry |

5.d

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

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001**Visit:** Unplanned 1 - Unscheduled Visit on  
Aug/31/2020**Form Version:** 21-Aug-2020 02:49**Site No:** 1001**Subject No:** 10011100**Generated By:** pfe.levissc**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION -  
SYSTEMIC EVENT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1001) NYU Langone Health**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

|   |                 |                                 |  |               |
|---|-----------------|---------------------------------|--|---------------|
| Sep-03-2020 13:50:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br><b>Symptom::</b> VOMITING<br><b>Symptom Present::</b> NO | Initial Entry |
|---|-----------------|---------------------------------|--|---------------|

**5.d Symptom:**

| Date  | Location        | User                            | Value                          | Reason        |
|---|-----------------|---------------------------------|--------------------------------|---------------|
| Sep-03-2020 13:50:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>VOMITING | Initial Entry |

**5.d Symptom Present:**

| Date  | Location        | User                            | Value                    | Reason        |
|---|-----------------|---------------------------------|--------------------------|---------------|
| Sep-03-2020 13:50:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NO | Initial Entry |

**5.e**

| Date  | Location        | User                            | Value  | Reason        |
|---|-----------------|---------------------------------|--|---------------|
| Sep-03-2020 13:50:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br><b>Symptom::</b> DIARRHEA<br><b>Symptom Present::</b> NO | Initial Entry |

**5.e Symptom:**

| Date  | Location        | User                            | Value                          | Reason        |
|---|-----------------|---------------------------------|--------------------------------|---------------|
| Sep-03-2020 13:50:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>DIARRHEA | Initial Entry |

**5.e Symptom Present:**

| Date  | Location        | User                            | Value                    | Reason        |
|---|-----------------|---------------------------------|--------------------------|---------------|
| Sep-03-2020 13:50:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NO | Initial Entry |

**5.f**

| Date                 | Location        | User  | Value              | Reason        |
|----------------------|-----------------|-------|--------------------|---------------|
| Sep-03-2020 13:50:34 | ACV0PFEINFP6000 | Akeem | <b>Data Entry:</b> | Initial Entry |

**Header Text:** c4591001**Visit:** Unplanned 1 - Unscheduled Visit on Aug/31/2020**Form Version:** 21-Aug-2020 02:49**Site No:** 1001**Subject No:** 10011100**Generated By:** pfe.levissc**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1001) NYU Langone Health**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

|   |  |                        |   |  |
|---|--|------------------------|---|--|
| (UTC-05:00) Eastern Time<br>(US & Canada) |  | Moore<br>(pfe.amoore1) | <b>Symptom:</b> NEW OR WORSENE<br>:<br>D MUSCLE PAIN<br><b>Symptom</b> NO<br><b>Present::</b> |  |
|---|--|------------------------|---|--|

**5.f Symptom:**

| Date  | Location        | User                            | Value   | Reason        |
|---|-----------------|---------------------------------|---|---------------|
| Sep-03-2020 13:50:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NEW OR WORSENE D MUSCLE<br>PAIN | Initial Entry |

**5.f Symptom Present:**

| Date  | Location        | User                            | Value                    | Reason        |
|---|-----------------|---------------------------------|--------------------------|---------------|
| Sep-03-2020 13:50:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NO | Initial Entry |

**5.g**

| Date  | Location        | User                            | Value   | Reason        |
|---|-----------------|---------------------------------|---|---------------|
| Sep-03-2020 13:50:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br><b>Symptom::</b> NEW OR WORSENE<br>D JOINT PAIN<br><b>Symptom P</b> NO<br><b>resent::</b> | Initial Entry |

**5.g Symptom:**

| Date  | Location        | User                            | Value   | Reason        |
|---|-----------------|---------------------------------|---|---------------|
| Sep-03-2020 13:50:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NEW OR WORSENE D JOINT PAI<br>N | Initial Entry |

**5.g Symptom Present:**

| Date  | Location        | User                            | Value                    | Reason        |
|---|-----------------|---------------------------------|--------------------------|---------------|
| Sep-03-2020 13:50:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NO | Initial Entry |

**5.h**

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Aug/31/2020

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.lewissc

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

| Date  | Location        | User                            | Value  | Reason        |
|---|-----------------|---------------------------------|--|---------------|
| Sep-03-2020 13:50:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br><b>Symptom::</b> CHILLS<br><b>Symptom Present::</b> NO | Initial Entry |

**5.h Symptom:**

| Date  | Location        | User                            | Value                        | Reason        |
|---|-----------------|---------------------------------|------------------------------|---------------|
| Sep-03-2020 13:50:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>CHILLS | Initial Entry |

**5.h Symptom Present:**

| Date  | Location        | User                            | Value                    | Reason        |
|---|-----------------|---------------------------------|--------------------------|---------------|
| Sep-03-2020 13:50:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)



**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levisse

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

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

**Site Name:** (1001) NYU Langone Health

**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        |
|---|-----------------|----------------------------|-----------------------------------|---------------|
| Sep-23-2020 09:44:19<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>Sep/22/2020 | Initial Entry |

**2. Phase of Disposition:**

| Date  | Location        | User                    | Value                             | Reason        |
|---|-----------------|-------------------------|-----------------------------------|---------------|
| Sep-23-2020 09:44:19<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>VACCINATION | Initial Entry |

**3. Status:**

| Date  | Location        | User                       | Value                           | Reason        |
|---|-----------------|----------------------------|---------------------------------|---------------|
| Sep-23-2020 09:44:19<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>COMPLETED | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001**Visit:** Follow-Up - Unscheduled**Form Version:** 15-Sep-2020 21:53**Site No:** 1001**Subject No:** 10011100**Generated By:** pfe.levisse**Form:** DISPOSITION - FOLLOW-UP - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1001) NYU Langone Health**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Date of Completion/Discontinuation/Death :**

| Date  | Location        | User                         | Value                             | Reason   |
|---|-----------------|------------------------------|-----------------------------------|--|
| Feb-19-2021 18:15:49<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Hayley Wyper<br>(pfe.wyperh) | Query 1: Closed                   | Response satisfies query   |
| Feb-19-2021 16:50:32<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria)      | <b>Data Entry:</b><br>Not Done    | Initial Entry  |
| Feb-19-2021 16:49:54<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)    | Query 1: Answered                 | data correction  |
| Feb-19-2021 16:49:54<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria)      | <b>Data Entry:</b>                | data correction  |
| Feb-19-2021 12:29:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Hayley Wyper<br>(pfe.wyperh) | Query 1: Opened                   | CLINQUERY:<br>Subject received vaccination 3 in January 2021 and per CRF remains on study. Please review the completion of this page - the Disp FUP page reports end of study. |
| Feb-16-2021 10:45:14<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria)      | <b>Data Entry:</b><br>Dec/13/2020 | Initial Entry  |

**2. Phase of Disposition:**

| Date  | Location        | User                    | Value                           | Reason          |
|---|-----------------|-------------------------|---------------------------------|-----------------|
| Feb-19-2021 16:50:32<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Not Done  | Initial Entry   |
| Feb-19-2021 16:49:54<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b>              | data correction |
| Feb-16-2021 10:45:14<br>(UTC-05:00) Eastern Time                  | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>FOLLOW-UP | Initial Entry   |

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levissc

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

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

3. Status:

| Date  | Location        | User                      | Value                               | Reason  |
|---|-----------------|---------------------------|-------------------------------------|---|
| Feb-19-2021 16:50:32<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe nria)   | <u>Data Entry:</u><br>Not Done      | Initial Entry   |
| Feb-19-2021 16:50:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Closed                     | Close Auto Query  |
| Feb-19-2021 16:50:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe nria)   | <u>Data Entry:</u>                  | data correction   |
| Feb-19-2021 16:50:07<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 2: Closed                     | Close Auto Query  |
| Feb-16-2021 10:45:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 2: Opened                     | Response to "Status" is ADVERSE EVENT but "Specify Status" is Provided.   |
| Feb-16-2021 10:45:14<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Opened                     | Status is reported as Adverse Event, but there is no Adverse Event with 'Did the adverse event cause the subject to be discontinued from the study' reported as YES. Please check and correct the data. |
| Feb-16-2021 10:45:14<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe nria)   | <u>Data Entry:</u><br>ADVERSE EVENT | Initial Entry   |

4. Specify Status:

| Date  | Location        | User                          | Value           | Reason                   |
|---|-----------------|-------------------------------|-----------------|--------------------------|
| Feb-21-2021 23:41:46<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Amol Shinde<br>(pfe.shinda18) | Query 1: Closed | Response satisfies query |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form:** DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

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

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

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

|   |   |                                   |   |  |
|---|---|-----------------------------------|---|--|
| Feb-19-2021<br>16:50:32<br>(UTC-05:00)<br>Eastern Time<br>(US & Canada) | ACV0PFEINFP6000                           | Nazia Ria (pfe nria)              | <b>Data Entry:</b><br>Not Done                      | Initial Entry  |
| Feb-19-2021<br>16:50:07<br>(UTC-05:00)<br>Eastern Time<br>(US & Canada) | ACV0PFEINFP6000                           | auto query<br>(autoquery)         | Query 1: An<br>swered                               | data correction  |
| Feb-19-2021<br>16:50:07<br>(UTC-05:00)<br>Eastern Time<br>(US & Canada) | ACV0PFEINFP6000                           | Nazia Ria (pfe nria)              | <b>Data Entry:</b>                                  | data correction  |
| Feb-18-2021<br>04:48:08<br>(UTC-05:00)<br>Eastern Time<br>(US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFE SDQ PROD<br>(pfe.PFESDQ_PROD) | Query 1: Op<br>ened                                 | Please review<br>Specify Status<br>field, the<br>following text<br>was indicated in<br>the comment<br>field [metatarsal<br>fracture]. Any<br>symptoms, AEs<br>or other key data<br>should be<br>collected on the<br>appropriate page.<br>Please review<br>and update as<br>necessary.<br>"[naikp09<br>SDQ=130530]" |
| Feb-16-2021<br>10:45:34<br>(UTC-05:00)<br>Eastern Time<br>(US & Canada) | ACV0PFEINFP6000                           | Nazia Ria (pfe nria)              | <b>Data Entry:</b><br>R 5th metata<br>rsal fracture | Initial Entry  |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001  
**Visit:** Logs - Unscheduled **Form:** ADVERSE EVENT REPORT - Audit Trail  
**Form Version:** 22-Apr-2020 21:02 **Form Status:**  
**Site No:** 1001 **Site Name:** (1001) NYU Langone Health  
**Subject No:** 10011100 **Subject Initials:** ---  
**Generated By:** pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:04

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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| Date  | Location        | User                         | Value        | Reason  |
|---|-----------------|------------------------------|--------------|---|
| Sep-23-2020 15:22:16<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman)   | Form Deleted | Per investigator discretion, updated AE of dermatitis is more appropriate |
| Aug-18-2020 13:52:16<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem Moore<br>(pfe.amoore1) | Form Created |   |

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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| Date  | Location        | User                         | Value        | Reason  |
|---|-----------------|------------------------------|--------------|---|
| Sep-23-2020 15:22:16<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman)   | Form Deleted | Per investigator discretion, updated AE of dermatitis is more appropriate |
| Sep-03-2020 13:43:36<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem Moore<br>(pfe.amoore1) | Form Created |   |

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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| Date  | Location        | User                         | Value        | Reason  |
|---|-----------------|------------------------------|--------------|---|
| Sep-23-2020 15:22:16<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman)   | Form Deleted | Per investigator discretion, updated AE of dermatitis is more appropriate |
| Sep-03-2020 13:45:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem Moore<br>(pfe.amoore1) | Form Created |   |

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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| Date  | Location        | User                         | Value        | Reason  |
|---|-----------------|------------------------------|--------------|---|
| Sep-23-2020 15:22:16<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman)   | Form Deleted | Per investigator discretion, updated AE of dermatitis is more appropriate |
| Sep-03-2020 13:48:15<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem Moore<br>(pfe.amoore1) | Form Created |   |



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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| Date  | Location        | User                       | Value        | Reason |
|---|-----------------|----------------------------|--------------|--------|
| Sep-23-2020 15:24:16<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | Form Created |        |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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| Date  | Location        | User                       | Value        | Reason |
|---|-----------------|----------------------------|--------------|--------|
| Sep-23-2020 15:26:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | Form Created |        |

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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| Date  | Location        | User                    | Value        | Reason |
|---|-----------------|-------------------------|--------------|--------|
| Feb-18-2021 13:47:10<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | Form Created |        |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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| Date  | Location        | User                    | Value        | Reason |
|---|-----------------|-------------------------|--------------|--------|
| Feb-18-2021 13:56:09<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | Form Created |        |

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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| Date  | Location        | User                    | Value        | Reason |
|---|-----------------|-------------------------|--------------|--------|
| Feb-18-2021 14:01:14<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | Form Created |        |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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| Date  | Location        | User                    | Value        | Reason |
|---|-----------------|-------------------------|--------------|--------|
| Feb-24-2021 12:28:53<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | Form Created |        |

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, Deleted, Locked, Frozen

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levissc

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

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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**1. Category:**

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Aug-18-2020 13:52:16<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ADVERSE EVENT | Initial Entry |

**2. AE ID:**

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-18-2020 13:52:16<br>(UTC-05:00) Eastern Time<br>(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   |
|---|-----------------|---|--|--|
| Aug-25-2020 08:36:34<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Gary Steven<br>Friedman<br>(pfe.friedg01) | Query 1: Closed                            | Response satisfies<br>query  |
| Aug-24-2020 17:03:23<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman)                | Query 1: Answered                          | have followed up<br>with clinician and<br>will update this when<br>I receive a response.   |
| Aug-24-2020 07:54:48<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Gary Steven<br>Friedman<br>(pfe.friedg01) | Query 1: Opened                            | MACULAR RASH<br>ON NECK: please<br>confirm that the event<br>has or has not<br>resolved to date<br>(currently ongoing<br>for approximately 10<br>days. |
| Aug-18-2020 13:52:16<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1)           | <b>Data Entry:</b><br>macular rash on neck | Initial Entry  |

**4. Start Date Time:**

| Date                 | Location        | User  | Value              | Reason          |
|----------------------|-----------------|-------|--------------------|-----------------|
| Sep-03-2020 13:40:23 | ACV0PFEINFP6000 | Akeem | <b>Data Entry:</b> | New Information |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1001**Subject No:** 10011100**Generated By:** pfe.levissc**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Deleted, Locked, Frozen**Site Name:** (1001) NYU Langone Health**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

|   |                 |                                 |   |               |
|---|-----------------|---------------------------------|---|---------------|
| (UTC-05:00) Eastern Time<br>(US & Canada)                         |                 | Moore<br>(pfe.amoore1)          | Aug/10/2020 UNK:UNK                       |               |
| Aug-18-2020 13:52:16<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>Aug/13/2020 UNK:UNK | Initial Entry |

**5. Is the adverse event still ongoing?**

| Date  | Location        | User                            | Value   | Reason          |
|---|-----------------|---------------------------------|---|-----------------|
| Aug-31-2020 16:20:59<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NO<br>End Date Time:<br>Aug/25/2020 UNK:UNK | New Information |
| Aug-18-2020 13:52:16<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>YES   | Initial Entry   |

**6. Toxicity Grade:**

| Date  | Location        | User                            | Value                   | Reason        |
|---|-----------------|---------------------------------|-------------------------|---------------|
| Aug-18-2020 13:52:16<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>2 | 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        |
|---|-----------------|---------------------------------|--------------------------|---------------|
| Aug-18-2020 13:52:16<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <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        |
|--|-----------------|----------------|--------------------------|---------------|
| Aug-18-2020 13:52:16<br>(UTC-05:00) Eastern Time | ACV0PFEINFP6000 | Akeem<br>Moore | <b>Data Entry:</b><br>NO | Initial Entry |



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, Deleted, Locked, Frozen

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levissc

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

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(US & Canada)

(pfe.amoore1)

9. Is this event related to study treatment:

| Date  | Location        | User                            | Value  | Reason        |
|---|-----------------|---------------------------------|--|---------------|
| Aug-18-2020 13:52:16<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NOT RELATED<br>If Not Related to study treatment(s<br>) , this event is due to:<br><br>OTHER<br><br>If Other, specify:<br><br>poison ivy | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date  | Location        | User                            | Value                                | Reason        |
|---|-----------------|---------------------------------|--------------------------------------|---------------|
| Aug-18-2020 13:52:16<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

| Date  | Location        | User                            | Value                     | Reason        |
|---|-----------------|---------------------------------|---------------------------|---------------|
| Aug-18-2020 13:52:16<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>YES | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date  | Location        | User                            | Value                    | Reason        |
|---|-----------------|---------------------------------|--------------------------|---------------|
| Aug-18-2020 13:52:16<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NO | Initial Entry |

13. What was the outcome of this adverse event?:

| Date  | Location        | User                      | Value           | Reason           |
|---|-----------------|---------------------------|-----------------|------------------|
| Aug-31-2020 16:21:48<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Closed | Close Auto Query |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (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, Deleted, Locked, Frozen

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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|   |                 |                                 |  |  |
|---|-----------------|---------------------------------|--|--|
| Aug-31-2020 16:21:48<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>RECOVERED/RESOLVED   | New Information  |
| Aug-31-2020 16:20:59<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)       | Query 1: Opened                            | For AE macular rash<br>on neck: Response to<br>"What was the outcome<br>of this adverse event?"<br>is<br>'Recovering/Resolving'<br>but AE End Date/Time<br>is present. |
| Aug-18-2020 13:52:16<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>RECOVERING/RESOLVING | Initial Entry  |

**14. Did the adverse event cause the subject to be discontinued from the study?**

| Date  | Location        | User                            | Value                    | Reason        |
|---|-----------------|---------------------------------|--------------------------|---------------|
| Aug-18-2020 13:52:16<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1001

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Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Locked, Frozen

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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**1. Category:**

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Sep-03-2020 13:43:36<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ADVERSE EVENT | Initial Entry |

**2. AE ID:**

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-03-2020 13:43:36<br>(UTC-05:00) Eastern Time<br>(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        |
|---|-----------------|---------------------------------|---|---------------|
| Sep-03-2020 13:43:36<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>Dermatitis with red patch on left abdomen | Initial Entry |

**4. Start Date Time:**

| Date  | Location        | User                            | Value                                     | Reason        |
|---|-----------------|---------------------------------|---|---------------|
| Sep-03-2020 13:43:36<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>Aug/10/2020 UNK:UNK | Initial Entry |

**5. Is the adverse event still ongoing?**

| Date  | Location        | User                            | Value  | Reason          |
|---|-----------------|---------------------------------|--|-----------------|
| Sep-16-2020 13:15:44<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NO<br>End Date Time:<br>Sep/9/2020 UNK:UNK | New Information |
| Sep-03-2020 13:43:36<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>YES  | Initial Entry   |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (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, Deleted, Locked, Frozen

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levissc

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

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6. Toxicity Grade:

| Date  | Location        | User                            | Value                   | Reason        |
|---|-----------------|---------------------------------|-------------------------|---------------|
| Sep-03-2020 13:43:36<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <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        |
|---|-----------------|---------------------------------|--------------------------|---------------|
| Sep-03-2020 13:43:36<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <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        |
|---|-----------------|---------------------------------|--------------------------|---------------|
| Sep-03-2020 13:43:36<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NO | Initial Entry |

9. Is this event related to study treatment:

| Date  | Location        | User                            | Value  | Reason        |
|---|-----------------|---------------------------------|--|---------------|
| Sep-03-2020 13:43:36<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NOT RELATED<br>If Not Related to study treatment(s)<br>, this event is due to:<br><br>OTHER<br><br>If Other, specify:<br><br>Unspecified | Initial Entry |

10. Latest Action Taken with Study Treatment:

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

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Subject Initials: ---

Generated By: pfe.levissc

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

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|   |                 |                                 |                                      |               |
|---|-----------------|---------------------------------|--------------------------------------|---------------|
| Sep-03-2020 13:43:36<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NOT APPLICABLE | Initial Entry |
|---|-----------------|---------------------------------|--------------------------------------|---------------|

**11. Was a Concomitant Medication given?**

| Date   | Location        | User                                   | Value                     | Reason  |
|--|-----------------|--|---------------------------|---|
| Sep-17-2020 10:57:31<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Gary Steven Friedman<br>(pfe.friedg01) | Query 1: Closed           | Response satisfies query  |
| Sep-16-2020 13:15:22<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)              | Query 1: Answered         | Not prohibited concomitant medication.  |
| Sep-16-2020 13:15:22<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Akeem Moore<br>(pfe.amoore1)           | <b>Data Entry:</b><br>NO  | Not prohibited concomitant medication.  |
| Sep-16-2020 07:46:05<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Gary Steven Friedman<br>(pfe.friedg01) | Query 1: Opened           | CON MED TREATMENT: please confirm the participant IS or IS NOT receiving ORAL OR PARENTERAL CORTICOSTEROIDS for this ONGOING adverse event. |
| Sep-03-2020 13:43:36<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Akeem Moore<br>(pfe.amoore1)           | <b>Data Entry:</b><br>YES | Initial Entry   |

**12. Was a Non-Drug Treatment given?**

| Date   | Location        | User                         | Value                    | Reason        |
|--|-----------------|------------------------------|--------------------------|---------------|
| Sep-03-2020 13:43:36<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Akeem Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NO | Initial Entry |

**13. What was the outcome of this adverse event?:**

| Date   | Location        | User                      | Value           | Reason           |
|--|-----------------|---------------------------|-----------------|------------------|
| Sep-16-2020 13:17:06<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Closed | Close Auto Query |

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**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, Deleted, Locked, Frozen

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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|   |                 |                                 |  |  |
|---|-----------------|---------------------------------|--|--|
| Sep-16-2020 13:17:06<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>RECOVERED/RESOLVED   | New Information  |
| Sep-16-2020 13:15:44<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)       | Query 1: Opened                            | For AE Dermatitis with<br>red patch on left<br>abdomen: Response to<br>"What was the outcome<br>of this adverse event?"<br>is<br>'Recovering/Resolving'<br>but AE End Date/Time<br>is present. |
| Sep-03-2020 13:43:36<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>RECOVERING/RESOLVING | Initial Entry  |

**14. Did the adverse event cause the subject to be discontinued from the study?**

| Date  | Location        | User                            | Value                    | Reason        |
|---|-----------------|---------------------------------|--------------------------|---------------|
| Sep-03-2020 13:43:36<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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**Subject No:** 10011100

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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**1. Category:**

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Sep-03-2020 13:45:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ADVERSE EVENT | Initial Entry |

**2. AE ID:**

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-03-2020 13:45:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>3 | Initial Entry |

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

| Date  | Location        | User                            | Value   | Reason        |
|---|-----------------|---------------------------------|---|---------------|
| Sep-03-2020 13:45:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>Dermatitis with red patch on right b<br>reast | Initial Entry |

**4. Start Date Time:**

| Date  | Location        | User                            | Value                                     | Reason        |
|---|-----------------|---------------------------------|---|---------------|
| Sep-03-2020 13:45:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>Aug/10/2020 UNK:UNK | Initial Entry |

**5. Is the adverse event still ongoing?**

| Date  | Location        | User                            | Value  | Reason          |
|---|-----------------|---------------------------------|--|-----------------|
| Sep-16-2020 13:16:10<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NO<br>End Date Time:<br>Sep/9/2020 UNK:UNK | New Information |
| Sep-03-2020 13:45:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>YES  | Initial Entry   |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Deleted, Locked, Frozen

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levissc

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

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6. Toxicity Grade:

| Date  | Location        | User                            | Value                   | Reason        |
|---|-----------------|---------------------------------|-------------------------|---------------|
| Sep-03-2020 13:45:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <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        |
|---|-----------------|---------------------------------|--------------------------|---------------|
| Sep-03-2020 13:45:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <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        |
|---|-----------------|---------------------------------|--------------------------|---------------|
| Sep-03-2020 13:45:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NO | Initial Entry |

9. Is this event related to study treatment:

| Date  | Location        | User                            | Value  | Reason        |
|---|-----------------|---------------------------------|--|---------------|
| Sep-03-2020 13:45:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NOT RELATED<br>If Not Related to study treatment(s)<br>, this event is due to:<br><br>OTHER<br><br>If Other, specify:<br><br>Unspecified non-allergy | Initial Entry |

10. Latest Action Taken with Study Treatment:

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

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Header Text: c4591001

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Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levissc

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

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|   |                 |                                 |                                      |               |
|---|-----------------|---------------------------------|--------------------------------------|---------------|
| Sep-03-2020 13:45:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NOT APPLICABLE | Initial Entry |
|---|-----------------|---------------------------------|--------------------------------------|---------------|

**11. Was a Concomitant Medication given?**

| Date  | Location        | User                            | Value                     | Reason        |
|---|-----------------|---------------------------------|---------------------------|---------------|
| Sep-03-2020 13:45:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>YES | Initial Entry |

**12. Was a Non-Drug Treatment given?**

| Date  | Location        | User                            | Value                    | Reason        |
|---|-----------------|---------------------------------|--------------------------|---------------|
| Sep-03-2020 13:45:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NO | Initial Entry |

**13. What was the outcome of this adverse event?:**

| Date  | Location        | User                            | Value                                      | Reason   |
|---|-----------------|---------------------------------|--|--|
| Sep-16-2020 13:17:23<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)       | Query 1: Closed                            | Close Auto Query   |
| Sep-16-2020 13:17:23<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>RECOVERED/RESOLVED   | New Information  |
| Sep-16-2020 13:16:10<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)       | Query 1: Opened                            | For AE Dermatitis with<br>red patch on right<br>breast: Response to<br>"What was the outcome<br>of this adverse event?"<br>is<br>'Recovering/Resolving'<br>but AE End Date/Time<br>is present. |
| Sep-03-2020 13:45:34<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>RECOVERING/RESOLVING | Initial Entry  |

**14. Did the adverse event cause the subject to be discontinued from the study?**

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

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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|---|-----------------|---------------------------------|--------------------------|---------------|
| Sep-03-2020 13:45:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <u>Data Entry:</u><br>NO | Initial Entry |
|---|-----------------|---------------------------------|--------------------------|---------------|

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1001

Subject No: 10011100

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Locked, Frozen

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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**1. Category:**

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Sep-03-2020 13:48:15<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ADVERSE EVENT | Initial Entry |

**2. AE ID:**

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-03-2020 13:48:15<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>4 | Initial Entry |

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

| Date  | Location        | User                            | Value   | Reason        |
|---|-----------------|---------------------------------|---|---------------|
| Sep-03-2020 13:48:15<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>Dermatitis with red patch from left<br>areola extending laterally | Initial Entry |

**4. Start Date Time:**

| Date  | Location        | User                            | Value                                     | Reason  |
|---|-----------------|---------------------------------|---|---|
| Sep-09-2020 05:21:03<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Xiaoxia Liu<br>(pfe xiaoxl)     | Query 1: Closed                           | Response satisfies<br>query   |
| Sep-08-2020 19:12:59<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)       | Query 1: Answered                         | Transcription Error   |
| Sep-08-2020 19:12:59<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>Aug/10/2020 UNK:UNK | Transcription Error   |
| Sep-07-2020 20:45:26<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Xiaoxia Liu<br>(pfe xiaoxl)     | Query 1: Opened                           | ClinQuery:<br>Dermatitis with red<br>patch from left areola<br>extending laterally:<br>Please can you<br>review the start date<br>of this AE as it is a |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (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, Deleted, Locked, Frozen

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.lewissc

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

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

|  |                 |                              |   |   |
|--|-----------------|------------------------------|---|---|
|  |                 |                              |   | few days after the other AE's of dermatitis the subject experienced. Thanks |
| Sep-03-2020 13:48:15<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Akeem Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>Aug/13/2020 UNK:UNK | Initial Entry   |

5. Is the adverse event still ongoing?

| Date   | Location        | User                         | Value  | Reason  |
|--|-----------------|------------------------------|--|---|
| Sep-16-2020 13:16:30<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Akeem Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NO<br>End Date Time:<br>Sep/9/2020 UNK:UNK | New Information   |
| Sep-13-2020 20:43:57<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Xiaoxia Liu<br>(pfe.xiaoxl)  | Query 1: Closed  | Response satisfies query  |
| Sep-10-2020 11:34:19<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Akeem Moore<br>(pfe.amoore1) | Query 1: Answered  | AE is still ongoing.  |
| Sep-09-2020 20:32:33<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Xiaoxia Liu<br>(pfe.xiaoxl)  | Query 1: Opened  | ClinQuery:<br>Dermatitis with red patch from left areola extending laterally:<br>Please can you confirm if this AE is still ongoing? If not, please enter a stop date. Thanks |
| Sep-03-2020 13:48:15<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Akeem Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>YES  | Initial Entry   |

6. Toxicity Grade:

| Date   | Location        | User                         | Value                   | Reason        |
|--|-----------------|------------------------------|-------------------------|---------------|
| Sep-03-2020 13:48:15<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Akeem Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>1 | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (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, Deleted, Locked, Frozen

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levissc

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

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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        |
|---|-----------------|---------------------------------|--------------------------|---------------|
| Sep-03-2020 13:48:15<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <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        |
|---|-----------------|---------------------------------|--------------------------|---------------|
| Sep-03-2020 13:48:15<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NO | Initial Entry |

9. Is this event related to study treatment:

| Date  | Location        | User                            | Value  | Reason        |
|---|-----------------|---------------------------------|--|---------------|
| Sep-03-2020 13:48:15<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NOT RELATED<br>If Not Related to study treatment(s)<br>, this event is due to:<br><br>OTHER<br><br>If Other, specify:<br><br>unspecified non-allergic reacti<br>on | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date  | Location        | User                            | Value                                | Reason        |
|---|-----------------|---------------------------------|--------------------------------------|---------------|
| Sep-03-2020 13:48:15<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <b>Data Entry:</b><br>NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

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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, Deleted, Locked, Frozen

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.lewissc

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

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

| Date  | Location        | User                            | Value                     | Reason        |
|---|-----------------|---------------------------------|---------------------------|---------------|
| Sep-03-2020 13:48:15<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <u>Data Entry:</u><br>YES | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date  | Location        | User                            | Value                    | Reason        |
|---|-----------------|---------------------------------|--------------------------|---------------|
| Sep-03-2020 13:48:15<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <u>Data Entry:</u><br>NO | Initial Entry |

13. What was the outcome of this adverse event?:

| Date   | Location        | User                            | Value                                      | Reason  |
|--|-----------------|---------------------------------|--|---|
| Sep-16-2020 13:17:39<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)       | Query 1: Closed                            | Close Auto Query  |
| Sep-16-2020 13:17:39<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <u>Data Entry:</u><br>RECOVERED/RESOLVED   | New Information   |
| Sep-16-2020 13:16:30<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)       | Query 1: Opened                            | For AE Dermatitis with red patch from left areola extending laterally: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present. |
| Sep-03-2020 13:48:15<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <u>Data Entry:</u><br>RECOVERING/RESOLVING | Initial Entry   |

14. Did the adverse event cause the subject to be discontinued from the study?

| Date  | Location        | User                            | Value                    | Reason        |
|---|-----------------|---------------------------------|--------------------------|---------------|
| Sep-03-2020 13:48:15<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Akeem<br>Moore<br>(pfe.amoore1) | <u>Data Entry:</u><br>NO | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1001

Subject No: 10011100

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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**1. Category:**

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Sep-23-2020 15:24:16<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ADVERSE EVENT | Initial Entry |

**2. AE ID:**

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-23-2020 15:24:16<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>5 | Initial Entry |

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

| Date  | Location        | User                       | Value                                     | Reason        |
|---|-----------------|----------------------------|---|---------------|
| Sep-23-2020 15:24:16<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>Dermatitis of trunk | Initial Entry |

**4. Start Date Time:**

| Date  | Location        | User                       | Value                                     | Reason        |
|---|-----------------|----------------------------|---|---------------|
| Sep-23-2020 15:24:16<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>Aug/25/2020 UNK:UNK | Initial Entry |

**5. Is the adverse event still ongoing?**

| Date  | Location        | User                       | Value  | Reason        |
|---|-----------------|----------------------------|--|---------------|
| Sep-23-2020 15:24:16<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>NO<br>End Date Time:<br>Sep/3/2020 UNK:UNK | Initial Entry |

**6. Toxicity Grade:**

| Date   | Location        | User                       | Value                   | Reason        |
|--|-----------------|----------------------------|-------------------------|---------------|
| Sep-23-2020 15:24:16<br>(UTC-05:00) Eastern Time | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>2 | Initial Entry |

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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, Locked, Frozen

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.lewissc

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

(US & Canada)

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        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Sep-23-2020 15:24:16<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <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        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Sep-23-2020 15:24:16<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>NO | Initial Entry |

9. Is this event related to study treatment:

| Date  | Location        | User                       | Value   | Reason        |
|---|-----------------|----------------------------|---|---------------|
| Sep-23-2020 15:24:16<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>NOT RELATED<br>If Not Related to study treatment(s)<br>, this event is due to:<br><br>OTHER<br><br>If Other, specify:<br><br>poison ivy | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date  | Location        | User                       | Value                                | Reason        |
|---|-----------------|----------------------------|--------------------------------------|---------------|
| Sep-23-2020 15:24:16<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

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

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**Visit:** Logs - Unscheduled

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**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

|   |                 |                            |                           |               |
|---|-----------------|----------------------------|---------------------------|---------------|
| Sep-23-2020 15:24:16<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>YES | Initial Entry |
|---|-----------------|----------------------------|---------------------------|---------------|

**12. Was a Non-Drug Treatment given?**

| Date  | Location        | User                       | Value                    | Reason        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Sep-23-2020 15:24:16<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>NO | Initial Entry |

**13. What was the outcome of this adverse event?:**

| Date  | Location        | User                       | Value                                    | Reason        |
|---|-----------------|----------------------------|--|---------------|
| Sep-23-2020 15:24:16<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <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        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Sep-23-2020 15:24:16<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1001

Subject No: 10011100

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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**1. Category:**

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Sep-23-2020 15:26:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ADVERSE EVENT | Initial Entry |

**2. AE ID:**

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-23-2020 15:26:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>6 | Initial Entry |

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

| Date  | Location        | User                       | Value                            | Reason        |
|---|-----------------|----------------------------|----------------------------------|---------------|
| Sep-23-2020 15:26:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>poison ivy | Initial Entry |

**4. Start Date Time:**

| Date  | Location        | User                       | Value                                     | Reason        |
|---|-----------------|----------------------------|---|---------------|
| Sep-23-2020 15:26:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>Aug/11/2020 UNK:UNK | Initial Entry |

**5. Is the adverse event still ongoing?**

| Date  | Location        | User                       | Value   | Reason        |
|---|-----------------|----------------------------|---|---------------|
| Sep-23-2020 15:26:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>NO<br>End Date Time:<br><br>Aug/31/2020 UNK:UNK | Initial Entry |

**6. Toxicity Grade:**

| Date   | Location        | User                       | Value                   | Reason        |
|--|-----------------|----------------------------|-------------------------|---------------|
| Sep-23-2020 15:26:24<br>(UTC-05:00) Eastern Time | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>2 | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (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, Locked, Frozen

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levissc

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

(US & Canada)

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        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Sep-23-2020 15:26:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <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        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Sep-23-2020 15:26:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>NO | Initial Entry |

9. Is this event related to study treatment:

| Date  | Location        | User                       | Value   | Reason        |
|---|-----------------|----------------------------|---|---------------|
| Sep-23-2020 15:26:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>NOT RELATED<br>If Not Related to study treatment(s)<br>, this event is due to:<br><br>OTHER<br><br>If Other, specify:<br><br>exposure to poison ivy | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date  | Location        | User                       | Value                                | Reason        |
|---|-----------------|----------------------------|--------------------------------------|---------------|
| Sep-23-2020 15:26:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

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

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

|   |                 |                            |                           |               |
|---|-----------------|----------------------------|---------------------------|---------------|
| Sep-23-2020 15:26:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>YES | Initial Entry |
|---|-----------------|----------------------------|---------------------------|---------------|

**12. Was a Non-Drug Treatment given?**

| Date  | Location        | User                       | Value                    | Reason        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Sep-23-2020 15:26:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>NO | Initial Entry |

**13. What was the outcome of this adverse event?:**

| Date  | Location        | User                       | Value                                    | Reason        |
|---|-----------------|----------------------------|--|---------------|
| Sep-23-2020 15:26:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <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        |
|---|-----------------|----------------------------|--------------------------|---------------|
| Sep-23-2020 15:26:24<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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**1. Category:**

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Feb-18-2021 13:47:10<br>(UTC-05:00) Eastern Time<br>(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-18-2021 13:47:10<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>7 | Initial Entry |

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

| Date  | Location        | User                    | Value   | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Feb-18-2021 13:47:10<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br>R 5th metatarsal fracture | Initial Entry |

**4. Start Date Time:**

| Date  | Location        | User                                | Value                                     | Reason  |
|---|-----------------|-------------------------------------|---|---|
| Feb-22-2021 17:40:27<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Gladys Noi<br>(pfe.noig)            | Query 2: Closed                           | Response satisfies<br>query   |
| Feb-22-2021 12:03:07<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)           | Query 2: Answered                         | Data updated  |
| Feb-22-2021 12:03:07<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria)             | <b>Data Entry:</b><br>Dec/12/2020 UNK:UNK | Data updated  |
| Feb-21-2021 07:28:33<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Ricell Ann<br>Piojo<br>(pfe.quitor) | Query 2: Opened                           | SAE RECON:<br>AER#2021139022,onset<br>date was recorded as<br>12Dec2020 in Safety<br>database however,<br>recorded as 13Dec2020<br>on AE CRF. Please<br>confirm correct Onset |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1001**Subject No:** 10011100**Generated By:** pfe.levissc**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1001) NYU Langone Health**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

|  |                 |                                  |   |   |
|--|-----------------|----------------------------------|---|---|
|  |                 |                                  |   | Date.If safety update is required, please submit a follow-up SAE form   |
| Feb-21-2021 07:26:37<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Ricell Ann Piojo<br>(pfe.quoter) | Query 1: Closed                           | updated query text  |
| Feb-21-2021 07:25:15<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Ricell Ann Piojo<br>(pfe.quoter) | Query 1: Opened                           | SAE RECON: AER#2021139022,onset date was recorded as 12Dec2020 in Safety database however, recorded as 13Dec2020 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form |
| Feb-18-2021 13:47:10<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria)          | <b>Data Entry:</b><br>Dec/13/2020 UNK:UNK | Initial Entry   |

**5. Is the adverse event still ongoing?**

| Date   | Location        | User                      | Value                     | Reason   |
|--|-----------------|---------------------------|---------------------------|--|
| Feb-19-2021 16:49:54<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Closed           | Close Auto Query   |
| Feb-18-2021 13:47:10<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Opened           | 'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate. |
| Feb-18-2021 13:47:10<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria)   | <b>Data Entry:</b><br>YES | Initial Entry  |

**6. Toxicity Grade:**

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Feb-18-2021 13:47:10<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br>2 | Initial Entry |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1001

Subject No: 10011100

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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-19-2021 04:45:08<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted  | Close Auto Query  |
| Feb-18-2021 13:47:10<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate  | For AE R 5th metatarsal fracture: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank. |
| Feb-18-2021 13:47:10<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe nria)   | <p><b>Data Entry:</b></p> <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> | Initial Entry   |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.lewissc

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

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | Other medically important serious event |  |
|  |  |  | NO                                      |  |

**8. Is this adverse event the result of a study Medication Error?**  
**If Yes, record the type of medication error on the Medication Error Log.**

| Date  | Location        | User                    | Value                    | Reason        |
|---|-----------------|-------------------------|--------------------------|---------------|
| Feb-18-2021 13:47:10<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br>NO | Initial Entry |

**9. Is this event related to study treatment:**

| Date  | Location        | User                             | Value   | Reason   |
|---|-----------------|----------------------------------|---|--|
| Feb-23-2021 15:10:04<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Kathryn Sewell<br>(pfe.sewelk02) | Query 1: Closed   | Response satisfies query   |
| Feb-22-2021 12:06:14<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)        | Query 1: Answered   | data updated   |
| Feb-22-2021 12:06:14<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria)          | <b>Data Entry:</b><br>NOT RELATED<br>If Not Related to study treatment(s), this event is due to:<br><br>OTHER<br><br><i>If Other, specify:</i><br><br>Participant tripped and fell down | data updated   |
| Feb-22-2021 11:07:32<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Kathryn Sewell<br>(pfe.sewelk02) | Query 1: Opened   | CLINICAL 'Other' relationship for SAE of Fracture cannot be Fracture. SAE report stated subject experienced a fall. Please review 'Other' relationship, and update as applicable |
| Feb-18-2021 13:48:23<br>(UTC-05:00) Eastern                       | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria)          | <b>Data Entry:</b><br>NOT RELATED   | data update  |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)



Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.lewissc

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

|   |                 |                      |  |               |
|---|-----------------|----------------------|--|---------------|
| Time (US & Canada)  |                 |                      | If Not Related to study treatment(s), this event is due to:<br><br>OTHER<br><br><i>If Other, specify:</i><br><br>R 5th metatarsal fracture |               |
| Feb-18-2021 13:47:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Nazia Ria (pfe.nria) | <b>Data Entry:</b><br>NOT RELATED  | Initial Entry |

**10. Latest Action Taken with Study Treatment:**

| Date  | Location        | User                 | Value                                | Reason        |
|---|-----------------|----------------------|--------------------------------------|---------------|
| Feb-18-2021 13:47:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Nazia Ria (pfe.nria) | <b>Data Entry:</b><br>NOT APPLICABLE | Initial Entry |

**11. Was a Concomitant Medication given?**

| Date  | Location        | User                 | Value                     | Reason        |
|---|-----------------|----------------------|---------------------------|---------------|
| Feb-18-2021 13:47:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Nazia Ria (pfe.nria) | <b>Data Entry:</b><br>YES | Initial Entry |

**12. Was a Non-Drug Treatment given?**

| Date  | Location        | User                 | Value                     | Reason        |
|---|-----------------|----------------------|---------------------------|---------------|
| Feb-18-2021 13:47:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Nazia Ria (pfe.nria) | <b>Data Entry:</b><br>YES | Initial Entry |

**13. What was the outcome of this adverse event?:**

| Date  | Location        | User                 | Value                                      | Reason        |
|---|-----------------|----------------------|--|---------------|
| Feb-18-2021 13:47:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Nazia Ria (pfe.nria) | <b>Data Entry:</b><br>RECOVERING/RESOLVING | Initial Entry |

**14. Did the adverse event cause the subject to be discontinued from the study?**

| Date  | Location        | User                 | Value                    | Reason        |
|---|-----------------|----------------------|--------------------------|---------------|
| Feb-18-2021 13:47:10 (UTC-05:00) Eastern Time | ACV0PFEINFP6000 | Nazia Ria (pfe.nria) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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

**15. Serious Adverse Event Number: For Pfizer Use Only**

| <b>Date</b>   | <b>Location</b> | <b>User</b>                         | <b>Value</b>                     | <b>Reason</b> |
|---|-----------------|-------------------------------------|----------------------------------|---------------|
| Feb-19-2021 04:45:08<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Ricell Ann<br>Piojo<br>(pfe.quitor) | <b>Data Entry:</b><br>2021139022 | Initial Entry |

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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**1. Category:**

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Feb-18-2021 13:56:09<br>(UTC-05:00) Eastern Time<br>(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-18-2021 13:56:09<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>8 | Initial Entry |

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

| Date  | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Feb-18-2021 13:56:09<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br>L radial head fracture | Initial Entry |

**4. Start Date Time:**

| Date  | Location        | User                                | Value                                     | Reason  |
|---|-----------------|-------------------------------------|---|---|
| Feb-22-2021 17:40:59<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Gladys Noi<br>(pfe.noig)            | Query 1: Closed                           | Response satisfies<br>query   |
| Feb-22-2021 12:04:06<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)           | Query 1: Answered                         | Data updated  |
| Feb-22-2021 12:04:06<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria)             | <b>Data Entry:</b><br>Dec/12/2020 UNK:UNK | Data updated  |
| Feb-21-2021 07:27:29<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Ricell Ann<br>Piojo<br>(pfe.quitor) | Query 1: Opened                           | SAE RECON:<br>AER#2021139022,onset<br>date was recorded as<br>12Dec2020 in Safety<br>database however,<br>recorded as 13Dec2020<br>on AE CRF. Please<br>confirm correct Onset |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1001**Subject No:** 10011100**Generated By:** pfe.levissc**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1001) NYU Langone Health**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

|  |                 |                         |   |  |
|--|-----------------|-------------------------|---|--|
|  |                 |                         |   | Date. If safety update is required, please submit a follow-up SAE form |
| Feb-18-2021 13:56:09<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br>Dec/13/2020 UNK:UNK | Initial Entry  |

**5. Is the adverse event still ongoing?**

| Date   | Location        | User                      | Value                     | Reason   |
|--|-----------------|---------------------------|---------------------------|--|
| Feb-19-2021 16:49:54<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Closed           | Close Auto Query   |
| Feb-18-2021 13:56:09<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Opened           | 'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate. |
| Feb-18-2021 13:56:09<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria)   | <b>Data Entry:</b><br>YES | Initial Entry  |

**6. Toxicity Grade:**

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Feb-18-2021 13:56:09<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br>2 | 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  |
|--|-----------------|----------------------------------|-----------------|---|
| Mar-03-2021 10:13:08<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Kathryn Sewell<br>(pfe.sewelk02) | Query 2: Closed | Query closed; will follow for requested COVID test information. |

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1001**Subject No:** 10011100**Generated By:** pfe.levissc**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1001) NYU Langone Health**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

|   |                 |                                     |  |  |
|---|-----------------|-------------------------------------|--|--|
| Mar-02-2021 09:39:13<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria)             | Query 2: Answered  | This will be<br>submitted in follow<br>up report.  |
| Feb-22-2021 11:10:40<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Kathryn<br>Sewell<br>(pfe.sewelk02) | Query 2: Opened  | Clinical COVID test<br>status (yes/no) during<br>Hosp was not<br>reported in the SAE.<br>Please submit a<br>follow-up SAE form<br>[#2021139022] to<br>document if COVID<br>testing was performed<br>(YES/NO or info not<br>available) and if yes,<br>the date and results. |
| Feb-19-2021 04:45:19<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)           | Query 1: Deleted   | Close Auto Query   |
| Feb-18-2021 13:56:09<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)           | Query 1: Candidate   | For AE L radial head<br>fracture: Response to<br>"Is the adverse event<br>serious?" is 'Yes' but<br>"Serious Adverse<br>Event Number" is<br>blank.   |
| Feb-18-2021 13:56:09<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria)             | <b>Data Entry:</b><br>YES<br>Is this serious event associated with congenital anomaly or birth defect?<br><br>NO<br><br>Did this serious event result in death?<br><br>NO<br><br>Did this serious event require or prolong hospitalization?<br><br>YES<br><br>Did this serious event result in persistent or significant disability/in capacity? | Initial Entry  |

Header Text: c4591001

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Site No: 1001

Subject No: 10011100

Generated By: pfe.levissc

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Form Status: Data Complete

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | NO                                      |  |
|  |  |  | Is this serious event life threatening? |  |
|  |  |  | NO                                      |  |
|  |  |  | Other medically important serious event |  |
|  |  |  | NO                                      |  |

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

| Date  | Location        | User                    | Value                    | Reason        |
|---|-----------------|-------------------------|--------------------------|---------------|
| Feb-18-2021 13:56:09<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br>NO | Initial Entry |

9. Is this event related to study treatment:

| Date  | Location        | User                            | Value   | Reason   |
|---|-----------------|---------------------------------|---|--|
| Feb-22-2021 17:42:09<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Gladys Noi<br>(pfe.noig)        | Query 1: Closed   | Response satisfies query   |
| Feb-22-2021 12:06:53<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)       | Query 1: Answered   | data update  |
| Feb-22-2021 12:06:53<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria)         | <b>Data Entry:</b><br>NOT RELATED<br>If Not Related to study treatment(s), this event is due to:<br><br>OTHER<br><br><i>If Other, specify:</i><br><br>Participant tripped and fell down | data update  |
| Feb-21-2021 07:30:47<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Ricell Ann Piojo<br>(pfe.QUITO) | Query 1: Opened   | SAE<br>RECON:AER#2021139022,causality was recorded as UNRELATED in Safety database but was recorded as |

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levissc

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

|  |                 |                         |                               |  |
|--|-----------------|-------------------------|-------------------------------|--|
|  |                 |                         |                               | RELATED in AE CRF. Please confirm correct causality. If safety update is required, please submit a follow-up form. |
| Feb-18-2021 13:56:09<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br>RELATED | Initial Entry  |

**10. Latest Action Taken with Study Treatment:**

| Date   | Location        | User                    | Value                                | Reason        |
|--|-----------------|-------------------------|--------------------------------------|---------------|
| Feb-18-2021 13:56:09<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br>NOT APPLICABLE | Initial Entry |

**11. Was a Concomitant Medication given?**

| Date   | Location        | User                    | Value                     | Reason        |
|--|-----------------|-------------------------|---------------------------|---------------|
| Feb-18-2021 13:56:09<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br>YES | Initial Entry |

**12. Was a Non-Drug Treatment given?**

| Date   | Location        | User                    | Value                     | Reason        |
|--|-----------------|-------------------------|---------------------------|---------------|
| Feb-18-2021 13:56:09<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br>YES | Initial Entry |

**13. What was the outcome of this adverse event?:**

| Date   | Location        | User                    | Value                                      | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Feb-18-2021 13:56:09<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br>RECOVERING/RESOLVING | Initial Entry |

**14. Did the adverse event cause the subject to be discontinued from the study?**

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Feb-18-2021 13:56:09<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br>NO | Initial Entry |

**15. Serious Adverse Event Number: For Pfizer Use Only**

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

| Date  | Location        | User                                | Value                            | Reason        |
|---|-----------------|-------------------------------------|----------------------------------|---------------|
| Feb-19-2021 04:45:19<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Ricell Ann<br>Piojo<br>(pfe.quitor) | <u>Data Entry:</u><br>2021139022 | Initial Entry |



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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**1. Category:**

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Feb-18-2021 14:01:14<br>(UTC-05:00) Eastern Time<br>(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-18-2021 14:01:14<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>9 | Initial Entry |

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

| Date  | Location        | User                    | Value   | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Feb-18-2021 14:01:14<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br>R pinky finger trigger finger | Initial Entry |

**4. Start Date Time:**

| Date  | Location                                  | User                         | Value   | Reason  |
|---|---|------------------------------|---|---|
| Feb-20-2021 20:41:20<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY<br>(pfe.DMW_QUERY) | Query 1: Closed                                   | Auto closed by Validation Check: VC_AE001_09_AN   |
| Feb-18-2021 23:31:40<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY<br>(pfe.DMW_QUERY) | Query 1: Opened                                   | DMW7314888;Start Date' is after 'Date of Completion/Discontinuation /Death' on the Disposition - Follow-up eCRF. Please clarify or correct. |
| Feb-18-2021 14:01:14<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000                           | Nazia Ria (pfe.nria)         | <b>Data Entry:</b><br>:<br>Jan/1/<br>2021<br>UNK: | Initial Entry   |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levissc

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

UNK

5. Is the adverse event still ongoing?

| Date  | Location        | User                      | Value                     | Reason   |
|---|-----------------|---------------------------|---------------------------|--|
| Feb-19-2021 16:49:54<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Closed           | Close Auto Query   |
| Feb-18-2021 14:01:14<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Opened           | 'Disposition<br>Follow-up form is<br>completed and this<br>Adverse Event is still<br>ongoing. Please<br>review and update as<br>appropriate. |
| Feb-18-2021 14:01:14<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria)   | <u>Data Entry:</u><br>YES | Initial Entry  |

6. Toxicity Grade:

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Feb-18-2021 14:01:14<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <u>Data Entry:</u><br>2 | 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-18-2021 14:01:14<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <u>Data Entry:</u><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-18-2021 14:01:14<br>(UTC-05:00) Eastern Time | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <u>Data Entry:</u><br>NO | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1001

Subject No: 10011100

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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

9. Is this event related to study treatment:

| Date  | Location        | User                    | Value   | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Feb-18-2021 14:01:14<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br>NOT RELATED<br>If Not Related to study treatment(s),<br>this event is due to:<br><br>OTHER<br><br>If Other, specify:<br><br>R pinky finger trigger finger | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date  | Location        | User                    | Value                                | Reason        |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Feb-18-2021 14:01:14<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br>NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

| Date  | Location        | User                    | Value                    | Reason        |
|---|-----------------|-------------------------|--------------------------|---------------|
| Feb-18-2021 14:01:14<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br>NO | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date  | Location        | User                    | Value                     | Reason        |
|---|-----------------|-------------------------|---------------------------|---------------|
| Feb-18-2021 14:01:14<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br>YES | Initial Entry |

13. What was the outcome of this adverse event?:

| Date  | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Feb-18-2021 14:01:14<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br>NOT RECOVERED/NOT RESOLVE<br>D | Initial Entry |

14. Did the adverse event cause the subject to be discontinued from the study?

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

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

| Date  | Location        | User                    | Value                    | Reason        |
|---|-----------------|-------------------------|--------------------------|---------------|
| Feb-18-2021 14:01:14<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <u>Data Entry:</u><br>NO | Initial Entry |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1001

Subject No: 10011100

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Queries

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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**1. Category:**

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Feb-24-2021 12:28:53<br>(UTC-05:00) Eastern Time<br>(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-24-2021 12:28:53<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>10 | Initial Entry |

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Feb-24-2021 12:28:53<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br>fall | Initial Entry |

**4. Start Date Time:**

| Date  | Location        | User                    | Value                                     | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Feb-24-2021 12:28:53<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br>Dec/12/2020 UNK:UNK | Initial Entry |

**5. Is the adverse event still ongoing?**

| Date  | Location        | User                                | Value                                      | Reason                      |
|---|-----------------|-------------------------------------|--|-----------------------------|
| Mar-09-2021 01:41:30<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Kathryn<br>Sewell<br>(pfe.sewelk02) | Query 1: Closed                            | Response satisfies<br>query |
| Mar-08-2021 14:53:44<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)           | Query 2: Closed                            | Close Auto Query            |
| Mar-08-2021 14:53:44<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria)             | <b>Data Entry:</b><br>NO<br>End Date Time: | data correction             |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1001**Subject No:** 10011100**Generated By:** pfe.lewissc**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Queries**Site Name:** (1001) NYU Langone Health**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

|   |                 |                                     |   |  |
|---|-----------------|-------------------------------------|---|--|
|   |                 |                                     | Dec/12/2020 UNK:UNK   |  |
| Mar-08-2021 14:53:19<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)           | Query 2: Opened   | For fall End Date<br>12/Mar/2021, is a<br>future date relative<br>to when it was<br>entered on 08/Mar<br>/2021. Please<br>correct.   |
| Mar-08-2021 14:53:19<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)           | Query 1: Answered   | Data added   |
| Mar-08-2021 14:53:19<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria)             | <b>Data Entry:</b><br>NO<br>End Date Time:<br>Mar/12/2021 UNK:UNK | Data added   |
| Feb-25-2021 22:20:22<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Kathryn<br>Sewell<br>(pfe.sewelk02) | Query 1: Opened   | Clinical Event of<br>'Fall' has no End<br>date; typically the<br>Fall end date is the<br>same date (other<br>injuries continue for<br>as long as they last).<br>Please review &<br>update End date in<br>AE and SAE report |
| Feb-24-2021 12:28:53<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria)             | <b>Data Entry:</b><br>YES   | Initial Entry  |

**6. Toxicity Grade:**

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Feb-24-2021 12:28:53<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br>2 | 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).**

**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, Queries

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

| Date  | Location        | User                                | Value                       | Reason   |
|---|-----------------|-------------------------------------|-----------------------------|--|
| Mar-12-2021 07:12:13<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Ricell Ann<br>Piojo<br>(pfe.QUITOR) | Query 2: Reissued:Opened    | SAE<br>RECON:AER#2021139022,2<br>events are captured in the<br>Safety Database as SAEs:<br>Foot Fracture and radius<br>Fracture Onset dates<br>12-Dec-2020. Please submit<br>a follow up SAE form to<br>indicate FALL as a separate<br>SAE.                                  |
| Mar-11-2021 17:38:34<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Kathryn<br>Sewell<br>(pfe.sewelk02) | Query 4: Opened             | Clinical - Followup; there<br>has not been a SAE<br>submission sine 02Mar21<br>and the serious event 'FALL'<br>is not reported as a SAE (on<br>a separate event tab) in the<br>SAE yet. Please submit a<br>SAE update to report SAE of<br>FALL                               |
| Mar-10-2021 14:35:34<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Kathryn<br>Sewell<br>(pfe.sewelk02) | Query 3: Closed             | Query closed; will follow for<br>requested FALL SAE<br>information.  |
| Mar-10-2021 05:01:35<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Ricell Ann<br>Piojo<br>(pfe.QUITOR) | Query 2: Reissued:Candidate | For PSSR review  |
| Mar-09-2021 12:36:22<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria)             | Query 2: Answered           | This was marked as SAE and<br>submitted in SAE report.   |
| Mar-09-2021 12:35:30<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria)             | Query 3: Answered           | this was submitted in he SAE<br>report   |
| Mar-09-2021 01:49:11<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Kathryn<br>Sewell<br>(pfe.sewelk02) | Query 3: Opened             | CLINICAL - please confirm<br>that the event FALL is<br>serious (would the Fall by<br>itself lead to hospitalization;<br>the injuries are separate<br>SAEs); not reported as<br>serious to SAE. Please<br>harmonize reporting in both<br>AE & SAE - is this serious or<br>not |
| Mar-01-2021 02:58:44  | ACV0PFEINFP6000 | Ricell Ann                          | Query 2: Opened             | SAE RECON: Fall is not   |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Queries

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

|   |                 |                               |   |   |
|---|-----------------|-------------------------------|---|---|
| (UTC-05:00) Eastern Time (US & Canada)                      |                 | Piojo (pfe.quitor)            |   | reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF |
| Feb-26-2021 05:03:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Ricell Ann Piojo (pfe.quitor) | Query 1: Deleted  | Query can be addressed internally   |
| Feb-24-2021 12:28:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery)        | Query 1: Candidate  | For AE fall: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.  |
| Feb-24-2021 12:28:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Nazia Ria (pfe.nria)          | <p><b>Data Entry:</b></p> <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>YES</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> | Initial Entry   |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (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, Queries

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levissc

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

|  |  |  |    |  |
|--|--|--|----|--|
|  |  |  | NO |  |
|--|--|--|----|--|

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

| Date  | Location        | User                    | Value                    | Reason        |
|---|-----------------|-------------------------|--------------------------|---------------|
| Feb-24-2021 12:28:53<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br>NO | Initial Entry |

9. Is this event related to study treatment:

| Date  | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Feb-24-2021 12:28:53<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br>NOT RELATED<br>If Not Related to study treatment(s),<br>this event is due to:<br><br>OTHER<br><br>If Other, specify:<br><br>fall | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date  | Location        | User                    | Value                                | Reason        |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Feb-24-2021 12:28:53<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br>NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

| Date  | Location        | User                    | Value                    | Reason        |
|---|-----------------|-------------------------|--------------------------|---------------|
| Feb-24-2021 12:28:53<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br>NO | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date  | Location        | User                    | Value                    | Reason        |
|---|-----------------|-------------------------|--------------------------|---------------|
| Feb-24-2021 12:28:53<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br>NO | Initial Entry |

13. What was the outcome of this adverse event?:

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

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (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, Queries

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

| Date  | Location        | User                               | Value                                      | Reason  |
|---|-----------------|------------------------------------|--|---|
| Mar-10-2021 04:35:15<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Amol<br>Deshmukh<br>(pfe.deshma24) | Query 1: Reissued:Opened                   | DM1: If AE is still<br>on-going, please mark<br>response to 'Is the<br>adverse event still<br>ongoing?' as Yes.<br>Thank you.                       |
| Mar-09-2021 12:36:40<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria)            | Query 1: Answered                          | This is still ongoing.  |
| Mar-08-2021 14:53:19<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)          | Query 1: Opened                            | For AE fall: Response<br>to "What was the<br>outcome of this adverse<br>event?" is<br>'Recovering/Resolving'<br>but AE End Date/Time<br>is present. |
| Feb-24-2021 12:28:53<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria)            | <b>Data Entry:</b><br>RECOVERING/RESOLVING | Initial Entry   |

**14. Did the adverse event cause the subject to be discontinued from the study?**

| Date  | Location        | User                    | Value                    | Reason        |
|---|-----------------|-------------------------|--------------------------|---------------|
| Feb-24-2021 12:28:53<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levisse

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

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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**I. Date of Visit**

| Date   | Location                                  | User                         | Value   | Reason   |
|--|---|------------------------------|---|--|
| Feb-20-2021<br>20:41:20<br>(UTC-05:00)<br>Eastern Time<br>(US &<br>Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY<br>(pfe.DMW_QUERY) | Query<br>2: Clo<br>sed                        | Auto closed by Validation<br>Check: VC_SV001_04_AN   |
| Feb-19-2021<br>16:49:54<br>(UTC-05:00)<br>Eastern Time<br>(US &<br>Canada) | ACV0PFEINFP6000                           | auto query<br>(autoquery)    | Query<br>1: Clo<br>sed                        | Close Auto Query   |
| Feb-16-2021<br>16:03:07<br>(UTC-05:00)<br>Eastern Time<br>(US &<br>Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY<br>(pfe.DMW_QUERY) | Query<br>2: Op<br>ened                        | DMW7271380;'Date of<br>Visit' is after 'Date of<br>Completion/Discontinuation<br>/Death' on the Disposition -<br>Follow-up eCRF. Please<br>clarify or correct.     |
| Feb-16-2021<br>10:45:14<br>(UTC-05:00)<br>Eastern Time<br>(US &<br>Canada) | ACV0PFEINFP6000                           | auto query<br>(autoquery)    | Query<br>1: Op<br>ened                        | Date of Visit is after the<br>Date of<br>Completion/Discontinuation<br>/Death on the Follow-Up<br>Disposition form. Please<br>review and update as<br>appropriate. |
| Jan-20-2021<br>15:43:43<br>(UTC-05:00)<br>Eastern Time<br>(US &<br>Canada) | ACV0PFEINFP6000                           | Gali Moritz<br>(pfe.gmoritz) | <b>Data<br/>Entry</b><br>:<br>Jan/15<br>/2021 | Initial Entry  |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

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

**Form Status:** Data Complete, Frozen

**Site Name:** (1001) NYU Langone Health

**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        |
|---|-----------------|------------------------------|---|---------------|
| Jan-20-2021 15:43:29<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Gali Moritz<br>(pfe.gmoritz) | <b>Data Entry:</b><br>Participant is willing to return for Vaccination 3<br>Participant is:<br><br>eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2 | Initial Entry |

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levisse

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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***1. Date Treatment Unblinded :***

| <b>Date</b>  | <b>Location</b>                           | <b>User</b>                  | <b>Value</b>                                  | <b>Reason</b>  |
|--|---|------------------------------|---|--|
| Feb-20-2021<br>20:41:20<br>(UTC-05:00)<br>Eastern Time<br>(US &<br>Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY<br>(pfe.DMW_QUERY) | Query<br>1: Clo<br>sed                        | Auto closed by Validation<br>Check: VC_DS001_15_AN   |
| Feb-16-2021<br>16:39:03<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                        | DMW7271618;'Date<br>Treatment Unblinded' is<br>after 'Date of<br>Completion/Discontinuation<br>/Death' on the Disposition -<br>Follow-up eCRF. Please<br>clarify or correct. |
| Jan-20-2021<br>15:43:08<br>(UTC-05:00)<br>Eastern Time<br>(US &<br>Canada) | ACV0PFEINFP6000                           | Gali Moritz<br>(pfe.gmoritz) | <b>Data<br/>Entry</b><br>:<br>Jan/15<br>/2021 | Initial Entry  |

***2. Primary Reason for Unblinding:***

| <b>Date</b>   | <b>Location</b> | <b>User</b>                  | <b>Value</b>  | <b>Reason</b> |
|---|-----------------|------------------------------|---|---------------|
| Jan-20-2021 15:43:08<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Gali Moritz<br>(pfe.gmoritz) | <b>Data Entry:</b><br>ASSESS ELIGIBILITY FOR ADDI<br>TIONAL VACCINATION | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levisse

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

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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*I. Date of Visit*

| Date   | Location                                  | User                                | Value                    | Reason   |
|--|---|-------------------------------------|--------------------------|--|
| Feb-20-2021<br>20:41:20<br>(UTC-05:00)<br>Eastern Time<br>(US &<br>Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY<br>(pfe.DMW_QUERY)        | Query<br>3: Clo<br>sed   | Auto closed by Validation<br>Check: VC_SV001_04_AN   |
| Feb-19-2021<br>16:49:54<br>(UTC-05:00)<br>Eastern Time<br>(US &<br>Canada) | ACV0PFEINFP6000                           | auto query<br>(autoquery)           | Query<br>2: Clo<br>sed   | Close Auto Query   |
| Feb-16-2021<br>16:03:07<br>(UTC-05:00)<br>Eastern Time<br>(US &<br>Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY<br>(pfe.DMW_QUERY)        | Query<br>3: Op<br>ened   | DMW7271379;'Date of<br>Visit' is after 'Date of<br>Completion/Discontinuation<br>/Death' on the Disposition -<br>Follow-up eCRF. Please<br>clarify or correct.     |
| Feb-16-2021<br>10:45:14<br>(UTC-05:00)<br>Eastern Time<br>(US &<br>Canada) | ACV0PFEINFP6000                           | auto query<br>(autoquery)           | Query<br>2: Op<br>ened   | Date of Visit is after the<br>Date of<br>Completion/Discontinuation<br>/Death on the Follow-Up<br>Disposition form. Please<br>review and update as<br>appropriate. |
| Jan-22-2021<br>00:36:34<br>(UTC-05:00)<br>Eastern Time<br>(US &<br>Canada) | ACV0PFEINFP6000                           | Pratiksha Mahadik<br>(pfe mahadp07) | Query<br>1: Clo<br>sed   | Closed as data updated.  |
| Jan-21-2021<br>11:57:41<br>(UTC-05:00)<br>Eastern Time<br>(US &<br>Canada) | ACV0PFEINFP6000                           | Nazia Ria (pfe nria)                | Query<br>1: Ans<br>wered | Not Applicable by selected   |
| Jan-21-2021  | ACV0PFEINFP6000                           | Amol Shinde                         | Query                    | DM: Please consider  |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

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

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

|  |                 |                              |   |  |
|--|-----------------|------------------------------|---|--|
| 05:11:09<br>(UTC-05:00)<br>Eastern Time<br>(US &<br>Canada)                |                 | (pfe.shinda18)               | 1: Op<br>ened                                 | updating<br>INCLUSION/EXCLUSION<br>CRITERIA - FURTHER<br>VACCINATION form as<br>Not Applicable by selecting<br>form level comment. Thank<br>you. |
| Jan-20-2021<br>15:43:53<br>(UTC-05:00)<br>Eastern Time<br>(US &<br>Canada) | ACV0PFEINFP6000 | Gali Moritz<br>(pfe.gmoritz) | <b>Data<br/>Entry</b><br>:<br>Jan/20<br>/2021 | Initial Entry  |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (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:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**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        |
|---|-----------------|------------------------------|--|---------------|
| Jan-20-2021 15:44:04<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Gali Moritz<br>(pfe.gmoritz) | <b>Data Entry:</b><br>OBTAINED<br>Date Written Consent Obtained<br><br>Jan/20/2021 | Initial Entry |



**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:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**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        |
|---|-----------------|------------------------------|-----------------------------------|---------------|
| Jan-20-2021 15:44:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Gali Moritz<br>(pfe.gmoritz) | <b>Data Entry:</b><br>Jan/20/2021 | Initial Entry |

**2. Phase of Disposition:**

| Date  | Location        | User                    | Value                                    | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Jan-20-2021 15:44:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>REPEAT SCREENING 1 | Initial Entry |

**3. Status:**

| Date  | Location        | User                         | Value                           | Reason        |
|---|-----------------|------------------------------|---------------------------------|---------------|
| Jan-20-2021 15:44:34<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Gali Moritz<br>(pfe.gmoritz) | <b>Data Entry:</b><br>COMPLETED | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Form Version:** 14-Jan-2021 02:21

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

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**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        |
|---|-----------------|----------------------------|--------------------------------|---------------|
| Feb-01-2021 15:21:55<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**2. Lab Sub-Panel:**

| Date  | Location        | User                       | Value                          | Reason        |
|---|-----------------|----------------------------|--------------------------------|---------------|
| Feb-01-2021 15:21:55<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**3. Collection Date:**

| Date  | Location        | User                                     | Value                          | Reason   |
|---|-----------------|--|--------------------------------|--|
| Feb-02-2021 06:56:31<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Azeemuddin<br>Mohammed<br>(pfe.mohaa117) | Query 1: Closed                | Form Level<br>comment updated  |
| Feb-01-2021 15:21:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman)               | Query 1: Answered              | Changed data per<br>query  |
| Jan-27-2021 10:13:54<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Cavin van<br>Schalkwyk<br>(pfe.vanscc01) | Query 1: Reissued:Opened       | Please remove all<br>data from CRF then<br>enter a FORM<br>LEVEL comment of<br>NOT DONE. Please<br>refer to CCG section<br>4.10. Add Item/Form<br>Level Comment for<br>instructions. Thank<br>you. |
| Jan-26-2021 13:46:22<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Gali Moritz<br>(pfe.gmoritz)             | Query 1: Answered              | Changed data per<br>query  |
| Jan-26-2021 13:46:00<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Gali Moritz<br>(pfe.gmoritz)             | <b>Data Entry:</b><br>Not Done | Initial Entry  |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001**Visit:** V101\_VAX3**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Version:** 14-Jan-2021 02:21**Form Status:** Data Complete, Frozen, Verified**Site No:** 1001**Site Name:** (1001) NYU Langone Health**Subject No:** 10011100**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04

|  |                 |  |                                      |   |
|--|-----------------|--|--------------------------------------|---|
| Jan-25-2021 09:30:35<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Gbenga Akinkunmi<br>(pfe.akinkg)       | Query 1: Reissued:Opened             | DM: Please consider to update data per query response provided.   |
| Jan-25-2021 07:48:23<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Cavin van Schalkwyk<br>(pfe.vanscc01)  | Query 1: Reissued:Candidate          | DM: Please consider to update data per query response provided.   |
| Jan-22-2021 12:09:09<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria)                | Query 1: Answered                    | this will be done   |
| Jan-22-2021 02:39:51<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Astrud van der Merwe<br>(pfe.vandea62) | Query 1: Reissued:Opened             | Please remove all data from CRF then enter a FORM LEVEL comment of NOT DONE. Please refer to CCG section 4.10. Add Item/Form Level Comment for instructions. Thank you. |
| Jan-21-2021 11:57:32<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria)                | Query 1: Answered                    | Not Applicable  |
| Jan-21-2021 11:57:08<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria)                | <b>Data Entry:</b><br>Not Applicable | Initial Entry   |
| Jan-21-2021 04:52:43<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Rajashekhar Reddy<br>(pfe.reddy51)     | Query 1: Opened                      | DM: Since Pregnancy test is Not done, kindly update form level comment as Not Done.   |

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

| Date   | Location        | User                       | Value                          | Reason        |
|--|-----------------|----------------------------|--------------------------------|---------------|
| Feb-01-2021 15:21:55<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5. Specimen Type:**

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

Header Text: c4591001

Visit: V101\_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levissc

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

|   |                 |                            |                                |               |
|---|-----------------|----------------------------|--------------------------------|---------------|
| Feb-01-2021 15:21:55<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>Not Done | Initial Entry |
|---|-----------------|----------------------------|--------------------------------|---------------|

6.a

| Date  | Location        | User                    | Value   | Reason             |
|---|-----------------|-------------------------|---|--------------------|
| Feb-01-2021 15:21:55<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Choriogonadotropin Beta_PX113<br><b>Result::</b> Not Done<br><b>Not Done::</b> Not Done             | Initial Entry      |
| Jan-22-2021 12:10:36<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Choriogonadotropin Beta_PX113<br><b>Result::</b> Not Applicable<br><b>Not Done::</b> Not Applicable | Initial Entry      |
| Jan-22-2021 12:10:14<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Choriogonadotropin Beta_PX113<br><b>Result::</b> Not Applicable<br><b>Not Done::</b>                | Initial Entry      |
| Jan-22-2021 12:09:59<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Choriogonadotropin Beta_PX113<br><b>Result::</b><br><b>Not Done::</b>                               | data clarification |
| Jan-20-2021 15:45:04<br>(UTC-05:00) Eastern Time<br>(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   | Initial Entry      |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levissc

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

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | <b>Result::</b><br><b>Not Done::</b> NOT DONE |  |
|--|--|--|---|--|

**6.a Sponsor ID:**

| Date  | Location        | User                    | Value                          | Reason             |
|---|-----------------|-------------------------|--------------------------------|--------------------|
| Feb-01-2021 15:21:55<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Not Done | Initial Entry      |
| Jan-22-2021 12:09:59<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b>             | data clarification |
| Jan-20-2021 15:45:04<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>113      | Initial Entry      |

**6.a Test:**

| Date  | Location        | User                         | Value   | Reason        |
|---|-----------------|------------------------------|---|---------------|
| Jan-20-2021 15:45:04<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Gali Moritz<br>(pfe.gmoritz) | <b>Data Entry:</b><br>Choriogonadotropin Beta_PX113 | Initial Entry |

**6.a Result:**

| Date  | Location        | User                       | Value                                | Reason        |
|---|-----------------|----------------------------|--------------------------------------|---------------|
| Feb-01-2021 15:21:55<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>Not Done       | Initial Entry |
| Jan-22-2021 12:10:14<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria)    | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

**6.a Not Done:**

| Date  | Location        | User                       | Value                                | Reason        |
|---|-----------------|----------------------------|--------------------------------------|---------------|
| Feb-01-2021 15:21:55<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>Not Done       | Initial Entry |
| Jan-22-2021 12:10:36<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria)    | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Form Version:** 14-Jan-2021 02:21

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

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

|   |                 |                              |                                |                    |
|---|-----------------|------------------------------|--------------------------------|--------------------|
| Jan-22-2021 12:09:59<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria)      | <b>Data Entry:</b>             | data clarification |
| Jan-20-2021 15:45:04<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Gali Moritz<br>(pfe.gmoritz) | <b>Data Entry:</b><br>NOT DONE | Initial Entry      |

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: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

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        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Jan-20-2021 15:45:39<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date  | Location        | User                    | Value                       | Reason        |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Jan-20-2021 15:45:39<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SERUM | Initial Entry |

**3. Sample Collected?**

| Date  | Location        | User                         | Value   | Reason   |
|---|-----------------|------------------------------|---|--|
| Jan-20-2021 17:01:16<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)    | Query 1: Deleted  | Close Auto Query   |
| Jan-20-2021 15:45:39<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)    | Query 1: Candidate  | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Jan-20-2021 15:45:39<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Gali Moritz<br>(pfe.gmoritz) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Jan/20/2021 | Initial Entry  |

**5.a**

| Date  | Location        | User                         | Value  | Reason        |
|---|-----------------|------------------------------|--|---------------|
| Jan-20-2021 17:01:16<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Gali Moritz<br>(pfe.gmoritz) | <b>Data Entry:</b><br><b>Sample ID:</b> BP27DN | Initial Entry |

**5.a Sample ID**

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

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (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: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levisse

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

|   |                 |                              |                              |               |
|---|-----------------|------------------------------|------------------------------|---------------|
| Jan-20-2021 17:01:16<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Gali Moritz<br>(pfe.gmoritz) | <b>Data Entry:</b><br>BP27DN | Initial Entry |
|---|-----------------|------------------------------|------------------------------|---------------|

5.b

| Date  | Location        | User                         | Value  | Reason        |
|---|-----------------|------------------------------|--|---------------|
| Jan-20-2021 17:01:32<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Gali Moritz<br>(pfe.gmoritz) | <b>Data Entry:</b><br><b>Sample ID:</b> BNW7R0 | Initial Entry |

5.b Sample ID

| Date  | Location        | User                         | Value                        | Reason        |
|---|-----------------|------------------------------|------------------------------|---------------|
| Jan-20-2021 17:01:32<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Gali Moritz<br>(pfe.gmoritz) | <b>Data Entry:</b><br>BNW7R0 | Initial Entry |

5.c

| Date  | Location        | User                         | Value  | Reason        |
|---|-----------------|------------------------------|--|---------------|
| Jan-20-2021 17:01:44<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Gali Moritz<br>(pfe.gmoritz) | <b>Data Entry:</b><br><b>Sample ID:</b> BNW7NP | Initial Entry |

5.c Sample ID

| Date  | Location        | User                         | Value                        | Reason        |
|---|-----------------|------------------------------|------------------------------|---------------|
| Jan-20-2021 17:01:44<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Gali Moritz<br>(pfe.gmoritz) | <b>Data Entry:</b><br>BNW7NP | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)



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: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

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        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Jan-20-2021 15:45:50<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date  | Location        | User                    | Value                            | Reason        |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Jan-20-2021 15:45:50<br>(UTC-05:00) Eastern Time<br>(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-20-2021 17:02:41<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)    | Query 1: Deleted  | Close Auto Query  |
| Jan-20-2021 15:45:50<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)    | Query 1: Candidate  | 'Sample Collected?'<br>is Yes, however no<br>barcodes are entered.<br>Please review and<br>correct as<br>appropriate. |
| Jan-20-2021 15:45:50<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Gali Moritz<br>(pfe.gmoritz) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Jan/20/2021 | Initial Entry   |

**5.a**

| Date  | Location        | User                         | Value  | Reason        |
|---|-----------------|------------------------------|--|---------------|
| Jan-20-2021 17:02:41<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Gali Moritz<br>(pfe.gmoritz) | <b>Data Entry:</b><br><b>Sample ID:</b> BP27DL | Initial Entry |

**5.a Sample ID**

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

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**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:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

|   |                 |                              |                              |               |
|---|-----------------|------------------------------|------------------------------|---------------|
| Jan-20-2021 17:02:41<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Gali Moritz<br>(pfe.gmoritz) | <b>Data Entry:</b><br>BP27DL | Initial Entry |
|---|-----------------|------------------------------|------------------------------|---------------|

Header Text: c4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1001

Subject No: 10011100

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1001) NYU Langone Health

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-20-2021 15:46:57<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Gali Moritz<br>(pfe.gmoritz) | <b>Data Entry:</b><br>NO | Initial Entry |

**2. Treatment Name**

| Date  | Location        | User                    | Value                          | Reason        |
|---|-----------------|-------------------------|--------------------------------|---------------|
| Jan-20-2021 15:46:57<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>BNT162b2 | Initial Entry |

**3. Formulation:**

| Date  | Location        | User                    | Value                           | Reason        |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Jan-20-2021 15:46:57<br>(UTC-05:00) Eastern Time<br>(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-20-2021 15:46:57<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Gali Moritz<br>(pfe.gmoritz) | <b>Data Entry:</b><br>Jan/20/2021 12:15 | Initial Entry |

**5. Anatomical Location:**

| Date  | Location        | User                    | Value                                | Reason        |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Jan-20-2021 15:46:57<br>(UTC-05:00) Eastern Time<br>(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-20-2021 15:46:57<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Gali Moritz<br>(pfe.gmoritz) | <b>Data Entry:</b><br>LEFT | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levissc

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

**7. Route:**

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Jan-20-2021 15:46:57<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INTRAMUSCULAR | Initial Entry |

**8. Actual Dose:**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Jan-20-2021 15:46:57<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>30.0 | Initial Entry |

**9. Unit:**

| Date  | Location        | User                    | Value                    | Reason        |
|---|-----------------|-------------------------|--------------------------|---------------|
| Jan-20-2021 15:46:57<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ug | Initial Entry |

**10. Timeframe Subject Was Observed**

| Date  | Location        | User                    | Value                            | Reason        |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Jan-20-2021 15:46:57<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><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-20-2021 15:46:57<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Gali Moritz<br>(pfe.gmoritz) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levisse

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

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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**I. Date of Visit**

| Date   | Location                                  | User                         | Value  | Reason   |
|--|---|------------------------------|--|--|
| Feb-20-2021<br>20:41:20<br>(UTC-05:00)<br>Eastern Time<br>(US &<br>Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY<br>(pfe.DMW_QUERY) | Query<br>2: Clo<br>sed                       | Auto closed by Validation<br>Check: VC_SV001_04_AN   |
| Feb-19-2021<br>16:49:54<br>(UTC-05:00)<br>Eastern Time<br>(US &<br>Canada) | ACV0PFEINFP6000                           | auto query<br>(autoquery)    | Query<br>1: Clo<br>sed                       | Close Auto Query   |
| Feb-16-2021<br>16:03:07<br>(UTC-05:00)<br>Eastern Time<br>(US &<br>Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY<br>(pfe.DMW_QUERY) | Query<br>2: Op<br>ened                       | DMW7271381;'Date of<br>Visit' is after 'Date of<br>Completion/Discontinuation<br>/Death' on the Disposition -<br>Follow-up eCRF. Please<br>clarify or correct.     |
| Feb-16-2021<br>10:45:14<br>(UTC-05:00)<br>Eastern Time<br>(US &<br>Canada) | ACV0PFEINFP6000                           | auto query<br>(autoquery)    | Query<br>1: Op<br>ened                       | Date of Visit is after the<br>Date of<br>Completion/Discontinuation<br>/Death on the Follow-Up<br>Disposition form. Please<br>review and update as<br>appropriate. |
| Feb-08-2021<br>17:07:18<br>(UTC-05:00)<br>Eastern Time<br>(US &<br>Canada) | ACV0PFEINFP6000                           | Nazia Ria (pfe nria)         | <b>Data<br/>Entry</b><br>:<br>Feb/8/<br>2021 | Initial Entry  |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V102\_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levissc

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

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**3. Collection Date:**

| Date  | Location        | User                    | Value                                | Reason        |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Feb-08-2021 17:07:32<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

**6.a**

| Date  | Location        | User                    | Value   | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Feb-08-2021 17:07:50<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Choriogonadotropin Beta_PX113<br><b>Result::</b> Not Applicable<br><b>Not Done::</b> Not Applicable | Initial Entry |
| Feb-08-2021 17:07:32<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Choriogonadotropin Beta_PX113<br><b>Result::</b><br><b>Not Done::</b>                               | Initial Entry |

**6.a Sponsor ID:**

| Date  | Location        | User                    | Value                                | Reason        |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Feb-08-2021 17:07:50<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

**6.a Test:**

| Date  | Location        | User                    | Value   | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Feb-08-2021 17:07:32<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br>Choriogonadotropin Beta_PX113 | Initial Entry |

**6.a Result:**

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Form Version:** 14-Jan-2021 02:21

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

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

| Date  | Location        | User                    | Value                                | Reason        |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Feb-08-2021 17:07:50<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

**6.a Not Done:**

| Date  | Location        | User                    | Value                                | Reason        |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Feb-08-2021 17:07:50<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br>Not Applicable | 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: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

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        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Feb-08-2021 17:08:01<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date  | Location        | User                    | Value                            | Reason        |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Feb-08-2021 17:08:01<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB | Initial Entry |

**3. Sample Collected?**

| Date  | Location        | User                      | Value  | Reason   |
|---|-----------------|---------------------------|--|--|
| Feb-08-2021 17:08:21<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted   | Close Auto Query   |
| Feb-08-2021 17:08:01<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate   | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Feb-08-2021 17:08:01<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe nria)   | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Feb/8/2021 | Initial Entry  |

**5.a**

| Date  | Location        | User                    | Value   | Reason             |
|---|-----------------|-------------------------|---|--------------------|
| Feb-08-2021 17:08:45<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe nria) | <b>Data Entry:</b><br><b>Sample ID:</b> BP27FN  | data clarification |
| Feb-08-2021 17:08:21<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe nria) | <b>Data Entry:</b><br><b>Sample ID:</b> BP27FNs | Initial Entry      |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)



**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:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**5.a Sample ID**

| Date  | Location        | User                      | Value                         | Reason  |
|---|-----------------|---------------------------|-------------------------------|---|
| Feb-08-2021 17:08:45<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 2: Closed               | Close Auto Query  |
| Feb-08-2021 17:08:45<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Closed               | Close Auto Query  |
| Feb-08-2021 17:08:45<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe nria)   | <b>Data Entry:</b><br>BP27FN  | data clarification  |
| Feb-08-2021 17:08:21<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 2: Opened               | Barcode contains<br>lower case letters<br>which is not the<br>correct format. Please<br>review and correct as<br>appropriate. |
| Feb-08-2021 17:08:21<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Opened               | Barcode is not 6<br>characters in length.<br>Please review and<br>correct as<br>appropriate.                                  |
| Feb-08-2021 17:08:21<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe nria)   | <b>Data Entry:</b><br>BP27FNs | Initial Entry   |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1001

Subject No: 10011100

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1001) NYU Langone Health

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        |
|---|-----------------|-------------------------|--------------------------|---------------|
| Feb-08-2021 17:18:49<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br>NO | Initial Entry |

**2. Treatment Name**

| Date  | Location        | User                    | Value                          | Reason        |
|---|-----------------|-------------------------|--------------------------------|---------------|
| Feb-08-2021 17:18:49<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>BNT162b2 | Initial Entry |

**3. Formulation:**

| Date  | Location        | User                    | Value                           | Reason        |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Feb-08-2021 17:18:49<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INJECTION | Initial Entry |

**4. Dose Date Time:**

| Date  | Location        | User                    | Value                                  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Feb-08-2021 17:18:49<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br>Feb/8/2021 12:21 | Initial Entry |

**5. Anatomical Location:**

| Date  | Location        | User                    | Value                                | Reason        |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Feb-08-2021 17:18:49<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>DELTOID MUSCLE | Initial Entry |

**6. Body Side:**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Feb-08-2021 17:18:49<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br>LEFT | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V102\_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011100

Subject Initials: ---

Generated By: pfe.levissc

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

**7. Route:**

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Feb-08-2021 17:18:49<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INTRAMUSCULAR | Initial Entry |

**8. Actual Dose:**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Feb-08-2021 17:18:49<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>30.0 | Initial Entry |

**9. Unit:**

| Date  | Location        | User                    | Value                    | Reason        |
|---|-----------------|-------------------------|--------------------------|---------------|
| Feb-08-2021 17:18:49<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ug | Initial Entry |

**10. Timeframe Subject Was Observed**

| Date  | Location        | User                    | Value                            | Reason        |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Feb-08-2021 17:18:49<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><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        |
|---|-----------------|-------------------------|---------------------------|---------------|
| Feb-08-2021 17:18:49<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V103\_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1001

Subject No: 10011100

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Queries, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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*I. Date of Visit*

| Date   | Location        | User                                | Value                            | Reason  |
|--|-----------------|-------------------------------------|----------------------------------|---|
| Mar-10-2021 01:54:45<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Jayesh Yeole<br>(pfe.yeolej)        | Query 3: Opened                  | Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level. |
| Mar-09-2021 11:01:43<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)           | Query 3: Candidate               | Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level. |
| Mar-09-2021 11:01:43<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria)             | <b>Data Entry:</b><br>Mar/8/2021 | data correction   |
| Feb-19-2021 16:49:54<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)           | Query 2: Closed                  | Close Auto Query  |
| Feb-16-2021 10:45:14<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)           | Query 2: Opened                  | Date of Visit is after the Date of Completion/Discontinuation /Death on the Follow-Up Disposition form. Please review and update as appropriate.  |
| Feb-10-2021 01:46:22<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Jayesh Yeole<br>(pfe.yeolej)        | Query 1: Closed                  | Closed as rest of form not initiated.   |
| Feb-09-2021 13:39:13<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Erik Sundgaard<br>(pfe.sundgaardea) | Query 1: Opened                  | Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if   |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

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

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

**Site No:** 1001

**Site Name:** (1001) NYU Langone Health

**Subject No:** 10011100

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

|  |                 |                           |                                  |   |
|--|-----------------|---------------------------|----------------------------------|---|
|  |                 |                           |                                  | visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level.   |
| Feb-08-2021 17:17:50<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate               | Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level. |
| Feb-08-2021 17:17:20<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria)   | <b>Data Entry:</b><br>Feb/8/2021 | Initial Entry   |

**2. Erroneous Visit**

| Date   | Location        | User                    | Value                                 | Reason        |
|--|-----------------|-------------------------|---------------------------------------|---------------|
| Feb-08-2021 17:17:50<br>(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria) | <b>Data Entry:</b><br>ERRONEOUS VISIT | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levissc

**Form:** CONTACT OUTCOME - eCRF Audit Trail History

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

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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**I. Contact Type:**

| Date  | Location        | User                    | Value                                 | Reason        |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Mar-08-2021 16:17:55<br>(UTC-05:00) Eastern Time<br>(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  |
|---|-----------------|---------------------------|---|---|
| Mar-09-2021 11:01:43<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Closed   | Close Auto Query  |
| Mar-08-2021 16:17:55<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Opened   | Date of Contact<br>08/Mar/2021 is not<br>equal to the Date of<br>Visit 08/Feb/2021<br>within same visit.<br>Please review and<br>update as appropriate. |
| Mar-08-2021 16:17:55<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe nria)   | <b>Data Entry:</b><br>YES<br>Date of Contact:<br><br>Mar/8/2021 | Initial Entry   |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)

**Header Text:** c4591001**Visit:** Subject Status - Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1001**Subject No:** 10011100**Generated By:** pfe.lewissc**Form:** SUBJECT STATUS - eCRF Audit Trail History**Form Status:** Data Complete, Verified**Site Name:** (1001) NYU Langone Health**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Subject Status**

| Date  | Location        | User                    | Value                                     | Reason          |
|---|-----------------|-------------------------|---|-----------------|
| Feb-19-2021 16:50:18<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>FOLLOW-UP           | data correction |
| Feb-16-2021 10:45:14<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>DISCONTINUED        | Initial Entry   |
| Sep-23-2020 09:44:19<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>FOLLOW-UP           | Initial Entry   |
| Jul-30-2020 12:36:59<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ENROLLED/RANDOMIZED | Initial Entry   |
| Jul-30-2020 12:36:38<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SCREENED            | Initial Entry   |

**2. Subject Status Date**

| Date  | Location        | User                     | Value                             | Reason                   |
|---|-----------------|--------------------------|-----------------------------------|--------------------------|
| Feb-24-2021 13:20:59<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Gladys Noi<br>(pfe noig) | Query 1: Closed                   | Response satisfies query |
| Feb-24-2021 13:20:47<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Gladys Noi<br>(pfe noig) | Query 2: Closed                   | Response satisfies query |
| Feb-24-2021 11:38:49<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe nria)  | Query 2: Answered                 | Data updated             |
| Feb-24-2021 11:10:53<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe nria)  | Query 1: Answered                 | noted                    |
| Feb-19-2021 16:50:18<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc)  | <b>Data Entry:</b><br>Sep/22/2020 | data correction          |
| Feb-19-2021 16:49:54<br>(UTC-05:00) Eastern                       | ACV0PFEINFP6000 | auto calc<br>(autocalc)  | <b>Data Entry:</b><br>Sep/22/2020 | data correction          |

**Header Text:** c4591001**Visit:** Subject Status - Unscheduled**Form:** SUBJECT STATUS - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Verified**Site No:** 1001**Site Name:** (1001) NYU Langone Health**Subject No:** 10011100**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04

|   |                 |                                     |                                   |  |
|---|-----------------|-------------------------------------|-----------------------------------|--|
| Time (US & Canada)  |                 |                                     |                                   |  |
| Feb-16-2021 10:45:14<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc)             | <b>Data Entry:</b><br>Dec/13/2020 | Initial Entry  |
| Feb-15-2021 05:24:54<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Ricell Ann<br>Piojo<br>(pfe.QUITOR) | Query 2: Opened                   | SAE<br>RECON:AER#2021139022<br>left radial head<br>fracture(onset<br>date:12Dec2020)was<br>reported as serious in<br>Safety database but<br>missing in AE CRF. Please<br>confirm and update CRF. If<br>safety update is required,<br>submit a follow-up SAE<br>Form.       |
| Feb-15-2021 04:25:31<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Ricell Ann<br>Piojo<br>(pfe.QUITOR) | Query 1: Reissued:Opened          | SAE RECON 1:Please add<br>event by creating new form<br>in the AE CRF log page.  |
| Feb-14-2021 20:32:20<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Nazia Ria<br>(pfe.nria)             | Query 1: Answered                 | I have not been able to add<br>AE. Please advice on how I<br>can enter this AE.  |
| Feb-11-2021 03:23:46<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | Ricell Ann<br>Piojo<br>(pfe.QUITOR) | Query 1: Opened                   | SAE<br>RECON:AER#2021139022<br>right fifth metatarsal<br>fracture(onset<br>date:12Jan2021)was<br>reported as serious in<br>Safety database but<br>missing in AE CRF. Please<br>confirm and update CRF. If<br>safety update is required,<br>submit a follow-up SAE<br>Form. |
| Sep-23-2020 09:44:19<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc)             | <b>Data Entry:</b><br>Sep/22/2020 | Initial Entry  |
| Jul-30-2020 12:36:59<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc)             | <b>Data Entry:</b><br>Jul/30/2020 | Initial Entry  |
| Jul-30-2020 12:36:38<br>(UTC-05:00) Eastern<br>Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc)             | <b>Data Entry:</b><br>Jul/30/2020 | Initial Entry  |



**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1001

**Subject No:** 10011100

**Generated By:** pfe.levisse

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1001) NYU Langone Health

**Subject Initials:** ---

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

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*I. Casebook Signature*

| Date  | Location        | User                       | Value                                      | Reason        |
|---|-----------------|----------------------------|--|---------------|
| Aug-25-2020 12:54:10<br>(UTC-05:00) Eastern Time<br>(US & Canada) | ACV0PFEINFP6000 | Sara Hyman<br>(pfe.shyman) | <b>Data Entry:</b><br>Click Here to Enable | Initial Entry |

090177e196ae2f42\Final\Final On: 01-Apr-2021 03:38 (GMT)