

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

**Form:** COHORT\_SELECTION

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

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

**Cohort Selection**

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

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

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

**Form:** MAIN INFORMED CONSENT

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

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

**Informed Consent**

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

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

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

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

**Site No:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

**Demography**

|    |                                 |  |
|----|---------------------------------|--|
| 1. | Subject ID                      | [10851116]                                     |
| 2. | Birth Date:                     | (b) (6)/1951                                   |
| 3. | Sex:                            | MALE   |
| 4. | Ethnicity:                      | NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN |
| 5. | Race: (Check X all that apply): | WHITE  |
| 6. | Racial Designation:             |  |

**Header Text:** c4591001

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

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

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

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

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

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

**Form Comments**

**Inclusion Criteria Not Met**

|    |   |                         |
|----|---|-------------------------|
| 1. | Description of Inclusion Criterion<br>Not Met | Not Applicable<br>_____ |
|----|---|-------------------------|

**Exclusion Criteria Met**

|    |   |                         |
|----|---|-------------------------|
| 2. | Description of Exclusion Criterion<br>Met | Not Applicable<br>_____ |
|----|---|-------------------------|

**Header Text:** c4591001

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

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

**Disposition - Screening**

|    |   |             |
|----|---|-------------|
| 1. | Date of Completion/Discontinuation /Death | Aug/18/2020 |
| 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: 1085

Subject No: 10851116

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

eCRF Audit Trail History

**Medical History Details**

|     |   |                                 |
|-----|---|---------------------------------|
| 1.a | Line/MH Number:   | [1]                             |
|     | Disease/Syndrome/Surgery<br>/Non-Drug Allergies/Drug Allergies: | [Aortic Valve Repair]           |
|     | Start Date:   | UNK/UNK/2010                    |
|     | Ongoing:  | NO<br>End Date:<br>UNK/UNK/2010 |
| 1.b | Line/MH Number:   | [2]                             |
|     | Disease/Syndrome/Surgery<br>/Non-Drug Allergies/Drug Allergies: | [Vasectomy]                     |
|     | Start Date:   | UNK/UNK/1990                    |
|     | Ongoing:  | NO<br>End Date:<br>UNK/UNK/1990 |
| 1.c | Line/MH Number:   | [3]                             |
|     | Disease/Syndrome/Surgery<br>/Non-Drug Allergies/Drug Allergies: | [Hypertension]                  |
|     | Start Date:   | UNK/UNK/2007                    |
|     | Ongoing:  | YES                             |
| 1.d | Line/MH Number:   | [4]                             |
|     | Disease/Syndrome/Surgery<br>/Non-Drug Allergies/Drug Allergies: | [Hypercholesterolemia]          |
|     | Start Date:   | UNK/UNK/2010                    |
|     | Ongoing:  | YES                             |
| 1.e | Line/MH Number:   | [5]                             |
|     | Disease/Syndrome/Surgery<br>/Non-Drug Allergies/Drug Allergies: | [L4-L5 Lumbar Fusion]           |
|     | Start Date:   | UNK/UNK/2000                    |
|     | Ongoing:  | NO<br>End Date:<br>UNK/UNK/2000 |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisc

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

|     |   |              |
|-----|---|--------------|
| 1.f | Line/MH Number:   | [6]          |
|     | Disease/Syndrome/Surgery<br>/Non-Drug Allergies/Drug Allergies: | [Arthritis]  |
|     | Start Date:   | UNK/UNK/2015 |
|     | Ongoing:  | YES          |
| 1.g | Line/MH Number:   | [7]          |
|     | Disease/Syndrome/Surgery<br>/Non-Drug Allergies/Drug Allergies: | [Gout]       |
|     | Start Date:   | UNK/UNK/2009 |
|     | Ongoing:  | YES          |



**Header Text:** c4591001

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

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

**Form:** VITAL SIGNS - BASELINE

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

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

**eCRF Audit Trail History**

**Vital Signs**

|    |                  |             |
|----|------------------|-------------|
| 1. | Date:            | Aug/18/2020 |
| 2. | Weight:          | [190.3]     |
| 3. | Unit:            | LB          |
| 4. | Height:          | [74.5]      |
| 5. | Unit:            | in          |
| 6. | Body Mass Index: | [24.1]      |

**Vital Signs Details**

|     |                       |             |
|-----|-----------------------|-------------|
| 7.a | Record Identifier:    | 1           |
|     | Temperature:          | [96.9]      |
|     | Unit:                 | F           |
|     | Temperature Location: | ORAL CAVITY |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

**Form:** RANDOMIZATION

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

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

**Disposition**

|    |                       |             |
|----|-----------------------|-------------|
| 1. | Randomization Date :  | Aug/18/2020 |
| 2. | Randomization Number: | [232003]    |
| 3. | Randomization Group:  | [ ]         |

**Header Text:** c4591001

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

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |   |
|----|--|---|
| 1. | Data Origin  | SITE                                      |
| 2. | Sample Type  | SERUM                                     |
| 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 | [BP5C5N] |
| 5.b | Sample ID | [BP5C5P] |
| 5.c | Sample ID | [BP5C5R] |
| 5.d | Sample ID | [BKH4DN] |
| 5.e | Sample ID | [BKH4DM] |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

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

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

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[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 | [BP5C5S] |
|-----|-----------|----------|

**Header Text:** c4591001

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

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

**Form:** VACCINATION

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

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

**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 12:25                         |
| 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                                       |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

|  |   |
|--|---|
| <b>Header Text:</b> c4591001           | <b>Form:</b> REACTOGENICITY DIARY                           |
| <b>Visit:</b> V1_DAY1_VAX1_L           | <b>Form Status:</b> Data Complete, Locked, Frozen, Verified |
| <b>Form Version:</b> 06-Jul-2020 21:53 | <b>Site Name:</b> (1085) Ventavia Research Group            |
| <b>Site No:</b> 1085                   | <b>Subject Initials:</b> ---                                |
| <b>Subject No:</b> 10851116            | <b>Generated Time (GMT):</b> 29-Mar-2021 10:22              |
| <b>Generated By:</b> pfe.levisse       |   |

[eCRF Audit Trail History](#)

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

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

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

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

**Date of Visit**

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

|  |   |
|--|---|
| <b>Header Text:</b> c4591001           | <b>Form:</b> VITAL SIGNS - TEMP                             |
| <b>Visit:</b> V2_VAX2_L                | <b>Form Status:</b> Data Complete, Locked, Frozen, Verified |
| <b>Form Version:</b> 21-Aug-2020 02:51 | <b>Site Name:</b> (1085) Ventavia Research Group            |
| <b>Site No:</b> 1085                   | <b>Subject Initials:</b> ---                                |
| <b>Subject No:</b> 10851116            | <b>Generated Time (GMT):</b> 29-Mar-2021 10:22              |
| <b>Generated By:</b> pfe.levisse       |   |

[eCRF Audit Trail History](#)

**Vital Signs**

|    |       |             |
|----|-------|-------------|
| 1. | Date: | Sep/10/2020 |
|----|-------|-------------|

**Vital Signs Details**

|     |                       |             |
|-----|-----------------------|-------------|
| 2.a | Record Identifier:    | 1           |
|     | Temperature:          | [97.1]      |
|     | Unit:                 | F           |
|     | Temperature Location: | ORAL CAVITY |



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

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

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

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |   |
|----|--|---|
| 1. | Data Origin  | SITE                                      |
| 2. | Sample Type  | NASAL_SWAB                                |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Sep/10/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ]                                       |

**Aliquot**

Please enter barcode for each aliquot.

|     |           |          |
|-----|-----------|----------|
| 5.a | Sample ID | [BNZL1T] |
|-----|-----------|----------|

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

**Form:** VACCINATION

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

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

**Vaccination**

|     |   |   |
|-----|---|---|
| 1.  | Was there a temporary delay of vaccination?   | NO  |
| 2.  | Treatment Name  | [BLINDED THERAPY]                         |
| 3.  | Formulation:  | INJECTION                                 |
| 4.  | Dose Date Time:   | Sep/10/2020 09:13                         |
| 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                                       |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (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:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |            |
|----|-----------------|------------|
| 1. | Date of Visit   | Oct/7/2020 |
| 2. | Erroneous Visit |            |

**Header Text:** c4591001

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

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |  |
|----|--|--|
| 1. | Data Origin  | SITE                                     |
| 2. | Sample Type  | SERUM                                    |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Oct/7/2020 |
| 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 | [BP9NG1] |
| 5.b | Sample ID | [BNVTGH] |
| 5.c | Sample ID | [BNVTGJ] |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT

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

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |            |
|----|-----------------|------------|
| 1. | Date of Visit   | Mar/4/2021 |
| 2. | Erroneous Visit |            |

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |  |
|----|--|--|
| 1. | Data Origin  | SITE                                     |
| 2. | Sample Type  | SERUM                                    |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Mar/4/2021 |
| 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 | [BR6WHG] |
| 5.b | Sample ID | [BSG00X] |
| 5.c | Sample ID | [BSG00Y] |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

**Date of Visit**

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

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

**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:** V6\_MONTH24\_L

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

**Date of Visit**

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

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

**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:** DATE OF VISIT - ILLNESS ONSET

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

**Form Status:** Not Started

**Site No:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 10:22

**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:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 10:22

**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:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 10:22

**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:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 10:22

**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:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 10:22

**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:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 10:22

**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:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 10:22

**Date of Visit**

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

**COVID-19 Illness Visit**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA - New Unscheduled Visit      **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 10:22

**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 - New Unscheduled Visit

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 10:22

**Date of Visit**

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

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** UNPLANNED VISIT

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

**Form Status:** Not Started

**Site No:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 10:22

**Unplanned Assessments**

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

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT

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

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

**Site No:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

**Disposition - Treatment**

|    |   |             |
|----|---|-------------|
| 1. | Date of Completion/Discontinuation /Death : | Oct/7/2020  |
| 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:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levissc

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

**Disposition - Follow-Up**

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

**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:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 10:22

**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:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 10:22

**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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851116

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

| #  | Category      | AE Identifier | Adverse Event  | Start Date             | Is the Adverse Event Still Ongoing                  | Form Instance                   |
|----|---------------|---------------|--|------------------------|---|---------------------------------|
| 1. | ADVERSE EVENT | 1             | ACUTE NON ST ELEVATION MYOCARDIAL INFARCTION (MI) - NSTEMI | Dec/26/2020<br>UNK:UNK | NO<br>End Date Time:<br><br>Dec/29/2020 UNK:<br>UNK | <a href="#">Repeating Pages</a> |
| 2. | ADVERSE EVENT | 2             | ACUTE DIASTOLIC CONGESTIVE HEART FAILURE (CHF)             | Dec/26/2020<br>UNK:UNK | NO<br>End Date Time:<br><br>Dec/29/2020 UNK:<br>UNK | <a href="#">Repeating Pages</a> |
| 3. | ADVERSE EVENT | 3             | MILD HEMOPTYSIS  | Dec/26/2020<br>UNK:UNK | NO<br>End Date Time:<br><br>Dec/30/2020 UNK:<br>UNK | <a href="#">Repeating Pages</a> |
| 4. | ADVERSE EVENT | 4             | Acute Kidney Injury  | Dec/26/2020<br>UNK:UNK | NO<br>End Date Time:<br><br>Dec/29/2020 UNK:<br>UNK | <a href="#">Repeating Pages</a> |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851116

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Queries

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

**Adverse Event Report**

|     |   |   |
|-----|---|---|
| 1.  | Category:   | ADVERSE EVENT   |
| 2.  | AE ID:  | [1]   |
| 3.  | Adverse Event:<br>(If possible specify diagnosis, not individual symptoms)  | [ACUTE NON ST ELEVATION MYOCARDIAL INFARCTION (MI) - NSTEMI]  |
| 4.  | Start Date Time:  | Dec/26/2020 UNK:UNK   |
| 5.  | Is the adverse event still ongoing?   | NO<br>End Date Time:<br>Dec/29/2020 UNK:UNK   |
| 6.  | Toxicity Grade:   | 4   |
| 7.  | Is the adverse event serious?<br><br>If Yes, NOTIFY PFIZER IMMEDIATELY.<br><br>Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | 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>YES<br><br>Other medically important serious event<br>YES |
| 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>[MEDICAL HISTORY]  |
| 10. | Latest Action Taken with Study Treatment:   | NOT APPLICABLE  |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Queries

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

|     |  |                    |
|-----|--|--------------------|
| 11. | Was a Concomitant Medication given?  | YES                |
| 12. | Was a Non-Drug Treatment given?  | YES                |
| 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                          | [2021247780]       |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851116

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Queries

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)  
[eCRF Audit Trail History](#)  
[Form Audit Trail](#)

**Adverse Event Report**

|    |   |   |
|----|---|---|
| 1. | Category:   | ADVERSE EVENT   |
| 2. | AE ID:  | [2]   |
| 3. | Adverse Event:<br>(If possible specify diagnosis, not individual symptoms)  | [ACUTE DIASTOLIC CONGESTIVE HEART FAILURE (CHF)]  |
| 4. | Start Date Time:  | Dec/26/2020 UNK:UNK   |
| 5. | Is the adverse event still ongoing?   | NO<br>End Date Time:<br>Dec/29/2020 UNK:UNK   |
| 6. | Toxicity Grade:   | 4   |
| 7. | Is the adverse event serious?<br><br>If Yes, NOTIFY PFIZER IMMEDIATELY.<br><br>Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | 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>YES<br><br>Other medically important serious event<br>YES |
| 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>[MEDICAL HISTORY]  |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Queries

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

|     |  |                                  |
|-----|--|----------------------------------|
| 10. | Latest Action Taken with Study Treatment:                                  | NOT APPLICABLE                   |
| 11. | Was a Concomitant Medication given?  | YES                              |
| 12. | Was a Non-Drug Treatment given?  | YES                              |
| 13. | What was the outcome of this adverse event?:                               | RECOVERED/RESOLVED WITH SEQUELAE |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO                               |
| 15. | Serious Adverse Event Number: For Pfizer Use Only                          | [2021247780]                     |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.lewissc

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[Back to Form](#)  
[eCRF Audit Trail History](#)  
[Form Audit Trail](#)

**Adverse Event Report**

|     |   |   |
|-----|---|---|
| 1.  | Category:   | ADVERSE EVENT   |
| 2.  | AE ID:  | [3]   |
| 3.  | Adverse Event:<br>(If possible specify diagnosis, not individual symptoms)  | [MILD HEMOPTYSIS]   |
| 4.  | Start Date Time:  | Dec/26/2020 UNK:UNK   |
| 5.  | Is the adverse event still ongoing?   | NO<br>End Date Time:<br>Dec/30/2020 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>[CONGESTIVE HEART FAILURE] |
| 10. | Latest Action Taken with Study Treatment:   | NOT APPLICABLE  |
| 11. | Was a Concomitant Medication given?   | NO  |
| 12. | Was a Non-Drug Treatment given?   | NO  |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Queries

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[Back to Form](#)  
[eCRF Audit Trail History](#)  
[Form Audit Trail](#)

**Adverse Event Report**

|    |   |  |
|----|---|--|
| 1. | Category:   | ADVERSE EVENT  |
| 2. | AE ID:  | [4]  |
| 3. | Adverse Event:<br>(If possible specify diagnosis, not individual symptoms)  | [Acute Kidney Injury]  |
| 4. | Start Date Time:  | Dec/26/2020 UNK:UNK  |
| 5. | Is the adverse event still ongoing?   | NO<br>End Date Time:<br>Dec/29/2020 UNK:UNK  |
| 6. | Toxicity Grade:   | 3  |
| 7. | Is the adverse event serious?<br><br>If Yes, NOTIFY PFIZER IMMEDIATELY.<br><br>Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | 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>[Acute congestive heart failure]  |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Queries

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

|     |  |                    |
|-----|--|--------------------|
| 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?:                               | 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                          | [2021247780]       |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 10:22

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[Back to Form](#)

**Medication Error**

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

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 10:22

| #  | 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 Version:** 22-Apr-2020 21:03

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

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

**Form Status:** Not Started

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[Back to Form](#)

**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:   | //  |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 10:22

| #  | 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:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[Back to Form](#)

**Concomitant Medications**

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

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 10:22

| #  | 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:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[Back to Form](#)

**Radiation Treatment**

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 10:22

| #  | 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:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[Back to Form](#)

|    |                      |    |
|----|----------------------|----|
| 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:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 10:22

**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:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 10:22

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 10:22

**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? |     |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (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:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 10:22

**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:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 10:22

**Contact Outcome**

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



**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - Unscheduled **Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 10:22

**Date of Visit**

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

**Header Text:** c4591001

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

**Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

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

**Form Status:** Not Started

**Site No:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 10:22

**Informed Consent - Asymptomatic Surveillance**

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

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - Unscheduled    **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 10:22

**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:** V201\_SURVEIL\_CONSENT - Unscheduled    **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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

**Form Status:** Not Started

**Site No:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 10:22

**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:** Potential ReVax Initial Contact - Unscheduled **Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 10:22

**Date of Visit**

|    |                 |    |
|----|-----------------|----|
| 1. | Date of Visit   | // |
| 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:** Not Started

**Site No:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 10:22

**Further Vaccination Confirmation**

|    |   |  |
|----|---|--|
| 1. | Select appropriate response - Is participant willing to return for Vaccination 3? |  |
|----|---|--|

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levissc

**Form:** TREATMENT UNBLINDED

**Form Status:** Not Started

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

**Treatment Unblinded**

|    |                                |    |
|----|--------------------------------|----|
| 1. | Date Treatment Unblinded :     | // |
| 2. | Primary Reason for Unblinding: |    |

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

**Withdrawal Of Consent**

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



|   |  |
|---|--|
| <b>Header Text:</b> c4591001            | <b>Form:</b> DEATH DETAILS CODED                 |
| <b>Visit:</b> Disposition - Unscheduled | <b>Form Status:</b> Not Started                  |
| <b>Form Version:</b> 22-Apr-2020 21:03  | <b>Site Name:</b> (1085) Ventavia Research Group |
| <b>Site No:</b> 1085                    | <b>Subject Initials:</b> ---                     |
| <b>Subject No:</b> 10851116             | <b>Generated Time (GMT):</b> 29-Mar-2021 10:22   |
| <b>Generated By:</b> pfe.levisse        |  |

**Death Details**

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

**Cause of Death**

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

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisc

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

**Subject Status**

|    |                     |            |
|----|---------------------|------------|
| 1. | Subject Status      | FOLLOW-UP  |
| 2. | Subject Status Date | Oct/7/2020 |

**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:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

**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:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 10:22

[Audit Trail](#)

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

**Header Text:** c4591001

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

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

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

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

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[Back to Form](#)

| Item | Date  | User                           | Comment                              |
|------|---|--------------------------------|--------------------------------------|
| Form | Aug-18-2020 14:15:57 (UTC-06:00) Central Time (US & Canada) | Rebecca Iacullo (pfe riacullo) | subject met all eligibility criteria |
|      |   |                                | Not Applicable                       |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (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:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 10:22

[Back to Form](#)

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                            |
|---------------|-------------------|---|------|-----------------------------------|
| Linda Langdon | N/A               | Mar-04-2021 16:22:43 (UTC-06:00) Central Time (US & Canada) |      | Edit - All signatures invalidated |

**Affidavit:**

N/A

|                |          |   |      |        |
|----------------|----------|---|------|--------|
| Gregory Fuller | Approved | Oct-22-2020 11:10:57 (UTC-06:00) Central Time (US & Canada) | BOOK | Signed |
|----------------|----------|---|------|--------|

**Affidavit:**

By my dated signature below, I, GregoryFuller, 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.

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

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

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

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[Back to Form](#)

*1. Select appropriate response - Protocol version*

| Date  | Location        | User                                 | Value                             | Reason        |
|---|-----------------|--------------------------------------|-----------------------------------|---------------|
| Aug-18-2020 14:00:52<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Rebecca<br>Iacullo<br>(pfe riacullo) | <b>Data Entry:</b><br>24 JUL 2020 | Initial Entry |

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

| Date  | Location        | User                                 | Value                                 | Reason        |
|---|-----------------|--------------------------------------|---------------------------------------|---------------|
| Aug-18-2020 14:00:52<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Rebecca<br>Iacullo<br>(pfe riacullo) | <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:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

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

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

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[Back to Form](#)

*I. Consent Was:*

| Date  | Location        | User                                 | Value  | Reason        |
|---|-----------------|--------------------------------------|--|---------------|
| Aug-18-2020 14:01:00<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Rebecca<br>Iacullo<br>(pfe riacullo) | <b>Data Entry:</b><br>OBTAINED<br>Date Written Consent Obtained<br><br>Aug/18/2020 | Initial Entry |



Header Text: c4591001

Visit: COHORT\_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851116

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

**1. Subject ID**

| Date  | Location        | User                    | Value                          | Reason                            |
|---|-----------------|-------------------------|--------------------------------|-----------------------------------|
| Aug-18-2020 14:00:43<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>10851116 | Item copied from<br>previous form |

**2. Birth Date:**

| Date  | Location        | User                    | Value                              | Reason           |
|---|-----------------|-------------------------|------------------------------------|------------------|
| Aug-18-2020 14:00:39<br>(UTC-06:00) Central 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        |
|---|-----------------|--------------------------------------|----------------------------|---------------|
| Aug-18-2020 14:01:18<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Rebecca<br>Iacullo<br>(pfe riacullo) | <b>Data Entry:</b><br>MALE | Initial Entry |

**4. Ethnicity:**

| Date  | Location        | User                                 | Value   | Reason        |
|---|-----------------|--------------------------------------|---|---------------|
| Aug-18-2020 14:01:18<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Rebecca<br>Iacullo<br>(pfe riacullo) | <b>Data Entry:</b><br>NOT HISPANIC OR LATINO(A) OR<br>OF SPANISH ORIGIN | Initial Entry |

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

| Date  | Location        | User                                 | Value                       | Reason        |
|---|-----------------|--------------------------------------|-----------------------------|---------------|
| Aug-18-2020 14:01:18<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Rebecca<br>Iacullo<br>(pfe riacullo) | <b>Data Entry:</b><br>WHITE | Initial Entry |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.lewissc

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

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

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[Back to Form](#)

*1. Date of Visit*

| Date  | Location        | User                                 | Value                             | Reason        |
|---|-----------------|--------------------------------------|-----------------------------------|---------------|
| Aug-18-2020 14:01:46<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Rebecca<br>Iacullo<br>(pfe riacullo) | <b>Data Entry:</b><br>Aug/18/2020 | Initial Entry |

**Header Text:** c4591001

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

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

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

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

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[Back to Form](#)

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

| Date  | Location        | User                                 | Value                             | Reason        |
|---|-----------------|--------------------------------------|-----------------------------------|---------------|
| Aug-18-2020 14:17:12<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Rebecca<br>Iacullo<br>(pfe riacullo) | <b>Data Entry:</b><br>Aug/18/2020 | Initial Entry |

**2. Phase of Disposition:**

| Date  | Location        | User                    | Value                           | Reason        |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Aug-18-2020 14:17:12<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SCREENING | Initial Entry |

**3. Status:**

| Date  | Location        | User                                 | Value                           | Reason        |
|---|-----------------|--------------------------------------|---------------------------------|---------------|
| Aug-18-2020 14:17:12<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Rebecca<br>Iacullo<br>(pfe riacullo) | <b>Data Entry:</b><br>COMPLETED | Initial Entry |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851116

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

*I.a*

| Date  | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Aug-19-2020 15:03:54<br>(UTC-06:00) Central 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> Aortic Valve Repair<br><b>Start Date:</b> UNK/UNK/2010<br><b>Ongoing:</b> NO<br>End Date:<br><br>UNK/UNK/2010 | Initial Entry |

*I.a Line/MH Number:*

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-19-2020 15:03:54<br>(UTC-06:00) Central 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-19-2020 15:03:54<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>Aortic Valve Repair | Initial Entry |

*I.a Start Date:*

| Date  | Location        | User                    | Value                              | Reason        |
|---|-----------------|-------------------------|------------------------------------|---------------|
| Aug-19-2020 15:03:54<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>UNK/UNK/2010 | Initial Entry |

*I.a Ongoing:*

| Date  | Location        | User                    | Value   | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Aug-19-2020 15:03:54<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>NO<br>End Date:<br><br>UNK/UNK/2010 | Initial Entry |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851116

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

**I.b**

| Date  | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Aug-19-2020 15:04:25<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Line/MH Number:</b> 2<br><b>Medical History Term:</b> Vasectomy<br><b>Start Date:</b> UNK/UNK/1990<br><b>Ongoing:</b> NO<br>End Date:<br><br>UNK/UNK/1990 | Initial Entry |

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

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-19-2020 15:04:25<br>(UTC-06:00) Central 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-19-2020 15:04:25<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>Vasectomy | Initial Entry |

**I.b Start Date:**

| Date  | Location        | User                    | Value                              | Reason        |
|---|-----------------|-------------------------|------------------------------------|---------------|
| Aug-19-2020 15:04:25<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>UNK/UNK/1990 | Initial Entry |

**I.b Ongoing:**

| Date  | Location        | User                    | Value   | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Aug-19-2020 15:04:25<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>NO<br>End Date:<br><br>UNK/UNK/1990 | Initial Entry |

**I.c**

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

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851116

Generated By: pfe.lewissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

|   |                 |                         |   |               |
|---|-----------------|-------------------------|---|---------------|
| Aug-19-2020 15:04:46<br>(UTC-06:00) Central 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> Hypertension<br><b>Start Date:</b> UNK/UNK/2007<br><b>Ongoing:</b> YES | Initial Entry |
|---|-----------------|-------------------------|---|---------------|

*I.c Line/MH Number:*

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-19-2020 15:04:46<br>(UTC-06:00) Central 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-19-2020 15:04:46<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>Hypertension | Initial Entry |

*I.c Start Date:*

| Date  | Location        | User                    | Value                              | Reason        |
|---|-----------------|-------------------------|------------------------------------|---------------|
| Aug-19-2020 15:04:46<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>UNK/UNK/2007 | Initial Entry |

*I.c Ongoing:*

| Date  | Location        | User                    | Value                     | Reason        |
|---|-----------------|-------------------------|---------------------------|---------------|
| Aug-19-2020 15:04:46<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>YES | Initial Entry |

*I.d*

| Date  | Location        | User                    | Value   | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Aug-19-2020 15:05:10<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Line/MH Number</b> 4<br>:<br><b>Medical History Term:</b> Hypercholesterolemia<br><b>Start Date:</b> UNK/UNK/2010<br><b>Ongoing:</b> YES | Initial Entry |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851116

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-19-2020 15:05:10<br>(UTC-06:00) Central 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-19-2020 15:05:10<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>Hypercholesterolemia | Initial Entry |

**I.d Start Date:**

| Date  | Location        | User                    | Value                              | Reason        |
|---|-----------------|-------------------------|------------------------------------|---------------|
| Aug-19-2020 15:05:10<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>UNK/UNK/2010 | Initial Entry |

**I.d Ongoing:**

| Date  | Location        | User                    | Value                     | Reason        |
|---|-----------------|-------------------------|---------------------------|---------------|
| Aug-19-2020 15:05:10<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>YES | Initial Entry |

**I.e**

| Date  | Location        | User                    | Value   | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Aug-19-2020 15:07:18<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Line/MH Number 5<br>:<br>Medical History T L4-L5 Lumbar Fu<br>erm: sion<br>Start Date: UNK/UNK/2000<br>Ongoing: NO<br>End Date:<br>UNK/UNK/20<br>00 | Initial Entry |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851116

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

*I.e Line/MH Number:*

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-19-2020 15:07:18<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>5 | Initial Entry |

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

| Date  | Location        | User                    | Value                                     | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Aug-19-2020 15:07:18<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>L4-L5 Lumbar Fusion | Initial Entry |

*I.e Start Date:*

| Date  | Location        | User                    | Value                              | Reason        |
|---|-----------------|-------------------------|------------------------------------|---------------|
| Aug-19-2020 15:07:18<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>UNK/UNK/2000 | Initial Entry |

*I.e Ongoing:*

| Date  | Location        | User                    | Value   | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Aug-19-2020 15:07:18<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>NO<br>End Date:<br><br>UNK/UNK/2000 | Initial Entry |

*I.f*

| Date  | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Aug-19-2020 15:07:53<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Line/MH Number:</b> 6<br><b>Medical History Term:</b> Arthritis<br><b>Start Date:</b> UNK/UNK/2015<br><b>Ongoing:</b> YES | Initial Entry |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851116

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

*I.f Line/MH Number:*

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-19-2020 15:07:53<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>6 | Initial Entry |

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

| Date  | Location        | User                    | Value                           | Reason        |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Aug-19-2020 15:07:53<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>Arthritis | Initial Entry |

*I.f Start Date:*

| Date  | Location        | User                    | Value                              | Reason        |
|---|-----------------|-------------------------|------------------------------------|---------------|
| Aug-19-2020 15:07:53<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>UNK/UNK/2015 | Initial Entry |

*I.f Ongoing:*

| Date  | Location        | User                    | Value                     | Reason        |
|---|-----------------|-------------------------|---------------------------|---------------|
| Aug-19-2020 15:07:53<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>YES | Initial Entry |

*I.g*

| Date  | Location        | User                    | Value   | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Aug-19-2020 15:08:12<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Line/MH Number:</b> 7<br><b>Medical History Term:</b> Gout<br><b>Start Date:</b> UNK/UNK/2009<br><b>Ongoing:</b> YES | Initial Entry |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

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

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

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

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

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-19-2020 15:08:12<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>7 | Initial Entry |

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

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Aug-19-2020 15:08:12<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>Gout | Initial Entry |

***I.g Start Date:***

| Date  | Location        | User                    | Value                              | Reason        |
|---|-----------------|-------------------------|------------------------------------|---------------|
| Aug-19-2020 15:08:12<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>UNK/UNK/2009 | Initial Entry |

***I.g Ongoing:***

| Date  | Location        | User                    | Value                     | Reason        |
|---|-----------------|-------------------------|---------------------------|---------------|
| Aug-19-2020 15:08:12<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851116

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

**1. Date:**

| Date  | Location        | User                    | Value                             | Reason        |
|---|-----------------|-------------------------|-----------------------------------|---------------|
| Aug-19-2020 15:09:13<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>Aug/18/2020 | Initial Entry |

**2. Weight:**

| Date  | Location        | User                    | Value                       | Reason        |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Aug-19-2020 15:09:13<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>190.3 | Initial Entry |

**3. Unit:**

| Date  | Location        | User                    | Value                    | Reason        |
|---|-----------------|-------------------------|--------------------------|---------------|
| Aug-19-2020 15:09:13<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>LB | Initial Entry |

**4. Height:**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Aug-19-2020 15:09:13<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>74.5 | Initial Entry |

**5. Unit:**

| Date  | Location        | User                    | Value                    | Reason        |
|---|-----------------|-------------------------|--------------------------|---------------|
| Aug-19-2020 15:09:13<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>in | Initial Entry |

**6. Body Mass Index:**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Aug-19-2020 15:09:13<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>24.1 | Initial Entry |

**7.a**

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:28

Site No: 1085

Subject No: 10851116

Generated By: pfe.lewissc

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

| Date  | Location        | User                    | Value   | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Aug-19-2020 15:09:13<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br><b>Record Identifier::</b> 1<br><b>Temperature:</b> 96.9<br><b>Temperature Unit:</b> F<br><b>Temperature Location::</b> ORAL CAVITY | Initial Entry |

**7.a Record Identifier:**

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-19-2020 15:09:13<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>1 | Initial Entry |

**7.a Temperature:**

| Date  | Location        | User                      | Value                      | Reason   |
|---|-----------------|---------------------------|----------------------------|--|
| Aug-20-2020 05:07:46<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Sonal K<br>(pfe.ks66)     | Query 1: Closed            | As per site confirmation                                   |
| Aug-19-2020 15:10:20<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1)   | Query 1: Answered          | Original value is correct                                  |
| Aug-19-2020 15:09:13<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Opened            | Temperature 96.9 F is outside of Normal Range 97 - 99.5 F. |
| Aug-19-2020 15:09:13<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1)   | <b>Data Entry:</b><br>96.9 | Initial Entry  |

**7.a Unit:**

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-19-2020 15:09:13<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>F | Initial Entry |

**7.a Temperature Location:**

| Date  | Location        | User                    | Value                             | Reason        |
|---|-----------------|-------------------------|-----------------------------------|---------------|
| Aug-19-2020 15:09:13<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>ORAL CAVITY | Initial Entry |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

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

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

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[Back to Form](#)

**1. Randomization Date :**

| Date  | Location        | User                    | Value                             | Reason        |
|---|-----------------|-------------------------|-----------------------------------|---------------|
| Aug-19-2020 15:09:24<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>Aug/18/2020 | Initial Entry |

**2. Randomization Number:**

| Date  | Location        | User                    | Value                        | Reason        |
|---|-----------------|-------------------------|------------------------------|---------------|
| Aug-19-2020 15:09:24<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>232003 | Initial Entry |

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF  
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1085**Site Name:** (1085) Ventavia Research Group**Subject No:** 10851116**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 10:22[Back to Form](#)**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Aug-19-2020 08:39:30<br>(UTC-06:00) Central 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 08:39:30<br>(UTC-06:00) Central 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   |
|---|-----------------|---------------------------|---|--|
| Aug-19-2020 08:39:51<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted  | Close Auto Query   |
| Aug-19-2020 08:39:30<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate  | 'Sample Collected?' is<br>Yes, however no<br>barcodes are entered.<br>Please review and<br>correct as appropriate. |
| Aug-19-2020 08:39:30<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1)   | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Aug/18/2020 | Initial Entry  |

**5.a**

| Date  | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Aug-19-2020 08:39:51<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br><b>Sample ID:</b> BP5C5N | Initial Entry |

**5.a Sample ID**

| Date   | Location        | User                    | Value                        | Reason        |
|--|-----------------|-------------------------|------------------------------|---------------|
| Aug-19-2020 08:39:51<br>(UTC-06:00) Central Time | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>BP5C5N | Initial Entry |

Header Text: c4591001  
Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851116

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

(US & Canada)

5.b

| Date  | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Aug-19-2020 08:40:04<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br><b>Sample ID: BP5C5P</b> | Initial Entry |

5.b Sample ID

| Date  | Location        | User                    | Value                        | Reason        |
|---|-----------------|-------------------------|------------------------------|---------------|
| Aug-19-2020 08:40:04<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>BP5C5P | Initial Entry |

5.c

| Date  | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Aug-19-2020 08:40:12<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br><b>Sample ID: BP5C5R</b> | Initial Entry |

5.c Sample ID

| Date  | Location        | User                    | Value                        | Reason        |
|---|-----------------|-------------------------|------------------------------|---------------|
| Aug-19-2020 08:40:12<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>BP5C5R | Initial Entry |

5.d

| Date  | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Aug-19-2020 08:40:24<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br><b>Sample ID: BKH4DN</b> | Initial Entry |

5.d Sample ID

| Date  | Location        | User                    | Value                        | Reason        |
|---|-----------------|-------------------------|------------------------------|---------------|
| Aug-19-2020 08:40:24<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>BKH4DN | Initial Entry |

5.e

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (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:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 10:22

| Date  | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Aug-19-2020 08:40:46<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br><b>Sample ID:</b> BKH4DM | Initial Entry |

*5.e Sample ID*

| Date  | Location        | User                    | Value                        | Reason        |
|---|-----------------|-------------------------|------------------------------|---------------|
| Aug-19-2020 08:40:46<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>BKH4DM | Initial Entry |



**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1085**Site Name:** (1085) Ventavia Research Group**Subject No:** 10851116**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:22[Back to Form](#)**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Aug-19-2020 08:39:05<br>(UTC-06:00) Central 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 08:39:05<br>(UTC-06:00) Central 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-19-2020 08:39:21<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted  | Close Auto Query   |
| Aug-19-2020 08:39:05<br>(UTC-06:00) Central 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. |
| Aug-19-2020 08:39:05<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1)   | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Aug/18/2020 | Initial Entry  |

**5.a**

| Date  | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Aug-19-2020 08:39:21<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br><b>Sample ID:</b> BP5C5S | Initial Entry |

**5.a Sample ID**

| Date   | Location        | User                    | Value                        | Reason        |
|--|-----------------|-------------------------|------------------------------|---------------|
| Aug-19-2020 08:39:21<br>(UTC-06:00) Central Time | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>BP5C5S | Initial Entry |

**Header Text:** c4591001

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

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

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

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

**Site No:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 10:22

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

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1085

Subject No: 10851116

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

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

| Date  | Location        | User                    | Value                    | Reason        |
|---|-----------------|-------------------------|--------------------------|---------------|
| Aug-19-2020 15:09:49<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>NO | Initial Entry |

**2. Treatment Name**

| Date  | Location        | User                    | Value                                 | Reason        |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Aug-19-2020 15:09:49<br>(UTC-06:00) Central 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-19-2020 15:09:49<br>(UTC-06:00) Central 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-19-2020 15:09:49<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>Aug/18/2020 12:25 | Initial Entry |

**5. Anatomical Location:**

| Date  | Location        | User                    | Value                                | Reason        |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Aug-19-2020 15:09:49<br>(UTC-06:00) Central 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-19-2020 15:09:49<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>LEFT | Initial Entry |

**7. Route:**

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

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

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

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Aug-19-2020 15:09:49<br>(UTC-06:00) Central 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-19-2020 15:09:49<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>THE PROTOCOL SPECIFIED OBSE<br>RVATION 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-19-2020 15:09:49<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

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

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

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[Back to Form](#)

*1. Select appropriate response - Reactogenicity diary collection*

| Date  | Location        | User                    | Value   | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Aug-19-2020 15:09:58<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>NO - REACTOGENICITY E-DIARY<br>NOT COLLECTED FOR THIS SUBJ<br>ECT | Initial Entry |

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.lewissc

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

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

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[Back to Form](#)

*1. Date of Visit*

| Date  | Location        | User                    | Value                             | Reason        |
|---|-----------------|-------------------------|-----------------------------------|---------------|
| Sep-10-2020 10:00:01<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>Sep/10/2020 | Initial Entry |

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 21-Aug-2020 02:51

Site No: 1085

Subject No: 10851116

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

**1. Date:**

| Date  | Location        | User                    | Value                             | Reason        |
|---|-----------------|-------------------------|-----------------------------------|---------------|
| Sep-10-2020 10:00:12<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>Sep/10/2020 | Initial Entry |

**2.a**

| Date  | Location        | User                    | Value   | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Sep-10-2020 10:00:12<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br><b>Record Identifier::</b> 1<br><b>Temperature:</b> 97.1<br><b>Temperature Unit:</b> F<br><b>Temperature Location::</b> ORAL CAVITY | Initial Entry |

**2.a Record Identifier:**

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-10-2020 10:00:12<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>1 | Initial Entry |

**2.a Temperature:**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Sep-10-2020 10:00:12<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>97.1 | Initial Entry |

**2.a Unit:**

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-10-2020 10:00:12<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>F | Initial Entry |

**2.a Temperature Location:**

| Date   | Location        | User                    | Value                             | Reason        |
|--|-----------------|-------------------------|-----------------------------------|---------------|
| Sep-10-2020 10:00:12<br>(UTC-06:00) Central Time | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>ORAL CAVITY | Initial Entry |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

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

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

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

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

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851116

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Sep-11-2020 07:27:47<br>(UTC-06:00) Central 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-11-2020 07:27:47<br>(UTC-06:00) Central 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   |
|---|-----------------|---------------------------|---|--|
| Sep-11-2020 07:27:58<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted  | Close Auto Query   |
| Sep-11-2020 07:27:47<br>(UTC-06:00) Central 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-11-2020 07:27:47<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1)   | <b>Data Entry:</b><br>YES<br>Date of Collection:<br>Sep/10/2020 | Initial Entry  |

**5.a**

| Date  | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Sep-11-2020 07:27:58<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br><b>Sample ID:</b> BNZL1T | Initial Entry |

**5.a Sample ID**

| Date   | Location        | User                    | Value                        | Reason        |
|--|-----------------|-------------------------|------------------------------|---------------|
| Sep-11-2020 07:27:58<br>(UTC-06:00) Central Time | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>BNZL1T | Initial Entry |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (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:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 10:22

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

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1085

Subject No: 10851116

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

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

| Date  | Location        | User                    | Value                    | Reason        |
|---|-----------------|-------------------------|--------------------------|---------------|
| Sep-10-2020 10:00:32<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>NO | Initial Entry |

**2. Treatment Name**

| Date  | Location        | User                    | Value                                 | Reason        |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Sep-10-2020 10:00:32<br>(UTC-06:00) Central 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        |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Sep-10-2020 10:00:32<br>(UTC-06:00) Central 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        |
|---|-----------------|-------------------------|---|---------------|
| Sep-10-2020 10:00:32<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>Sep/10/2020 09:13 | Initial Entry |

**5. Anatomical Location:**

| Date  | Location        | User                    | Value                                | Reason        |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Sep-10-2020 10:00:32<br>(UTC-06:00) Central 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        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Sep-10-2020 10:00:32<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>LEFT | Initial Entry |

**7. Route:**

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

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

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

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Sep-10-2020 10:00:32<br>(UTC-06:00) Central 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        |
|---|-----------------|-------------------------|---|---------------|
| Sep-10-2020 10:00:32<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>THE PROTOCOL SPECIFIED OBSE<br>RVATION PERIOD | Initial Entry |

**11. Was the subject observed for at least the protocol specified observation period after investigational product administration?**

| Date  | Location        | User                    | Value                     | Reason        |
|---|-----------------|-------------------------|---------------------------|---------------|
| Sep-10-2020 10:00:32<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.lewissc

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

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

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[Back to Form](#)

***1. Date of Visit***

| <b>Date</b>  | <b>Location</b>                           | <b>User</b>                       | <b>Value</b>                                 | <b>Reason</b>   |
|--|---|-----------------------------------|--|---|
| Oct-09-2020<br>04:25:16<br>(UTC-06:00)<br>Central Time<br>(US &<br>Canada) | ACV0PFEINFP6000                           | Swapna Varikuti<br>(pfe.variks)   | Query<br>1: Clo<br>sed                       | As per site confirmation -<br>updated PD tracker  |
| Oct-08-2020<br>14:51:06<br>(UTC-06:00)<br>Central Time<br>(US &<br>Canada) | ACV0PFEINFP6000                           | Angi Cox (pfe.acox1)              | Query<br>1: Ans<br>wered                     | Original value is correct   |
| Oct-08-2020<br>04:49:16<br>(UTC-06:00)<br>Central Time<br>(US &<br>Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFE SDQ PROD<br>(pfe.PFESDQ_PROD) | Query<br>1: Op<br>ened                       | PDQ: Date of visit at<br>V3_MONTH1_POSTVAX2_L<br>is out of window for -1 days<br>from V2_VAX2_L DOV or<br>V2 Vaccination date. Please<br>verify and update. Else,<br>confirm in query response<br>appropriately. "[naikp09<br>SDQ=16005]" |
| Oct-07-2020<br>14:47:53<br>(UTC-06:00)<br>Central Time<br>(US &<br>Canada) | ACV0PFEINFP6000                           | Angi Cox (pfe.acox1)              | <b>Data<br/>Entry</b><br>:<br>Oct/7/<br>2020 | Initial Entry   |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (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:** 1085**Site Name:** (1085) Ventavia Research Group**Subject No:** 10851116**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:22[Back to Form](#)**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Oct-07-2020 14:49:00<br>(UTC-06:00) Central 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        |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Oct-07-2020 14:49:00<br>(UTC-06:00) Central 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   |
|---|-----------------|---------------------------|--|--|
| Oct-07-2020 15:37:14<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted   | Close Auto Query   |
| Oct-07-2020 14:49:00<br>(UTC-06:00) Central 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. |
| Oct-07-2020 14:49:00<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1)   | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Oct/7/2020 | Initial Entry  |

**5.a**

| Date  | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Oct-07-2020 15:37:14<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br><b>Sample ID:</b> BP9NG1 | Initial Entry |

**5.a Sample ID**

| Date   | Location        | User                    | Value                        | Reason        |
|--|-----------------|-------------------------|------------------------------|---------------|
| Oct-07-2020 15:37:14<br>(UTC-06:00) Central Time | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>BP9NG1 | Initial Entry |

**Header Text:** c4591001  
**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF  
 Audit Trail History  
**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1085 **Site Name:** (1085) Ventavia Research Group  
**Subject No:** 10851116 **Subject Initials:** ---  
**Generated By:** pfe.levisse **Generated Time (GMT):** 29-Mar-2021 10:22

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

**5.b**

| Date  | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Oct-07-2020 15:37:22<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br><b>Sample ID:</b> BNVTGH | Initial Entry |

**5.b Sample ID**

| Date  | Location        | User                    | Value                        | Reason        |
|---|-----------------|-------------------------|------------------------------|---------------|
| Oct-07-2020 15:37:22<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>BNVTGH | Initial Entry |

**5.c**

| Date  | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Oct-07-2020 15:37:28<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br><b>Sample ID:</b> BNVTGJ | Initial Entry |

**5.c Sample ID**

| Date  | Location        | User                    | Value                        | Reason        |
|---|-----------------|-------------------------|------------------------------|---------------|
| Oct-07-2020 15:37:28<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>BNVTGJ | Initial Entry |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.lewissc

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

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

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[Back to Form](#)

*1. Date of Visit*

| Date  | Location        | User                               | Value                            | Reason        |
|---|-----------------|------------------------------------|----------------------------------|---------------|
| Mar-04-2021 16:22:43<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda<br>Langdon<br>(pfe.llangdon) | <u>Data Entry:</u><br>Mar/4/2021 | Initial Entry |



Header Text: c4591001

Visit: V4\_MONTH6\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851116

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Mar-04-2021 16:23:01<br>(UTC-06:00) Central 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        |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Mar-04-2021 16:23:01<br>(UTC-06:00) Central 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   |
|---|-----------------|------------------------------------|--|--|
| Mar-04-2021 16:23:38<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)          | Query 1: Deleted   | Close Auto Query   |
| Mar-04-2021 16:23:01<br>(UTC-06:00) Central 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. |
| Mar-04-2021 16:23:01<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda<br>Langdon<br>(pfe.llangdon) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Mar/4/2021 | Initial Entry  |

**5.a**

| Date  | Location        | User                               | Value  | Reason        |
|---|-----------------|------------------------------------|--|---------------|
| Mar-04-2021 16:23:38<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda<br>Langdon<br>(pfe.llangdon) | <b>Data Entry:</b><br><b>Sample ID: BR6WHG</b> | Initial Entry |

**5.a Sample ID**

| Date   | Location        | User             | Value                        | Reason        |
|--|-----------------|------------------|------------------------------|---------------|
| Mar-04-2021 16:23:38<br>(UTC-06:00) Central Time | ACV0PFEINFP6000 | Linda<br>Langdon | <b>Data Entry:</b><br>BR6WHG | Initial Entry |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V4\_MONTH6\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851116

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

|               |  |                |  |
|---------------|--|----------------|--|
| (US & Canada) |  | (pfe.llangdon) |  |
|---------------|--|----------------|--|

5.b

| Date  | Location        | User                               | Value  | Reason        |
|---|-----------------|------------------------------------|--|---------------|
| Mar-04-2021 16:23:57<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda<br>Langdon<br>(pfe.llangdon) | <b>Data Entry:</b><br><b>Sample ID: BSG00X</b> | Initial Entry |

5.b Sample ID

| Date  | Location        | User                               | Value                               | Reason        |
|---|-----------------|------------------------------------|-------------------------------------|---------------|
| Mar-04-2021 16:23:57<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda<br>Langdon<br>(pfe.llangdon) | <b>Data Entry:</b><br><b>BSG00X</b> | Initial Entry |

5.c

| Date  | Location        | User                               | Value  | Reason        |
|---|-----------------|------------------------------------|--|---------------|
| Mar-04-2021 16:24:04<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda<br>Langdon<br>(pfe.llangdon) | <b>Data Entry:</b><br><b>Sample ID: BSG00Y</b> | Initial Entry |

5.c Sample ID

| Date  | Location        | User                               | Value                               | Reason        |
|---|-----------------|------------------------------------|-------------------------------------|---------------|
| Mar-04-2021 16:24:04<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda<br>Langdon<br>(pfe.llangdon) | <b>Data Entry:</b><br><b>BSG00Y</b> | Initial Entry |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.lewissc

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

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

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[Back to Form](#)

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

| Date  | Location        | User                    | Value                             | Reason              |
|---|-----------------|-------------------------|-----------------------------------|---------------------|
| Oct-07-2020 14:49:13<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>Oct/7/2020  | Transcription Error |
| Sep-21-2020 14:50:58<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>Sep/10/2020 | Initial Entry       |

**2. Phase of Disposition:**

| Date  | Location        | User                    | Value                             | Reason        |
|---|-----------------|-------------------------|-----------------------------------|---------------|
| Sep-21-2020 14:50:58<br>(UTC-06:00) Central 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-21-2020 14:50:58<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>COMPLETED | Initial Entry |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.lewissc

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[Back to Form](#)

| Date  | Location        | User                               | Value        | Reason |
|---|-----------------|------------------------------------|--------------|--------|
| Mar-05-2021 15:30:58<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda<br>Langdon<br>(pfe.llangdon) | Form Created |        |

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[Back to Form](#)

| Date  | Location        | User                               | Value        | Reason |
|---|-----------------|------------------------------------|--------------|--------|
| Mar-05-2021 15:35:26<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda<br>Langdon<br>(pfe.llangdon) | Form Created |        |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[Back to Form](#)

| Date  | Location        | User                               | Value        | Reason |
|---|-----------------|------------------------------------|--------------|--------|
| Mar-05-2021 15:45:55<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda<br>Langdon<br>(pfe.llangdon) | Form Created |        |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[Back to Form](#)

| Date  | Location        | User                    | Value        | Reason |
|---|-----------------|-------------------------|--------------|--------|
| Mar-09-2021 14:04:30<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | Form Created |        |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851116

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

**1. Category:**

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Mar-05-2021 15:30:58<br>(UTC-06:00) Central 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        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Mar-05-2021 15:30:58<br>(UTC-06:00) Central 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        |
|---|-----------------|------------------------------------|--|---------------|
| Mar-05-2021 15:30:58<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda<br>Langdon<br>(pfe.llangdon) | <b>Data Entry:</b><br>ACUTE NON ST ELEVATION MY<br>OCARDIAL INFARCTION (MI) - N<br>STEMI | Initial Entry |

**4. Start Date Time:**

| Date  | Location        | User                               | Value                                     | Reason        |
|---|-----------------|------------------------------------|---|---------------|
| Mar-05-2021 15:30:58<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda<br>Langdon<br>(pfe.llangdon) | <b>Data Entry:</b><br>Dec/26/2020 UNK:UNK | Initial Entry |

**5. Is the adverse event still ongoing?**

| Date  | Location        | User                                | Value   | Reason                      |
|---|-----------------|-------------------------------------|---|-----------------------------|
| Mar-11-2021 21:35:59<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Kathryn<br>Sewell<br>(pfe.sewelk02) | Query 1: Closed   | Response satisfies<br>query |
| Mar-11-2021 08:43:52<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)           | Query 1: Answered   | Transcription Error         |
| Mar-11-2021 08:43:52<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1)             | <b>Data Entry:</b><br>NO<br>End Date Time:<br><br>Dec/29/2020 UNK:UNK | Transcription Error         |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851116

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:22

|   |                 |                                  |   |  |
|---|-----------------|----------------------------------|---|--|
| Mar-10-2021 13:24:59<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Kathryn Sewell<br>(pfe.sewelk02) | Query 1: Opened   | Clinical - End date is 30Dec2020; however, end date in SAE is 29Dec2020. Please review, harmonize reporting, and update where applicable |
| Mar-05-2021 15:30:58<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda Langdon<br>(pfe.llangdon)  | <b>Data Entry:</b><br>NO<br>End Date Time:<br><br>Dec/30/2020 UNK:UNK | Initial Entry  |

6. Toxicity Grade:

| Date  | Location        | User                            | Value                   | Reason              |
|---|-----------------|---------------------------------|-------------------------|---------------------|
| Mar-05-2021 15:33:46<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda Langdon<br>(pfe.llangdon) | <b>Data Entry:</b><br>4 | Transcription Error |
| Mar-05-2021 15:30:58<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda Langdon<br>(pfe.llangdon) | <b>Data Entry:</b><br>3 | Initial Entry       |

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

| Date  | Location        | User                             | Value                    | Reason  |
|---|-----------------|----------------------------------|--------------------------|---|
| Mar-11-2021 21:36:47<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Kathryn Sewell<br>(pfe.sewelk02) | Query 3: Closed          | Query closed; will follow for requested COVID test information.   |
| Mar-11-2021 21:36:19<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Kathryn Sewell<br>(pfe.sewelk02) | Query 2: Reissued:Opened | Clinical For data lock, the AE/SAE reporting must harmonize now (can be updated later when med records arrive). As AE is grade 4 severity (=life threatening), addition of life-threatening to SAE would harmonize current reporting. |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

| <b>Header Text:</b> c4591001<br><b>Visit:</b> Logs - Unscheduled<br><b>Form Version:</b> 22-Apr-2020 21:02<br><b>Site No:</b> 1085<br><b>Subject No:</b> 10851116<br><b>Generated By:</b> pfe.lewissc  |                 |                                     |   |   |
|--|-----------------|-------------------------------------|---|---|
| <b>Form:</b> ADVERSE EVENT REPORT - eCRF Audit Trail History<br><b>Form Status:</b> Data Complete, Queries<br><b>Site Name:</b> (1085) Ventavia Research Group<br><b>Subject Initials:</b> ---<br><b>Generated Time (GMT):</b> 29-Mar-2021 10:22 |                 |                                     |   |   |
| Mar-11-2021 17:24:03<br>(UTC-06:00) Central Time<br>(US & Canada)  | ACV0PFEINFP6000 | Michael Johnson<br>(pfe.mjohanson3) | Query 3: Answered   | Will update SAE form when medical records are obtained  |
| Mar-11-2021 17:16:25<br>(UTC-06:00) Central Time<br>(US & Canada)  | ACV0PFEINFP6000 | Michael Johnson<br>(pfe.mjohanson3) | Query 2: Answered   | Subject was hospitalized for a surgical procedure. Will update SAE form when medical records are obtained   |
| Mar-10-2021 13:30:27<br>(UTC-06:00) Central Time<br>(US & Canada)  | ACV0PFEINFP6000 | Kathryn Sewell<br>(pfe.sewelk02)    | Query 3: Opened   | Clinical COVID test status (yes/no) during Hosp was not reported in the SAE. Please submit a follow-up SAE form [#2021247780] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results. |
| Mar-10-2021 13:27:31<br>(UTC-06:00) Central Time<br>(US & Canada)  | ACV0PFEINFP6000 | Kathryn Sewell<br>(pfe.sewelk02)    | Query 2: Opened   | Clinical Serious criteria are HOSP, Life-threatening and Med Important/Significant; however, SAE report has serious criterion HOSP. Please review, harmonize reporting, and update where applicable                                       |
| Mar-08-2021 03:20:33<br>(UTC-06:00) Central Time<br>(US & Canada)  | ACV0PFEINFP6000 | auto query<br>(autoquery)           | Query 1: Deleted  | Close Auto Query  |
| Mar-05-2021 15:30:58<br>(UTC-06:00) Central Time<br>(US & Canada)  | ACV0PFEINFP6000 | auto query<br>(autoquery)           | Query 1: Candidate  | For AE ACUTE NON ST ELEVATION MYOCARDIAL INFARCTION (MI) - NSTEMI: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.  |
| Mar-05-2021 15:30:58<br>(UTC-06:00) Central Time<br>(US & Canada)  | ACV0PFEINFP6000 | Linda Langdon<br>(pfe.llangdon)     | <b>Data Entry:</b><br>YES<br>Is this serious event associated w | Initial Entry   |

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1085**Subject No:** 10851116**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Queries**Site Name:** (1085) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:22

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | ith 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?<br><br>NO<br><br>Is this serious event life threatening?<br><br>YES<br><br>Other medically important serious event<br><br>YES |  |
|--|--|--|---|--|

**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        |
|---|-----------------|------------------------------------|--------------------------|---------------|
| Mar-05-2021 15:30:58<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda<br>Langdon<br>(pfe.llangdon) | <b>Data Entry:</b><br>NO | Initial Entry |

**9. Is this event related to study treatment:**

| Date  | Location        | User                               | Value   | Reason        |
|---|-----------------|------------------------------------|---|---------------|
| Mar-05-2021 15:30:58<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda<br>Langdon<br>(pfe.llangdon) | <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><i>If Other, specify:</i> | 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, Queries

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851116

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

|  |  |  |                 |  |
|--|--|--|-----------------|--|
|  |  |  | MEDICAL HISTORY |  |
|--|--|--|-----------------|--|

10. Latest Action Taken with Study Treatment:

| Date  | Location        | User                               | Value                                | Reason        |
|---|-----------------|------------------------------------|--------------------------------------|---------------|
| Mar-05-2021 15:30:58<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda<br>Langdon<br>(pfe.llangdon) | <b>Data Entry:</b><br>NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

| Date  | Location        | User                               | Value                     | Reason        |
|---|-----------------|------------------------------------|---------------------------|---------------|
| Mar-05-2021 15:30:58<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda<br>Langdon<br>(pfe.llangdon) | <b>Data Entry:</b><br>YES | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date  | Location        | User                               | Value                     | Reason        |
|---|-----------------|------------------------------------|---------------------------|---------------|
| Mar-05-2021 15:30:58<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda<br>Langdon<br>(pfe.llangdon) | <b>Data Entry:</b><br>YES | Initial Entry |

13. What was the outcome of this adverse event?:

| Date  | Location        | User                               | Value                                    | Reason        |
|---|-----------------|------------------------------------|--|---------------|
| Mar-05-2021 15:30:58<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda<br>Langdon<br>(pfe.llangdon) | <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        |
|---|-----------------|------------------------------------|--------------------------|---------------|
| Mar-05-2021 15:30:58<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda<br>Langdon<br>(pfe.llangdon) | <b>Data Entry:</b><br>NO | Initial Entry |

15. Serious Adverse Event Number: For Pfizer Use Only

| Date  | Location        | User                                | Value                            | Reason        |
|---|-----------------|-------------------------------------|----------------------------------|---------------|
| Mar-08-2021 03:20:33<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Ricell Ann<br>Piojo<br>(pfe.quitor) | <b>Data Entry:</b><br>2021247780 | Initial Entry |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851116

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Queries

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

**1. Category:**

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Mar-05-2021 15:35:26<br>(UTC-06:00) Central 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        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Mar-05-2021 15:35:26<br>(UTC-06:00) Central 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        |
|---|-----------------|------------------------------------|---|---------------|
| Mar-05-2021 15:35:26<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda<br>Langdon<br>(pfe.llangdon) | <b>Data Entry:</b><br>ACUTE DIASTOLIC CONGESTIVE<br>HEART FAILURE (CHF) | Initial Entry |

**4. Start Date Time:**

| Date  | Location        | User                                | Value                                     | Reason   |
|---|-----------------|-------------------------------------|---|--|
| Mar-09-2021 19:24:48<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Ricell Ann<br>Piojo<br>(pfe.quitor) | Query 1: Closed                           | Response satisfies<br>query  |
| Mar-09-2021 13:45:05<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)           | Query 1: Answered                         | Transcription Error  |
| Mar-09-2021 13:45:05<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1)             | <b>Data Entry:</b><br>Dec/26/2020 UNK:UNK | Transcription Error  |
| Mar-09-2021 03:57:46<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Ricell Ann<br>Piojo<br>(pfe.quitor) | Query 1: Opened                           | SAE RECON:<br>AER#2021247780<br>,onset date was<br>recorded as<br>26Dec2020 in Safety<br>database however,<br>recorded as<br>30Dec2020on AE<br>CRF. Please confirm. If<br>safety update is |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

**Header Text:** c4591001  
**Visit:** Logs - Unscheduled  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1085  
**Subject No:** 10851116  
**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History  
**Form Status:** Data Complete, Queries  
**Site Name:** (1085) Ventavia Research Group  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:22

|   |                 |                                 |   |  |
|---|-----------------|---------------------------------|---|--|
|   |                 |                                 |   | required, please submit a follow up form |
| Mar-05-2021 15:35:26<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda Langdon<br>(pfe.llangdon) | <b>Data Entry:</b><br>Dec/30/2020 UNK:UNK | Initial Entry                            |

**5. Is the adverse event still ongoing?**

| Date  | Location        | User                             | Value   | Reason   |
|---|-----------------|----------------------------------|---|--|
| Mar-11-2021 21:33:09<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Kathryn Sewell<br>(pfe.sewelk02) | Query 1: Closed   | Response satisfies query   |
| Mar-11-2021 08:51:01<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)        | Query 1: Answered   | Transcription Error  |
| Mar-11-2021 08:51:01<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1)          | <b>Data Entry:</b><br>NO<br>End Date Time:<br>Dec/29/2020 UNK:UNK | Transcription Error  |
| Mar-10-2021 13:25:14<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Kathryn Sewell<br>(pfe.sewelk02) | Query 1: Opened   | Clinical - End date is 30Dec2020; however, end date in SAE is 29Dec2020. Please review, harmonize reporting, and update where applicable |
| Mar-05-2021 15:35:26<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda Langdon<br>(pfe.llangdon)  | <b>Data Entry:</b><br>NO<br>End Date Time:<br>Dec/30/2020 UNK:UNK | Initial Entry  |

**6. Toxicity Grade:**

| Date  | Location        | User                            | Value                   | Reason        |
|---|-----------------|---------------------------------|-------------------------|---------------|
| Mar-05-2021 15:35:26<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda Langdon<br>(pfe.llangdon) | <b>Data Entry:</b><br>4 | Initial Entry |

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

**Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require**

**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:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 10:22

*medical/surgical intervention to prevent above outcomes).*

| Date  | Location        | User                              | Value                    | Reason  |
|---|-----------------|-----------------------------------|--------------------------|---|
| Mar-11-2021 21:35:37<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Kathryn Sewell<br>(pfe.sewelk02)  | Query 3: Reissued:Opened | Clinical For data lock, the AE/SAE reporting must harmonize now (can be updated later when med records arrive). As AE is grade 4 severity (=life threatening), addition of life-threatening to SAE would harmonize current reporting. |
| Mar-11-2021 17:28:25<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Michael Johnson<br>(pfe mjohson3) | Query 3: Answered        | subject was hospitalized for a surgical procedure. Will update SAE form when medical records are obtained   |
| Mar-10-2021 13:27:12<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Kathryn Sewell<br>(pfe.sewelk02)  | Query 3: Opened          | Clinical Serious criteria are HOSP, Life-threatening and Med Important/Significant; however, SAE report has serious criterion HOSP. Please review, harmonize reporting, and update where applicable                                   |
| Mar-09-2021 19:25:27<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Ricell Ann Piojo<br>(pfe.quitor)  | Query 2: Closed          | Response satisfies query  |
| Mar-09-2021 13:48:06<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1)           | Query 2: Answered        | Incorrect it is reported on the SAE form submitted to the sponsor.  |
| Mar-08-2021 04:50:13<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Ricell Ann Piojo<br>(pfe.quitor)  | Query 1: Deleted         | Query can be addressed internally   |
| Mar-08-2021 04:50:00<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Ricell Ann Piojo<br>(pfe.quitor)  | Query 2: Opened          | SAE RECON: ACUTE DIASTOLIC CONGESTIVE HEART FAILURE (CHF) is not reported   |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Queries

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

|   |                 |                                 |   |  |
|---|-----------------|---------------------------------|---|--|
|   |                 |                                 |   | 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 |
| Mar-05-2021 15:35:26<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)       | Query 1: Candidate  | For AE ACUTE DIASTOLIC CONGESTIVE HEART FAILURE (CHF): Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.           |
| Mar-05-2021 15:35:26<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda Langdon<br>(pfe.llangdon) | <p><b>Data Entry:</b><br/>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/in capacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>YES</p> <p>Other medically important serious event</p> | Initial Entry  |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851116

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:22

|  |  |  |     |  |
|--|--|--|-----|--|
|  |  |  | YES |  |
|--|--|--|-----|--|

**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        |
|---|-----------------|------------------------------------|--------------------------|---------------|
| Mar-05-2021 15:35:26<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda<br>Langdon<br>(pfe.llangdon) | <b>Data Entry:</b><br>NO | Initial Entry |

**9. Is this event related to study treatment:**

| Date  | Location        | User                               | Value  | Reason        |
|---|-----------------|------------------------------------|--|---------------|
| Mar-05-2021 15:35:26<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda<br>Langdon<br>(pfe.llangdon) | <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><i>If Other, specify:</i><br><br>MEDICAL HISTORY | Initial Entry |

**10. Latest Action Taken with Study Treatment:**

| Date  | Location        | User                               | Value                                | Reason        |
|---|-----------------|------------------------------------|--------------------------------------|---------------|
| Mar-05-2021 15:35:26<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda<br>Langdon<br>(pfe.llangdon) | <b>Data Entry:</b><br>NOT APPLICABLE | Initial Entry |

**11. Was a Concomitant Medication given?**

| Date  | Location        | User                               | Value                     | Reason        |
|---|-----------------|------------------------------------|---------------------------|---------------|
| Mar-05-2021 15:35:26<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda<br>Langdon<br>(pfe.llangdon) | <b>Data Entry:</b><br>YES | Initial Entry |

**12. Was a Non-Drug Treatment given?**

| Date  | Location        | User                               | Value                     | Reason        |
|---|-----------------|------------------------------------|---------------------------|---------------|
| Mar-05-2021 15:35:26<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda<br>Langdon<br>(pfe.llangdon) | <b>Data Entry:</b><br>YES | Initial Entry |

**13. What was the outcome of this adverse event?:**

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

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

**Header Text:** c4591001  
**Visit:** Logs - Unscheduled  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1085  
**Subject No:** 10851116  
**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History  
**Form Status:** Data Complete, Queries  
**Site Name:** (1085) Ventavia Research Group  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:22

|   |                 |                                     |  |  |
|---|-----------------|-------------------------------------|--|--|
| Mar-10-2021 14:16:08<br>(UTC-06:00) Central<br>Time (US & Canada) | ACV0PFEINFP6000 | Gladys Noi<br>(pfe.noig)            | Query 2: Closed  | Response satisfies query   |
| Mar-10-2021 08:15:24<br>(UTC-06:00) Central<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)           | Query 2: Answered                                      | Transcription Error  |
| Mar-10-2021 08:15:24<br>(UTC-06:00) Central<br>Time (US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1)             | <b>Data Entry:</b><br>RECOVERED/RESOLVED WITH SEQUELAE | Transcription Error  |
| Mar-10-2021 05:50:27<br>(UTC-06:00) Central<br>Time (US & Canada) | ACV0PFEINFP6000 | Ricell Ann<br>Piojo<br>(pfe.QUITOR) | Query 2: Opened  | SAE<br>RECON:AER#2021247780<br>outcome was reported as<br>RECOVERED/RESOLVED<br>WITH SEQUELAE to<br>Safety DB however,<br>recorded as<br>RECOVERED/RESOLVED<br>on AE CRF. Please confirm<br>correct outcome. If safety<br>update is required, please<br>submit a follow-up form. |
| Mar-05-2021 15:46:24<br>(UTC-06:00) Central<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)           | Query 1: Closed  | Close Auto Query   |
| Mar-05-2021 15:46:24<br>(UTC-06:00) Central<br>Time (US & Canada) | ACV0PFEINFP6000 | Linda<br>Langdon<br>(pfe.llangdon)  | <b>Data Entry:</b><br>RECOVERED/RESOLVED               | Transcription Error  |
| Mar-05-2021 15:35:26<br>(UTC-06:00) Central<br>Time (US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)           | Query 1: Opened  | For AE ACUTE<br>DIASTOLIC<br>CONGESTIVE HEART<br>FAILURE (CHF): Response<br>to "What was the outcome<br>of this adverse event?" is<br>'Not Recovered/Not<br>Resolved' but AE End<br>Date/Time is present.  |
| Mar-05-2021 15:35:26<br>(UTC-06:00) Central<br>Time (US & Canada) | ACV0PFEINFP6000 | Linda<br>Langdon<br>(pfe.llangdon)  | <b>Data Entry:</b><br>NOT RECOVERED/NOT RESOLVED       | Initial Entry  |

**14. Did the adverse event cause the subject to be discontinued from the study?**

| Date   | Location        | User             | Value                    | Reason        |
|--|-----------------|------------------|--------------------------|---------------|
| Mar-05-2021 15:35:26<br>(UTC-06:00) Central Time | ACV0PFEINFP6000 | Linda<br>Langdon | <b>Data Entry:</b><br>NO | Initial Entry |

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Queries

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

(US & Canada)

(pfe.llangdon)

*15. Serious Adverse Event Number: For Pfizer Use Only*

| Date  | Location        | User                                | Value                            | Reason        |
|---|-----------------|-------------------------------------|----------------------------------|---------------|
| Mar-09-2021 03:53:42<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Ricell Ann<br>Piojo<br>(pfe.quiton) | <b>Data Entry:</b><br>2021247780 | Initial Entry |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851116

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

**1. Category:**

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Mar-05-2021 15:45:55<br>(UTC-06:00) Central 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        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Mar-05-2021 15:45:55<br>(UTC-06:00) Central 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        |
|---|-----------------|------------------------------------|---------------------------------------|---------------|
| Mar-05-2021 15:45:55<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda<br>Langdon<br>(pfe.llangdon) | <b>Data Entry:</b><br>MILD HEMOPTYSIS | Initial Entry |

**4. Start Date Time:**

| Date  | Location        | User                               | Value                                     | Reason        |
|---|-----------------|------------------------------------|---|---------------|
| Mar-05-2021 15:45:55<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda<br>Langdon<br>(pfe.llangdon) | <b>Data Entry:</b><br>Dec/26/2020 UNK:UNK | Initial Entry |

**5. Is the adverse event still ongoing?**

| Date  | Location        | User                               | Value   | Reason        |
|---|-----------------|------------------------------------|---|---------------|
| Mar-05-2021 15:45:55<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda<br>Langdon<br>(pfe.llangdon) | <b>Data Entry:</b><br>NO<br>End Date Time:<br>Dec/30/2020 UNK:UNK | Initial Entry |

**6. Toxicity Grade:**

| Date  | Location        | User                               | Value                   | Reason        |
|---|-----------------|------------------------------------|-------------------------|---------------|
| Mar-05-2021 15:45:55<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda<br>Langdon<br>(pfe.llangdon) | <b>Data Entry:</b><br>2 | Initial Entry |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (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, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851116

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

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-05-2021 15:45:55<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda<br>Langdon<br>(pfe.llangdon) | <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        |
|---|-----------------|------------------------------------|--------------------------|---------------|
| Mar-05-2021 15:45:55<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda<br>Langdon<br>(pfe.llangdon) | <u>Data Entry:</u><br>NO | Initial Entry |

9. Is this event related to study treatment:

| Date  | Location        | User                               | Value  | Reason        |
|---|-----------------|------------------------------------|--|---------------|
| Mar-05-2021 15:45:55<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda<br>Langdon<br>(pfe.llangdon) | <u>Data Entry:</u><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>CONGESTIVE HEART FAILURE | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date  | Location        | User                               | Value                                | Reason        |
|---|-----------------|------------------------------------|--------------------------------------|---------------|
| Mar-05-2021 15:45:55<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda<br>Langdon<br>(pfe.llangdon) | <u>Data Entry:</u><br>NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

| Date   | Location        | User             | Value                    | Reason        |
|--|-----------------|------------------|--------------------------|---------------|
| Mar-05-2021 15:45:55<br>(UTC-06:00) Central Time | ACV0PFEINFP6000 | Linda<br>Langdon | <u>Data Entry:</u><br>NO | Initial Entry |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

(US & Canada)

(pfe.llangdon)

**12. Was a Non-Drug Treatment given?**

| Date  | Location        | User                               | Value                    | Reason        |
|---|-----------------|------------------------------------|--------------------------|---------------|
| Mar-05-2021 15:45:55<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda<br>Langdon<br>(pfe.llangdon) | <b>Data Entry:</b><br>NO | Initial Entry |

**13. What was the outcome of this adverse event?:**

| Date  | Location        | User                               | Value                                    | Reason        |
|---|-----------------|------------------------------------|--|---------------|
| Mar-05-2021 15:45:55<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda<br>Langdon<br>(pfe.llangdon) | <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        |
|---|-----------------|------------------------------------|--------------------------|---------------|
| Mar-05-2021 15:45:55<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Linda<br>Langdon<br>(pfe.llangdon) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851116

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Queries

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

**1. Category:**

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Mar-09-2021 14:04:30<br>(UTC-06:00) Central 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        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Mar-09-2021 14:04:30<br>(UTC-06:00) Central 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   |
|---|-----------------|-------------------------------------|---|--|
| Mar-10-2021 13:23:45<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Kathryn<br>Sewell<br>(pfe.sewelk02) | Query 1: Opened                           | Clinical Med hx reports subject has gout (2009); however this is not reported in SAE Med Hx. Please safety relevance to event 'acute kidney injury', and update SAE Med Hx as applicable |
| Mar-09-2021 14:04:30<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1)             | <b>Data Entry:</b><br>Acute Kidney Injury | Initial Entry  |

**4. Start Date Time:**

| Date  | Location        | User                    | Value                                     | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Mar-09-2021 14:04:30<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>Dec/26/2020 UNK:UNK | Initial Entry |

**5. Is the adverse event still ongoing?**

| Date  | Location        | User                                | Value           | Reason                   |
|---|-----------------|-------------------------------------|-----------------|--------------------------|
| Mar-11-2021 21:32:33<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Kathryn<br>Sewell<br>(pfe.sewelk02) | Query 1: Closed | Response satisfies query |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

**Header Text:** c4591001  
**Visit:** Logs - Unscheduled  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1085  
**Subject No:** 10851116  
**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History  
**Form Status:** Data Complete, Queries  
**Site Name:** (1085) Ventavia Research Group  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:22

|   |                 |                                     |   |  |
|---|-----------------|-------------------------------------|---|--|
| Mar-11-2021 09:00:38<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery)           | Query 1: Answered   | Transcription Error  |
| Mar-11-2021 09:00:38<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1)             | <b>Data Entry:</b><br>NO<br>End Date Time:<br><br>Dec/29/2020 UNK:UNK | Transcription Error  |
| Mar-10-2021 13:24:47<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Kathryn<br>Sewell<br>(pfe.sewelk02) | Query 1: Opened   | Clinical - End date is 30Dec2020; however, end date in SAE is 29Dec2020. Please review, harmonize reporting, and update where applicable |
| Mar-09-2021 14:04:30<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1)             | <b>Data Entry:</b><br>NO<br>End Date Time:<br><br>Dec/30/2020 UNK:UNK | Initial Entry  |

**6. Toxicity Grade:**

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Mar-09-2021 14:04:30<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>3 | Initial Entry |

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

**Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).**

| Date  | Location        | User                                | Value           | Reason   |
|---|-----------------|-------------------------------------|-----------------|--|
| Mar-10-2021 13:29:00<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Kathryn<br>Sewell<br>(pfe.sewelk02) | Query 2: Opened | Clinical Serious criteria are HOSP and Disability/Incapacity; however, SAE report has serious criterion HOSP. Please report the Permanent Disability/Incapacity involved. Please review, harmonize |



Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851116

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Queries

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

|   |                 |                           |   |   |
|---|-----------------|---------------------------|---|---|
|   |                 |                           |   | reporting, and update where applicable  |
| Mar-09-2021 19:21:28<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted  | Close Auto Query  |
| Mar-09-2021 14:04:30<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate  | For AE Acute Kidney Injury: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank. |
| Mar-09-2021 14:04:30<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1)   | <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> <p>NO</p> | 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 |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (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:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 10:22

|   |                 |                         |                          |               |
|---|-----------------|-------------------------|--------------------------|---------------|
| Mar-09-2021 14:04:30<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <b>Data Entry:</b><br>NO | Initial Entry |
|---|-----------------|-------------------------|--------------------------|---------------|

**9. Is this event related to study treatment:**

| Date  | Location                                  | User                               | Value  | Reason   |
|---|---|------------------------------------|--|--|
| Mar-11-2021<br>12:10:42<br>(UTC-06:00)<br>Central Time<br>(US & Canada) | ACV0PFEINFP6000                           | Elizabeth Chatburn<br>(pfe.chatbe) | Query 1: Closed  | data is correct as is CHF is an AE   |
| Mar-11-2021<br>08:45:10<br>(UTC-06:00)<br>Central Time<br>(US & Canada) | ACV0PFEINFP6000                           | Angi Cox (pfe.acox1)               | Query 1: Answered  | Its related to CHF. MH does not need to be updated since its not pre existing.   |
| Mar-11-2021<br>08:38:27<br>(UTC-06:00)<br>Central Time<br>(US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFE SDQ PROD<br>(pfe.PFESDQ_PROD)  | Query 1: Opened  | Please review "If not related to study treatment other" field, the following text was indicated in the comment field [congestive heart failure]. Kindly confirm the AE " Acute Kidney Injury" is related to congestive heart failure or related to any pre existing event, if so please review and update the Medical History, else clarify. "[ks66 SDQ=156470]" |
| Mar-09-2021<br>14:04:30<br>(UTC-06:00)<br>Central Time<br>(US & Canada) | ACV0PFEINFP6000                           | Angi Cox (pfe.acox1)               | <b>Data Entry:</b><br>NOT RELATED<br>If Not Related to study treatment(s), this event is due to: | Initial Entry  |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851116

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:22

|  |  |  |  |   |
|--|--|--|--|---|
|  |  |  |  | OTHER<br><br>If Other, specify:<br><br>Acute congestive heart failure |
|--|--|--|--|---|

10. Latest Action Taken with Study Treatment:

| Date  | Location        | User                    | Value                                | Reason        |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Mar-09-2021 14:04:30<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <u>Data Entry:</u><br>NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

| Date  | Location        | User                    | Value                    | Reason        |
|---|-----------------|-------------------------|--------------------------|---------------|
| Mar-09-2021 14:04:45<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <u>Data Entry:</u><br>NO | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date  | Location        | User                    | Value                    | Reason        |
|---|-----------------|-------------------------|--------------------------|---------------|
| Mar-09-2021 14:04:30<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <u>Data Entry:</u><br>NO | Initial Entry |

13. What was the outcome of this adverse event?:

| Date  | Location        | User                    | Value                                    | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Mar-09-2021 14:04:30<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <u>Data Entry:</u><br>RECOVERED/RESOLVED | Initial Entry |

14. Did the adverse event cause the subject to be discontinued from the study?

| Date  | Location        | User                    | Value                    | Reason        |
|---|-----------------|-------------------------|--------------------------|---------------|
| Mar-09-2021 14:04:30<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1) | <u>Data Entry:</u><br>NO | Initial Entry |

15. Serious Adverse Event Number: For Pfizer Use Only

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

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Queries

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

|   |                 |                                     |                                  |               |
|---|-----------------|-------------------------------------|----------------------------------|---------------|
| Mar-09-2021 19:21:28<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Ricell Ann<br>Piojo<br>(pfe.quitor) | <b>Data Entry:</b><br>2021247780 | Initial Entry |
|---|-----------------|-------------------------------------|----------------------------------|---------------|

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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851116

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

**1. Subject Status**

| Date  | Location        | User                    | Value                                     | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Sep-21-2020 14:50:58<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>FOLLOW-UP           | Initial Entry |
| Aug-19-2020 15:09:24<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ENROLLED/RANDOMIZED | Initial Entry |
| Aug-18-2020 14:17:12<br>(UTC-06:00) Central 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   |
|---|-----------------|-------------------------------------|-----------------------------------|--|
| Mar-09-2021 19:26:41<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Ricell Ann<br>Piojo<br>(pfe.quitor) | Query 1: Closed                   | Response satisfies query   |
| Mar-09-2021 14:05:15<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Angi Cox<br>(pfe.acox1)             | Query 1: Answered                 | SAE now entered.   |
| Mar-09-2021 05:18:23<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Ricell Ann<br>Piojo<br>(pfe.quitor) | Query 1: Opened                   | SAE<br>RECON:AER#2021247780<br>Acute Kidney Injury(onset<br>date:26Dec2020)was<br>reported as serious in<br>Safety database but missing<br>in AE CRF. Please confirm<br>and update CRF. If safety<br>update is required, submit a<br>follow-up SAE Form. |
| Oct-07-2020 14:49:13<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc)             | <b>Data Entry:</b><br>Oct/7/2020  | Transcription Error  |
| Sep-21-2020 14:50:58<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc)             | <b>Data Entry:</b><br>Sep/10/2020 | Initial Entry  |
| Aug-19-2020 15:09:24<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc)             | <b>Data Entry:</b><br>Aug/18/2020 | Initial Entry  |

090177e196ae3d8f\Final\Final On: 01-Apr-2021 04:38 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1085

**Subject No:** 10851116

**Generated By:** pfe.levisse

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

**Form Status:** Data Complete, Verified

**Site Name:** (1085) Ventavia Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

|   |                 |                         |                                   |               |
|---|-----------------|-------------------------|-----------------------------------|---------------|
| Aug-18-2020 14:17:12<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Aug/18/2020 | Initial Entry |
|---|-----------------|-------------------------|-----------------------------------|---------------|

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

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

**Form Status:** Data Complete, Verified

**Site No:** 1085

**Site Name:** (1085) Ventavia Research Group

**Subject No:** 10851116

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 10:22

[Back to Form](#)

*I. Casebook Signature*

| Date  | Location        | User                          | Value                                      | Reason        |
|---|-----------------|-------------------------------|--|---------------|
| Oct-21-2020 11:17:40<br>(UTC-06:00) Central Time<br>(US & Canada) | ACV0PFEINFP6000 | Alicia<br>Cruz<br>(pfe.acruz) | <b>Data Entry:</b><br>Click Here to Enable | Initial Entry |