

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

[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 |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Informed Consent

| | | |
|----|--------------|---|
| 1. | Consent Was: | OBTAINED Date Written Consent Obtained Aug/5/2020 |
|----|--------------|---|

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Demography

| | | |
|----|---------------------------------|--|
| 1. | Subject ID | [10071124] |
| 2. | Birth Date: | (b) (6)/1951 |
| 3. | Sex: | FEMALE |
| 4. | Ethnicity: | NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN |
| 5. | Race: (Check X all that apply): | WHITE |
| 6. | Racial Designation: | |

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071124

Generated By: pfe.lewissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

| Date of Visit | | |
|---------------|-----------------|------------|
| 1. | Date of Visit | Aug/5/2020 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1007

Subject No: 10071124

Generated By: pfe.lewissc

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071124

Generated By: pfe.levissc

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Disposition - Screening

| | | |
|----|--|------------|
| 1. | Date of Completion/Discontinuation/Death | Aug/5/2020 |
| 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: 1007

Subject No: 10071124

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Medical History Details

| | | |
|-----|--|---------------------------------|
| 1.a | Line/MH Number: | [1] |
| | Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies: | [Drug allergy pencillin] |
| | Start Date: | UNK/UNK/1963 |
| | Ongoing: | YES |
| 1.b | Line/MH Number: | [2] |
| | Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies: | [Seasonal allergy] |
| | Start Date: | UNK/UNK/2000 |
| | Ongoing: | YES |
| 1.c | Line/MH Number: | [3] |
| | Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies: | [Breast cancer stage I] |
| | Start Date: | UNK/UNK/1993 |
| | Ongoing: | NO End Date: UNK/UNK/1998 |

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071124

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

| | | |
|-----|--|---------------------------------|
| 1.d | Line/MH Number: | [4] |
| | Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies: | [Lumpectomy (breast cancer)] |
| | Start Date: | UNK/UNK/1993 |
| | Ongoing: | NO End Date: UNK/UNK/1993 |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1007

Subject No: 10071124

Generated By: pfe.levissc

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Vital Signs

| | | |
|----|------------------|------------|
| 1. | Date: | Aug/5/2020 |
| 2. | Weight: | [67.0] |
| 3. | Unit: | kg |
| 4. | Height: | [163.2] |
| 5. | Unit: | cm |
| 6. | Body Mass Index: | [25.2] |

Vital Signs Details

| | | |
|-----|-----------------------|-------------|
| 7.a | Record Identifier: | 1 |
| | Temperature: | [36.6] |
| | Unit: | C |
| | Temperature Location: | ORAL CAVITY |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 30-Jul-2020 21:27**Site No:** 1007**Subject No:** 10071124**Generated By:** pfe.levissc**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12[Form Comments](#)[eCRF Audit Trail History](#)**Lab Urinalysis**

| | | | |
|----|---------------------------------------|--------------------------------|--------------------------|
| 1. | Lab Panel: | Not Applicable _____ | Comments |
| 2. | Lab Sub-Panel: | Not Applicable _____ | Comments |
| 3. | Collection Date: | Not Applicable _____ // | Comments |
| 4. | Laboratory Name and Address (Derived) | Not Applicable _____ [] | Comments |
| 5. | Specimen Type: | Not Applicable _____ | Comments |

Lab Result

| | | | |
|-----|-------------|--|--------------------------|
| 6.a | Sponsor ID: | Not Applicable _____ [] | Comments |
| | Test: | Not Applicable _____ Choriogonadotropin Beta_PX113 | |
| | Result: | Not Applicable _____ | Comments |
| | Not Done: | Not Applicable _____ | Comments |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071124

Generated By: pfe.levissc

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Disposition

| | | |
|----|-----------------------|------------|
| 1. | Randomization Date : | Aug/5/2020 |
| 2. | Randomization Number: | [222690] |
| 3. | Randomization Group: | [] |

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071124**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 04:12[eCRF Audit Trail History](#)**Electronic Sample Tracking**

| | | |
|----|--|--|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Aug/5/2020 |
| 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 | [BM89GZ] |
| 5.b | Sample ID | [BM89H0] |
| 5.c | Sample ID | [BM89H1] |
| 5.d | Sample ID | [BPFZZ0] |
| 5.e | Sample ID | [BPFZZ1] |

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071124**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 04:12[eCRF Audit Trail History](#)**Electronic Sample Tracking**

| | | |
|----|--|--|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Aug/5/2020 |
| 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 | [BM89F3] |
|-----|-----------|----------|

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071124

Generated By: pfe.lewissc

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[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/5/2020 11:14 |
| 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 |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1007

Subject No: 10071124

Generated By: pfe.levissc

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

Header Text: c4591001

Visit: V2_VAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

| Date of Visit | | |
|---------------|-----------------|-------------|
| 1. | Date of Visit | Aug/26/2020 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

| | | |
|-----|---|----------|
| 1. | Were medications to treat fever/pain given on the last day the Subject Diary was completed? | NO |
| 2.a | Symptom: | FEVER |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.b | Symptom: | FATIGUE |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.c | Symptom: | HEADACHE |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

| | | |
|-----|--|-------------------------------|
| 2.d | Symptom: | CHILLS |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.e | Symptom: | VOMITING |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.f | Symptom: | DIARRHEA |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.g | Symptom: | NEW OR WORSENERED MUSCLE PAIN |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.h | Symptom: | NEW OR WORSENERED JOINT PAIN |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

| | | |
|-----|--|------------------------|
| 3. | Injection Site Location: | DELTOID MUSCLE |
| 4. | Injection Site Body Side: | LEFT |
| 5.a | Injection Site Reaction: | REDNESS |
| | Were injection site reactions present on the last day the Subject Diary was completed? | NO |
| 5.b | Injection Site Reaction: | SWELLING |
| | Were injection site reactions present on the last day the Subject Diary was completed? | NO |
| 5.c | Injection Site Reaction: | PAIN AT INJECTION SITE |
| | Were injection site reactions present on the last day the Subject Diary was completed? | NO |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1007

Subject No: 10071124

Generated By: pfe.levissc

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Vital Signs

| | | |
|----|-------|-------------|
| 1. | Date: | Aug/26/2020 |
|----|-------|-------------|

Vital Signs Details

| | | |
|-----|-----------------------|-------------|
| 2.a | Record Identifier: | 1 |
| | Temperature: | [36.8] |
| | Unit: | C |
| | Temperature Location: | ORAL CAVITY |

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Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 30-Jul-2020 21:27**Site No:** 1007**Subject No:** 10071124**Generated By:** pfe.levissc**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12[Form Comments](#)[eCRF Audit Trail History](#)**Lab Urinalysis**

| | | | |
|----|---------------------------------------|--------------------------------|--------------------------|
| 1. | Lab Panel: | Not Applicable _____ | Comments |
| 2. | Lab Sub-Panel: | Not Applicable _____ | Comments |
| 3. | Collection Date: | Not Applicable _____ // | Comments |
| 4. | Laboratory Name and Address (Derived) | Not Applicable _____ [] | Comments |
| 5. | Specimen Type: | Not Applicable _____ | Comments |

Lab Result

| | | | |
|-----|-------------|--|--------------------------|
| 6.a | Sponsor ID: | Not Applicable _____ [] | Comments |
| | Test: | Not Applicable _____ Choriogonadotropin Beta_PX113 | |
| | Result: | Not Applicable _____ | Comments |
| | Not Done: | Not Applicable _____ | Comments |

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071124**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:12[eCRF Audit Trail History](#)**Electronic Sample Tracking**

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Aug/26/2020 |
| 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 | [BP75G9] |
|-----|-----------|----------|

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071124

Generated By: pfe.levissc

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[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/26/2020 12:16 |
| 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 |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (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: 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

| Date of Visit | | |
|---------------|-----------------|-------------|
| 1. | Date of Visit | Sep/23/2020 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124 **Subject Initials:** ---

Generated By: pfe.lewissc **Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

| | | |
|-----|---|----------|
| 1. | Were medications to treat fever/pain given on the last day the Subject Diary was completed? | NO |
| 2.a | Symptom: | FEVER |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.b | Symptom: | FATIGUE |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.c | Symptom: | HEADACHE |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:12

| | | |
|-----|--|-------------------------------|
| 2.d | Symptom: | CHILLS |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.e | Symptom: | VOMITING |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.f | Symptom: | DIARRHEA |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.g | Symptom: | NEW OR WORSENERED MUSCLE PAIN |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.h | Symptom: | NEW OR WORSENERED JOINT PAIN |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:12

| | | |
|-----|--|------------------------|
| 3. | Injection Site Location: | DELTOID MUSCLE |
| 4. | Injection Site Body Side: | LEFT |
| 5.a | Injection Site Reaction: | REDNESS |
| | Were injection site reactions present on the last day the Subject Diary was completed? | NO |
| 5.b | Injection Site Reaction: | SWELLING |
| | Were injection site reactions present on the last day the Subject Diary was completed? | NO |
| 5.c | Injection Site Reaction: | PAIN AT INJECTION SITE |
| | Were injection site reactions present on the last day the Subject Diary was completed? | NO |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071124**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 04:12[eCRF Audit Trail History](#)**Electronic Sample Tracking**

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Sep/23/2020 |
| 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 | [BPYTSS] |
| 5.b | Sample ID | [BMPSBH] |
| 5.c | Sample ID | [BMPSBJ] |

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: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

Date of Visit

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

COVID-19 Illness Visit

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

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

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:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject No:** 10071124**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 04:12**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: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL - New
Unscheduled Visit**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject No:** 10071124**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:12**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: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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? | |
|----|--|--|

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

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:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject No:** 10071124**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:12**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 **Form:** DATE OF VISIT
Visit

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

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

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: 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:12

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: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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Disposition - Treatment

| | | |
|----|---|-------------|
| 1. | Date of Completion/Discontinuation /Death : | Sep/23/2020 |
| 2. | Phase of Disposition: | VACCINATION |
| 3. | Status: | COMPLETED |
| 4. | Specify Status: | [] |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

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 **Form:** DATE OF VISIT - REPEAT SWAB
- New Unscheduled Visit

Form Version: 10-Oct-2020 15:57 **Form Status:** Not Started

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

Date of Visit

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

COVID-19 Repeat Swab

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

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

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:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071124**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:12**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: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

| # | Category | AE Identifier | Adverse Event | Start Date | Is the Adverse Event Still Ongoing | Form Instance |
|----|---------------|---------------|--------------------------|---------------------|---|---------------------------------|
| 1. | ADVERSE EVENT | 1 | generalized myalgia | Feb/9/2021 18:00 | NO End Date Time: Feb/10/2021 18:00 | Repeating Pages |
| 2. | ADVERSE EVENT | 2 | chills | Feb/9/2021 18:00 | NO End Date Time: Feb/10/2021 18:00 | Repeating Pages |
| 3. | ADVERSE EVENT | 3 | axillary lymphadenopathy | Feb/10/2021 UNK:UNK | NO End Date Time: Feb/12/2021 UNK:UNK | Repeating Pages |
| 4. | ADVERSE EVENT | 4 | headache | Feb/9/2021 18:00 | NO End Date Time: Feb/10/2021 18:00 | Repeating Pages |
| 5. | ADVERSE EVENT | 5 | injection site pain | Feb/10/2021 UNK:UNK | NO End Date Time: Feb/11/2021 UNK | Repeating Pages |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

| # | Category | AE Identifier | Adverse Event | Start Date | Is the Adverse Event Still Ongoing | Form Instance |
|---|----------|---------------|---------------|------------|------------------------------------|---------------|
| | | | | | :UNK | |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

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Adverse Event Report

| | | |
|----|--|---|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [1] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [generalized myalgia] |
| 4. | Start Date Time: | Feb/9/2021 18:00 |
| 5. | Is the adverse event still ongoing? | NO End Date Time: Feb/10/2021 18:00 |
| 6. | Toxicity Grade: | 1 |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071124

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

| | | |
|-----|---|----------------|
| 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). | NO |
| 8. | Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log. | NO |
| 9. | Is this event related to study treatment: | RELATED |
| 10. | Latest Action Taken with Study Treatment: | NOT APPLICABLE |
| 11. | Was a Concomitant Medication given? | NO |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071124

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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Adverse Event Report

| | | |
|----|--|---|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [2] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [chills] |
| 4. | Start Date Time: | Feb/9/2021 18:00 |
| 5. | Is the adverse event still ongoing? | NO End Date Time: Feb/10/2021 18:00 |
| 6. | Toxicity Grade: | 1 |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071124

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

| | | |
|-----|---|----------------|
| 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). | NO |
| 8. | Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log. | NO |
| 9. | Is this event related to study treatment: | RELATED |
| 10. | Latest Action Taken with Study Treatment: | NOT APPLICABLE |
| 11. | Was a Concomitant Medication given? | NO |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071124

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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Adverse Event Report

| | | |
|----|--|---|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [3] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [axillary lymphadenopathy] |
| 4. | Start Date Time: | Feb/10/2021 UNK:UNK |
| 5. | Is the adverse event still ongoing? | NO End Date Time: Feb/12/2021 UNK:UNK |
| 6. | Toxicity Grade: | 1 |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071124

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

| | | |
|-----|---|----------------|
| 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). | NO |
| 8. | Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log. | NO |
| 9. | Is this event related to study treatment: | RELATED |
| 10. | Latest Action Taken with Study Treatment: | NOT APPLICABLE |
| 11. | Was a Concomitant Medication given? | NO |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071124

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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Adverse Event Report

| | | |
|----|--|---|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [4] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [headache] |
| 4. | Start Date Time: | Feb/9/2021 18:00 |
| 5. | Is the adverse event still ongoing? | NO End Date Time: Feb/10/2021 18:00 |
| 6. | Toxicity Grade: | 2 |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071124

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

| | | |
|-----|---|----------------|
| 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). | NO |
| 8. | Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log. | NO |
| 9. | Is this event related to study treatment: | RELATED |
| 10. | Latest Action Taken with Study Treatment: | NOT APPLICABLE |
| 11. | Was a Concomitant Medication given? | NO |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071124

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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Adverse Event Report

| | | |
|----|--|---|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [5] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [injection site pain] |
| 4. | Start Date Time: | Feb/10/2021 UNK:UNK |
| 5. | Is the adverse event still ongoing? | NO End Date Time: Feb/11/2021 UNK:UNK |
| 6. | Toxicity Grade: | 1 |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071124

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

| | | |
|-----|---|----------------|
| 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). | NO |
| 8. | Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log. | NO |
| 9. | Is this event related to study treatment: | RELATED |
| 10. | Latest Action Taken with Study Treatment: | NOT APPLICABLE |
| 11. | Was a Concomitant Medication given? | NO |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

| # | Category | Medication Error | Start Date | Is the medication error Still Ongoing | Study Medication Errors Action | Form Instance |
|----|----------|------------------|------------|---------------------------------------|--------------------------------|---------------------------------|
| 1. | | | | | | Repeating Pages |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

[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 | [] |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

| # | Sponsor-Defined Identifier | Category for Medication | Concomitant Medications Pre-specified | Name of Medication | Start Date | Form Instance |
|----|----------------------------|-------------------------|---------------------------------------|--------------------|------------|---------------------------------|
| 1. | | | | | | Repeating Pages |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

Concomitant Medications

| | | |
|----|---|-----|
| 1. | What is the medication identifier? | [] |
| 2. | Category: | |
| 3. | Concomitant Medications Pre-specified: | |
| 4. | Medication: 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: | // |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

| # | Sponsor-Defined Identifier | Category for Medication | Concomitant Medications Pre-specified | Name of Medication | Dose Description | Form Instance |
|----|----------------------------|-------------------------|---------------------------------------|--------------------|------------------|---------------------------------|
| 1. | | | | | | Repeating Pages |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

Concomitant Medications

| | | |
|-----|---|-----|
| 1. | What is the medication identifier? | [] |
| 2. | Category: | |
| 3. | Concomitant Medications Pre-specified: | |
| 4. | Medication: 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? | |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

| # | Category | Treatment Identifier | Con Non-Drug Treatments Pre-specified | Treatment | Start Date | Form Instance |
|----|----------|----------------------|---------------------------------------|-----------|------------|---------------------------------|
| 1. | | | | | | Repeating Pages |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

[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? | |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

| # | Transfusion Type | Date of Transfusion | Form Instance |
|----|------------------|---------------------|---------------------------------|
| 1. | | | Repeating Pages |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

| 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: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

Vital Signs

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

Vital Signs Details

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

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001**Visit:** Unplanned Vaccination -
Unscheduled**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Version:** 20-Feb-2021 02:14**Form Status:** Not Started**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject No:** 10071124**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:12**Lab Urinalysis**

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

Lab Result

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

Header Text: c4591001**Visit:** Unplanned Vaccination -
Unscheduled**Form:** VACCINATION**Form Version:** 10-Dec-2020 02:26**Form Status:** Not Started**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject No:** 10071124**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:12**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? | |

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: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

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: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

Contact Outcome

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

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Jan/13/2021 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION
Unscheduled

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen, Verified

Site No: 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124 **Subject Initials:** ---

Generated By: pfe.lewissc **Generated Time (GMT):** 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

| | | |
|----|---|--|
| 1. | Select appropriate response - Is participant willing to return for Vaccination 3? | Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2 |
|----|---|--|

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Treatment Unblinded

| | | |
|----|--------------------------------|---|
| 1. | Date Treatment Unblinded : | Jan/14/2021 |
| 2. | Primary Reason for Unblinding: | ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION |

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071124

Generated By: pfe.levissc

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: V101_VAX3

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

| Date of Visit | | |
|---------------|-----------------|-------------|
| 1. | Date of Visit | Jan/19/2021 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER
VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

| | | |
|----|--------------|--|
| 1. | Consent Was: | OBTAINED Date Written Consent Obtained Jan/19/2021 |
|----|--------------|--|

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

[Form Comments](#)

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

| | | |
|----|--|--------------------|
| 1. | Date of Completion/Discontinuation/Death : | Jan/19/2021 |
| 2. | Phase of Disposition: | REPEAT SCREENING 1 |
| 3. | Status: | COMPLETED |
| 4. | Specify Status: | [] |

Header Text: c4591001**Visit:** V101_VAX3**Form Version:** 14-Jan-2021 02:21**Site No:** 1007**Subject No:** 10071124**Generated By:** pfe.levissc**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12[Form Comments](#)[eCRF Audit Trail History](#)**Lab Urinalysis**

| | | | |
|----|---------------------------------------|--------------------------------|--------------------------|
| 1. | Lab Panel: | Not Applicable _____ | Comments |
| 2. | Lab Sub-Panel: | Not Applicable _____ | Comments |
| 3. | Collection Date: | Not Applicable _____ // | Comments |
| 4. | Laboratory Name and Address (Derived) | Not Applicable _____ [] | Comments |
| 5. | Specimen Type: | Not Applicable _____ | Comments |

Lab Result

| | | | |
|-----|-------------|--|--------------------------|
| 6.a | Sponsor ID: | Not Applicable _____ [] | Comments |
| | Test: | Not Applicable _____ Choriogonadotropin Beta_PX113 | |
| | Result: | Not Applicable _____ | Comments |
| | Not Done: | Not Applicable _____ | Comments |

Header Text: c4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071124**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:12[eCRF Audit Trail History](#)**Electronic Sample Tracking**

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Jan/19/2021 |
| 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 | [BRB8NB] |
| 5.b | Sample ID | [BNWMN8] |
| 5.c | Sample ID | [BNWMNC] |

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Jan/19/2021 |
| 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 | [BRB8N9] |
|-----|-----------|----------|

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1007

Subject No: 10071124

Generated By: pfe.lewissc

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Vaccination

| | | |
|-----|---|-------------------|
| 1. | Was there a temporary delay of vaccination? | NO |
| 2. | Treatment Name | [BNT162b2] |
| 3. | Formulation: | INJECTION |
| 4. | Dose Date Time: | Jan/19/2021 10:46 |
| 5. | Anatomical Location: | DELTOID MUSCLE |
| 6. | Body Side: | LEFT |
| 7. | Route: | INTRAMUSCULAR |
| 8. | Actual Dose: | [30.0] |
| 9. | Unit: | ug |
| 10. | Timeframe Subject Was Observed | 30 MINUTES |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | YES |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

| Date of Visit | | |
|---------------|-----------------|------------|
| 1. | Date of Visit | Feb/9/2021 |
| 2. | Erroneous Visit | |

Header Text: c4591001**Visit:** V102_VAX4**Form Version:** 14-Jan-2021 02:21**Site No:** 1007**Subject No:** 10071124**Generated By:** pfe.levissc**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12[Form Comments](#)[eCRF Audit Trail History](#)**Lab Urinalysis**

| | | | |
|----|---------------------------------------|--------------------------------|--------------------------|
| 1. | Lab Panel: | Not Applicable _____ | Comments |
| 2. | Lab Sub-Panel: | Not Applicable _____ | Comments |
| 3. | Collection Date: | Not Applicable _____ // | Comments |
| 4. | Laboratory Name and Address (Derived) | Not Applicable _____ [] | Comments |
| 5. | Specimen Type: | Not Applicable _____ | Comments |

Lab Result

| | | | |
|-----|-------------|--|--------------------------|
| 6.a | Sponsor ID: | Not Applicable _____ [] | Comments |
| | Test: | Not Applicable _____ Choriogonadotropin Beta_PX113 | |
| | Result: | Not Applicable _____ | Comments |
| | Not Done: | Not Applicable _____ | Comments |

Header Text: c4591001**Visit:** V102_VAX4**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071124**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:12[eCRF Audit Trail History](#)**Electronic Sample Tracking**

| | | |
|----|--|--|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Feb/9/2021 |
| 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 | [BRB94Y] |
|-----|-----------|----------|

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1007

Subject No: 10071124

Generated By: pfe.levissc

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Vaccination

| | | |
|-----|---|------------------|
| 1. | Was there a temporary delay of vaccination? | NO |
| 2. | Treatment Name | [BNT162b2] |
| 3. | Formulation: | INJECTION |
| 4. | Dose Date Time: | Feb/9/2021 13:37 |
| 5. | Anatomical Location: | DELTOID MUSCLE |
| 6. | Body Side: | LEFT |
| 7. | Route: | INTRAMUSCULAR |
| 8. | Actual Dose: | [30.0] |
| 9. | Unit: | ug |
| 10. | Timeframe Subject Was Observed | 30 MINUTES |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | YES |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

| Date of Visit | | |
|---------------|-----------------|------------|
| 1. | Date of Visit | Mar/9/2021 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071124

Generated By: pfe.levissc

Form: CONTACT OUTCOME

Form Status: Data Complete, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Contact Outcome

| | | |
|----|-------------------|---------------------------------------|
| 1. | Contact Type: | TELEPHONE VISIT |
| 2. | Was contact made? | YES Date of Contact: Mar/9/2021 |
| 3. | Comments: | [] |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071124

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Date of Visit

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

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071124

Generated By: pfe.levissc

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Contact Outcome

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

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071124

Generated By: pfe.lewissc

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Date of Visit

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

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071124

Generated By: pfe.levisse

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Contact Outcome

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

Header Text: c4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Disposition - Treatment

| | | |
|----|--|----------------------|
| 1. | Date of Completion/Discontinuation/Death : | Mar/9/2021 |
| 2. | Phase of Disposition: | OPEN LABEL TREATMENT |
| 3. | Status: | COMPLETED |
| 4. | Specify Status: | [] |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Subject Status

| | | |
|----|---------------------|-------------|
| 1. | Subject Status | FOLLOW-UP |
| 2. | Subject Status Date | Sep/23/2020 |

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

[Audit Trail](#)

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

- CRF_Sign

| Name | Signature Meaning | Date | Type | Action |
|------------------|----------------------|--|------|--------|
| Robert Frenck | Approved | Mar-10-2021 13:35:35 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |

Affidavit:

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

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

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

| Item | Date | User | Comment |
|------|--|---------------------------|----------------|
| Form | Aug-05-2020 11:45:40 (UTC-05:00) Eastern Time (US & Canada) | Laura Pace (pfe.lpace) | Not Applicable |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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| Item | Date | User | Comment |
|------|--|---------------------------|----------------|
| Form | Aug-05-2020 11:46:46 (UTC-05:00) Eastern Time (US & Canada) | Laura Pace (pfe.lpace) | Not Applicable |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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| Item | Date | User | Comment |
|------|--|---------------------------|----------------|
| 1 | Aug-05-2020 11:46:46 (UTC-05:00) Eastern Time (US & Canada) | Laura Pace (pfe.lpace) | Not Applicable |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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| Item | Date | User | Comment |
|------|--|---------------------------|----------------|
| 2 | Aug-05-2020 11:46:46 (UTC-05:00) Eastern Time (US & Canada) | Laura Pace (pfe.lpace) | Not Applicable |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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| Item | Date | User | Comment |
|------|--|---------------------------|----------------|
| 3 | Aug-05-2020 11:46:46 (UTC-05:00) Eastern Time (US & Canada) | Laura Pace (pfe.lpace) | Not Applicable |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

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| Item | Date | User | Comment |
|------|--|---------------------------|----------------|
| 4 | Aug-05-2020 11:46:46 (UTC-05:00) Eastern Time (US & Canada) | Laura Pace (pfe.lpace) | Not Applicable |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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| Item | Date | User | Comment |
|------|--|---------------------------|----------------|
| 5 | Aug-05-2020 11:46:46 (UTC-05:00) Eastern Time (US & Canada) | Laura Pace (pfe.lpace) | Not Applicable |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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| Item | Date | User | Comment |
|------|--|---------------------------|----------------|
| 6.a | Aug-05-2020 11:46:46 (UTC-05:00) Eastern Time (US & Canada) | Laura Pace (pfe.lpace) | Not Applicable |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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| Item | Date | User | Comment |
|------|--|---------------------------|----------------|
| 6.a | Aug-05-2020 11:46:46 (UTC-05:00) Eastern Time (US & Canada) | Laura Pace (pfe.lpace) | Not Applicable |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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| Item | Date | User | Comment |
|------|--|---------------------------|----------------|
| 6.a | Aug-05-2020 11:46:46 (UTC-05:00) Eastern Time (US & Canada) | Laura Pace (pfe.lpace) | Not Applicable |

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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| Item | Date | User | Comment |
|------|--|---------------------------|----------------|
| Form | Aug-26-2020 12:07:43 (UTC-05:00) Eastern Time (US & Canada) | Laura Pace (pfe.lpace) | Not Applicable |

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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| Item | Date | User | Comment |
|------|--|---------------------------|----------------|
| 1 | Aug-26-2020 12:07:43 (UTC-05:00) Eastern Time (US & Canada) | Laura Pace (pfe.lpace) | Not Applicable |

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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| Item | Date | User | Comment |
|------|--|---------------------------|----------------|
| 2 | Aug-26-2020 12:07:43 (UTC-05:00) Eastern Time (US & Canada) | Laura Pace (pfe.lpace) | Not Applicable |

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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| Item | Date | User | Comment |
|------|--|---------------------------|----------------|
| 3 | Aug-26-2020 12:07:43 (UTC-05:00) Eastern Time (US & Canada) | Laura Pace (pfe.lpace) | Not Applicable |

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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| Item | Date | User | Comment |
|------|--|---------------------------|----------------|
| 4 | Aug-26-2020 12:07:43 (UTC-05:00) Eastern Time (US & Canada) | Laura Pace (pfe.lpace) | Not Applicable |

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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| Item | Date | User | Comment |
|------|--|---------------------------|----------------|
| 5 | Aug-26-2020 12:07:43 (UTC-05:00) Eastern Time (US & Canada) | Laura Pace (pfe.lpace) | Not Applicable |

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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| Item | Date | User | Comment |
|------|--|---------------------------|----------------|
| 6.a | Aug-26-2020 12:07:43 (UTC-05:00) Eastern Time (US & Canada) | Laura Pace (pfe.lpace) | Not Applicable |

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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| Item | Date | User | Comment |
|------|--|---------------------------|----------------|
| 6.a | Aug-26-2020 12:07:43 (UTC-05:00) Eastern Time (US & Canada) | Laura Pace (pfe.lpace) | Not Applicable |

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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| Item | Date | User | Comment |
|------|--|---------------------------|----------------|
| 6.a | Aug-26-2020 12:07:43 (UTC-05:00) Eastern Time (US & Canada) | Laura Pace (pfe.lpace) | Not Applicable |

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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| Item | Date | User | Comment |
|------|--|---------------------------|----------------|
| Form | Jan-19-2021 11:24:05 (UTC-05:00) Eastern Time (US & Canada) | Laura Pace (pfe.lpace) | Not Applicable |

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

| Item | Date | User | Comment |
|------|--|---------------------------|----------------|
| Form | Jan-19-2021 11:24:33 (UTC-05:00) Eastern Time (US & Canada) | Laura Pace (pfe.lpace) | Not Applicable |

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

| Item | Date | User | Comment |
|------|--|---------------------------|----------------|
| 1 | Jan-19-2021 11:24:33 (UTC-05:00) Eastern Time (US & Canada) | Laura Pace (pfe.lpace) | Not Applicable |

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

| Item | Date | User | Comment |
|------|--|---------------------------|----------------|
| 2 | Jan-19-2021 11:24:33 (UTC-05:00) Eastern Time (US & Canada) | Laura Pace (pfe.lpace) | Not Applicable |

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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| Item | Date | User | Comment |
|------|--|---------------------------|----------------|
| 3 | Jan-19-2021 11:24:33 (UTC-05:00) Eastern Time (US & Canada) | Laura Pace (pfe.lpace) | Not Applicable |

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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| Item | Date | User | Comment |
|------|--|---------------------------|----------------|
| 4 | Jan-19-2021 11:24:33 (UTC-05:00) Eastern Time (US & Canada) | Laura Pace (pfe.lpace) | Not Applicable |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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| Item | Date | User | Comment |
|------|--|---------------------------|----------------|
| 5 | Jan-19-2021 11:24:33 (UTC-05:00) Eastern Time (US & Canada) | Laura Pace (pfe.lpace) | Not Applicable |

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

| Item | Date | User | Comment |
|------|--|---------------------------|----------------|
| 6.a | Jan-19-2021 11:24:33 (UTC-05:00) Eastern Time (US & Canada) | Laura Pace (pfe.lpace) | Not Applicable |

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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| Item | Date | User | Comment |
|------|--|---------------------------|----------------|
| 6.a | Jan-19-2021 11:24:33 (UTC-05:00) Eastern Time (US & Canada) | Laura Pace (pfe.lpace) | Not Applicable |

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

| Item | Date | User | Comment |
|------|--|---------------------------|----------------|
| 6.a | Jan-19-2021 11:24:33 (UTC-05:00) Eastern Time (US & Canada) | Laura Pace (pfe.lpace) | Not Applicable |

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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| Item | Date | User | Comment |
|------|--|---------------------------|----------------|
| Form | Feb-09-2021 13:11:50 (UTC-05:00) Eastern Time (US & Canada) | Laura Pace (pfe.lpace) | Not Applicable |

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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| Item | Date | User | Comment |
|------|--|---------------------------|----------------|
| 1 | Feb-09-2021 13:11:50 (UTC-05:00) Eastern Time (US & Canada) | Laura Pace (pfe.lpace) | Not Applicable |

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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| Item | Date | User | Comment |
|------|--|---------------------------|----------------|
| 2 | Feb-09-2021 13:11:50 (UTC-05:00) Eastern Time (US & Canada) | Laura Pace (pfe.lpace) | Not Applicable |

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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| Item | Date | User | Comment |
|------|--|---------------------------|----------------|
| 3 | Feb-09-2021 13:11:50 (UTC-05:00) Eastern Time (US & Canada) | Laura Pace (pfe.lpace) | Not Applicable |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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| Item | Date | User | Comment |
|------|--|---------------------------|----------------|
| 4 | Feb-09-2021 13:11:50 (UTC-05:00) Eastern Time (US & Canada) | Laura Pace (pfe.lpace) | Not Applicable |

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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| Item | Date | User | Comment |
|------|--|---------------------------|----------------|
| 5 | Feb-09-2021 13:11:50 (UTC-05:00) Eastern Time (US & Canada) | Laura Pace (pfe.lpace) | Not Applicable |

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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| Item | Date | User | Comment |
|------|--|---------------------------|----------------|
| 6.a | Feb-09-2021 13:11:50 (UTC-05:00) Eastern Time (US & Canada) | Laura Pace (pfe.lpace) | Not Applicable |

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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| Item | Date | User | Comment |
|------|--|---------------------------|----------------|
| 6.a | Feb-09-2021 13:11:50 (UTC-05:00) Eastern Time (US & Canada) | Laura Pace (pfe.lpace) | Not Applicable |

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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| Item | Date | User | Comment |
|------|--|---------------------------|----------------|
| 6.a | Feb-09-2021 13:11:50 (UTC-05:00) Eastern Time (US & Canada) | Laura Pace (pfe.lpace) | Not Applicable |

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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

- CRF_Sign

| Name | Signature Meaning | Date | Type | Action |
|------------------|----------------------|--|------|--------|
| Robert Frenck | Approved | Mar-10-2021 13:35:35 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |

Affidavit:

By my dated signature below, I, RobertFrenck, 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.

| | | | | |
|------------|-----|--|--|---|
| Laura Pace | N/A | Mar-10-2021 09:26:20 (UTC-05:00) Eastern Time (US & Canada) | | Edit - All signatures invalidated |
|------------|-----|--|--|---|

Affidavit:

N/A

| | | | | |
|------------------|----------|--|------|--------|
| Robert Frenck | Approved | Mar-08-2021 08:57:32 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |
|------------------|----------|--|------|--------|

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Affidavit:

By my dated signature below, I, RobertFrenck, 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.

| | | | | |
|------------|-----|--|--|-----------------------------------|
| Laura Pace | N/A | Feb-21-2021 11:26:31 (UTC-05:00) Eastern Time (US & Canada) | | Edit - All signatures invalidated |
|------------|-----|--|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|---------------|----------|--|------|--------|
| Robert Frenck | Approved | Feb-15-2021 22:14:27 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |
|---------------|----------|--|------|--------|

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Affidavit:

By my dated signature below, I, RobertFrenck, 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.

| | | | | |
|------------|-----|--|--|---|
| Laura Pace | N/A | Feb-09-2021 13:11:38 (UTC-05:00) Eastern Time (US & Canada) | | Edit - All signatures invalidated |
|------------|-----|--|--|---|

Affidavit:

N/A

| | | | | |
|------------------|----------|--|------|--------|
| Robert Frenck | Approved | Jan-23-2021 17:08:52 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |
|------------------|----------|--|------|--------|

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Affidavit:

By my dated signature below, I, RobertFrenck, 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.

| | | | | |
|------------|-----|--|--|-----------------------------------|
| Laura Pace | N/A | Jan-19-2021 09:49:15 (UTC-05:00) Eastern Time (US & Canada) | | Edit - All signatures invalidated |
|------------|-----|--|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|---------------|----------|--|------|--------|
| Robert Frenck | Approved | Sep-23-2020 22:05:17 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |
|---------------|----------|--|------|--------|

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Affidavit:

By my dated signature below, I, RobertFrenck, 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.

| | | | | |
|------------|-----|--|--|---|
| Laura Pace | N/A | Sep-23-2020 11:10:59 (UTC-05:00) Eastern Time (US & Canada) | | Edit - All signatures invalidated |
|------------|-----|--|--|---|

Affidavit:

N/A

| | | | | |
|------------------|----------|--|------|--------|
| Robert Frenck | Approved | Sep-10-2020 14:55:44 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |
|------------------|----------|--|------|--------|

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071124

Generated By: pfe.levisse

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Status: Data Complete, Signed, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Affidavit:

By my dated signature below, I, RobertFrenck, 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.

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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1. Select appropriate response - Protocol version

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|-----------------------------------|---------------|
| Aug-05-2020 11:45:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: 24 JUL 2020 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|---------------------------------------|---------------|
| Aug-05-2020 11:45:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: STAGE 3 COHORTS | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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1. Consent Was:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--|---------------|
| Aug-05-2020 11:45:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: OBTAINED Date Written Consent Obtained Aug/5/2020 | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1007

Subject No: 10071124

Generated By: pfe.lewissc

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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1. Subject ID

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------|--------------------------------------|
| Aug-05-2020 11:44:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 10071124 | Item copied from previous form |

2. Birth Date:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|------------------------------------|---------------------|
| Aug-05-2020 11:44:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: (b) (6)/1951 | Enrollment Entry |

3. Sex:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|------------------------------|---------------|
| Aug-05-2020 11:45:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: FEMALE | Initial Entry |

4. Ethnicity:

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

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

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: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

| | | | | |
|---|-----------------|------------------------------|--|---------------|
| Aug-05-2020 11:45:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NOT HISPANIC OR L ATINO(A) OR OF SP ANISH ORIGIN | Initial Entry |
|---|-----------------|------------------------------|--|---------------|

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

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|-----------------------------|---------------|
| Aug-05-2020 11:45:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: WHITE | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071124

Generated By: pfe.lewissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|----------------------------------|---------------|
| Aug-05-2020 11:45:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Aug/5/2020 | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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1. Date of Completion/Discontinuation/Death

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------------|---------------|
| Aug-05-2020 11:45:51 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Aug/5/2020 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Aug-05-2020 11:45:51 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SCREENING | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------------|---------------|
| Aug-05-2020 11:45:51 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: COMPLETED | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071124**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)*1.a*

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Aug-05-2020 11:48:44 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH 1 Number: Medical H Drug aller istory Ter gy pencill m: in Start Date UNK/UN : K/1963 Ongoing: YES | Initial Entry |

1.a Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-05-2020 11:48:44 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 1 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|------------------------------|--|---------------|
| Aug-05-2020 11:48:44 (UTC-05:00) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Drug allergy pencillin | Initial Entry |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Eastern Time (US & Canada)

1.a Start Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|------------------------------------|---------------|
| Aug-05-2020 11:48:44 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: UNK/UNK/1963 | Initial Entry |

1.a Ongoing:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------|---------------|
| Aug-05-2020 11:48:44 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: YES | Initial Entry |

1.b

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Aug-05-2020 11:49:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH N 2 umber: Medical His Seasonal tory Term: allergy | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071124

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

| | | | | |
|--|--|--|---|--|
| | | | Start Date: UNK/U NK/200 0 | |
| | | | Ongoing: YES | |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

1.b Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-05-2020 11:49:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 2 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--|---------------|
| Aug-05-2020 11:49:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Seasonal allergy | Initial Entry |

1.b Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|------------------------------------|---------------|
| Aug-05-2020 11:49:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: UNK/UNK/2000 | Initial Entry |

1.b Ongoing:

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

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

| | | | | |
|---|-----------------|------------------------------|---------------------------|---------------|
| Aug-05-2020 11:49:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: YES | Initial Entry |
|---|-----------------|------------------------------|---------------------------|---------------|

I.c

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Aug-05-2020 11:49:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH 3 Number: Medical History Term: Breast cancer stage I m: Start Date UNK/UNK/1993 Ongoing: NO End Date : UNK/UNK/1993 8 | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

I.c Line/MH Number:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------|---------------|
| Aug-05-2020 11:49:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 3 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Aug-05-2020 11:49:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Breast cancer stage I | Initial Entry |

I.c Start Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|------------------------------------|---------------|
| Aug-05-2020 11:49:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: UNK/UNK/1993 | Initial Entry |

I.c Ongoing:

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

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

| | | | | |
|---|-----------------|------------------------------|---|---------------|
| Aug-05-2020 11:49:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO End Date: UNK/UNK/1998 | Initial Entry |
|---|-----------------|------------------------------|---|---------------|

1.d

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Aug-05-2020 11:50:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/M 4 H Numb er: Medical Lumpectom History y (breast can Term: cer) Start Da UNK/UNK/ te: 1993 Ongoing NO : End Date: UNK/UN K/1993 | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

1.d Line/MH Number:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------|---------------|
| Aug-05-2020 11:50:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 4 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Aug-05-2020 11:50:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Lumpectomy (breast c ancer) | Initial Entry |

1.d Start Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|------------------------------------|---------------|
| Aug-05-2020 11:50:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: UNK/UNK/1993 | Initial Entry |

1.d Ongoing:

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

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

| | | | | |
|---|-----------------|------------------------------|---|---------------|
| Aug-05-2020 11:50:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO End Date: UNK/UNK/1993 | Initial Entry |
|---|-----------------|------------------------------|---|---------------|

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (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: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------------|---------------|
| Aug-05-2020 11:47:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Aug/5/2020 | Initial Entry |

2. Weight:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------|---------------|
| Aug-05-2020 11:47:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: 67.0 | Initial Entry |

3. Unit:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Aug-05-2020 11:47:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: kg | Initial Entry |

4. Height:

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (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: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|-----------------------------|---------------|
| Aug-05-2020 11:47:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: 163.2 | Initial Entry |

5. Unit:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Aug-05-2020 11:47:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: cm | Initial Entry |

6. Body Mass Index:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Aug-05-2020 11:47:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 25.2 | Initial Entry |

7.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Aug-05-2020 11:47:27 (UTC-05:00) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Record Ide 1 | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (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: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

| | | | | |
|----------------------------|--|--|---|--|
| Eastern Time (US & Canada) | | | ntifier:: Temperatur 36.6 e: Temperatur C e Unit: Temperatur ORAL e Location:: CAVIT Y | |
|----------------------------|--|--|---|--|

7.a Record Identifier:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|-------------------------|---------------|
| Aug-05-2020 11:47:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: 1 | Initial Entry |

7.a Temperature:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|----------------------------|---------------|
| Aug-05-2020 11:47:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: 36.6 | Initial Entry |

7.a Unit:

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

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (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: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

| | | | | |
|---|-----------------|------------------------------|-------------------------|---------------|
| Aug-05-2020 11:47:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: C | Initial Entry |
|---|-----------------|------------------------------|-------------------------|---------------|

7.a Temperature Location:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|-----------------------------------|---------------|
| Aug-05-2020 11:47:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: ORAL CAVITY | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1007

Subject No: 10071124

Generated By: pfe.lewissc

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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1. Lab Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------------|---------------|
| Aug-05-2020 11:46:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Not Applicable | Initial Entry |

2. Lab Sub-Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------------|---------------|
| Aug-05-2020 11:46:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Not Applicable | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------------|---------------|
| Aug-05-2020 11:46:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Not Applicable | Initial Entry |

4. Laboratory Name and Address (Derived)

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------------|---------------|
| Aug-05-2020 11:46:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Not Applicable | Initial Entry |

5. Specimen Type:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------------|---------------|
| Aug-05-2020 11:46:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Not Applicable | Initial Entry |

6.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Aug-05-2020 11:46:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Sponsor-Defined Identifier: Not Applicable Test: Not Applicable Result: Not Applicable | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

| | | | | |
|--|--|--|--|--|
| | | | Not Done:: Not Ap plicabl e | |
|--|--|--|--|--|

6.a Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------------|---------------|
| Aug-05-2020 11:46:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Not Applicable | Initial Entry |

6.a Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------------|---------------|
| Aug-05-2020 11:46:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Not Applicable | Initial Entry |

6.a Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------------|---------------|
| Aug-05-2020 11:46:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Not Applicable | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

6.a Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------------|---------------|
| Aug-05-2020 11:46:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Not Applicable | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071124

Generated By: pfe.lewissc

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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1. Randomization Date :

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|----------------------------------|---------------|
| Aug-05-2020 11:50:32 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Aug/5/2020 | Initial Entry |

2. Randomization Number:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|------------------------------|---------------|
| Aug-05-2020 11:50:32 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: 222690 | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (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: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Aug-05-2020 11:46:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Aug-05-2020 11:46:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------|------------------------|
| Aug-05-2020 16:57:58 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Aug-05-2020 11:46:31 | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (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:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071124**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12

| | | | | |
|---|-----------------|---------------------------|--|--|
| (UTC-05:00) Eastern Time (US & Canada) | | | | Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Aug-05-2020 11:46:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: YES Date of Collection: Aug/5/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------------------|---|---------------|
| Aug-05-2020 16:57:58 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Jesse LePage (pfe.jlepage) | Data Entry: Sample ID BM89G : Z | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------------------|------------------------------|---------------|
| Aug-05-2020 16:57:58 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Jesse LePage (pfe.jlepage) | Data Entry: BM89GZ | Initial Entry |

5.b

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: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------------|---|---------------|
| Aug-05-2020 16:58:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Jesse LePage (pfe.jlepage) | Data Entry: Sample ID BM89H : 0 | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------------|------------------------------|---------------|
| Aug-05-2020 16:58:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Jesse LePage (pfe.jlepage) | Data Entry: BM89H0 | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------------|---|---------------|
| Aug-05-2020 16:58:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Jesse LePage (pfe.jlepage) | Data Entry: Sample ID BM89H : 1 | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (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: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

5.c Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------------|------------------------------|---------------|
| Aug-05-2020 16:58:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Jesse LePage (pfe.jlepage) | Data Entry: BM89H1 | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------------|---|---------------|
| Aug-05-2020 16:58:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Jesse LePage (pfe.jlepage) | Data Entry: Sample ID BPFZZ : 0 | Initial Entry |

5.d Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------------|------------------------------|---------------|
| Aug-05-2020 16:58:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Jesse LePage (pfe.jlepage) | Data Entry: BPFZZ0 | Initial Entry |

5.e

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

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (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: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

| | | | | |
|---|-----------------|----------------------------------|---|---------------|
| Aug-05-2020 16:58:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Jesse LePage (pfe.jlepage) | Data Entry: Sample ID BPFZZ : 1 | Initial Entry |
|---|-----------------|----------------------------------|---|---------------|

5.e Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------------------|------------------------------|---------------|
| Aug-05-2020 16:58:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Jesse LePage (pfe.jlepage) | Data Entry: BPFZZ1 | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071124

Generated By: pfe.lewissc

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Aug-05-2020 11:46:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Aug-05-2020 11:46:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--------------------|---------------------------|
| Aug-05-2020 16:57:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Aug-05-2020 11:46:38 | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

| | | | | |
|---|-----------------|---------------------------|--|--|
| (UTC-05:00) Eastern Time (US & Canada) | | | | Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Aug-05-2020 11:46:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: YES Date of Collection: Aug/5/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------------------|---|---------------|
| Aug-05-2020 16:57:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Jesse LePage (pfe.jlepage) | Data Entry: Sample ID BM89F : 3 | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------------------|------------------------------|---------------|
| Aug-05-2020 16:57:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Jesse LePage (pfe.jlepage) | Data Entry: BM89F3 | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071124

Generated By: pfe.lewissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------|---------------|
| Aug-05-2020 11:58:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Aug-05-2020 11:58:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BLINDED THERAPY | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Aug-05-2020 11:58:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INJECTION | Initial Entry |

4. Dose Date Time:

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

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

| | | | | |
|---|-----------------|------------------------------|--|---------------|
| Aug-05-2020 11:58:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Aug/5/2020 11:14 | Initial Entry |
|---|-----------------|------------------------------|--|---------------|

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Aug-05-2020 11:58:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|----------------------------|---------------|
| Aug-05-2020 11:58:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: LEFT | Initial Entry |

7. Route:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Aug-05-2020 11:58:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Aug-05-2020 11:58:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N 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-05-2020 11:58:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: YES | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1007

Subject No: 10071124

Generated By: pfe.lewissc

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|---|---------------|
| Aug-05-2020 11:58:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: YES - REACTOGENI CITY E-DIARY COL LECTED FOR THIS S UBJECT | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071124

Generated By: pfe.lewissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|-----------------------------------|---------------|
| Aug-26-2020 12:07:32 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Aug/26/2020 | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES - eCRF Audit Trail
History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject No:** 10071124**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------|---------------|
| Aug-26-2020 12:09:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|---|---------------|
| Aug-26-2020 12:09:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Symptom:: F E V E R Were fever or sys N temic symptoms O present on the las t day the Subject Diary was compl eted?: | Initial Entry |

2.a Symptom:

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

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

| | | | | |
|---|-----------------|------------------------------|-----------------------------|---------------|
| Aug-26-2020 12:09:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: FEVER | Initial Entry |
|---|-----------------|------------------------------|-----------------------------|---------------|

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------|---------------|
| Aug-26-2020 12:09:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

2.b

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--|---------------|
| Aug-26-2020 12:09:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Symptom:: FA TI G U E Were fever or sys N temic symptoms O present on the la st day the Subjec t Diary was com pleted?: | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES - eCRF Audit Trail
History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

2.b Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|-------------------------------|---------------|
| Aug-26-2020 12:09:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: FATIGUE | Initial Entry |

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------|---------------|
| Aug-26-2020 12:09:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

2.c

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|---|---------------|
| Aug-26-2020 12:09:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Symptom:: HE AD AC HE | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

| | | | | |
|--|--|--|--|--|
| | | | Were fever or sy NO stemic symptom s present on the l ast day the Subj ect Diary was co mpleted?: | |
|--|--|--|--|--|

2.c Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------|---------------|
| Aug-26-2020 12:09:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: HEADACHE | Initial Entry |

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------|---------------|
| Aug-26-2020 12:09:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

2.d

| Date | Location | User | Value | Reason |
|-------------------------|-----------------|---------------|--|---------------|
| Aug-26-2020 12:09:20 | ACV0PFEINFP6000 | Laura Pace | Data Entry: Symptom:: C | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lpace

Generated Time (GMT): 29-Mar-2021 04:12

| | | | | |
|---|--|-------------|---------------|--|
| (UTC-05:00) Eastern Time (US & Canada) | | (pfe.lpace) | HI L LS | |
| Were fever or systemic symptoms present on the last day the Subject Diary was completed?: | | | | |

2.d Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|------------------------------|---------------|
| Aug-26-2020 12:09:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: CHILLS | Initial Entry |

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------|---------------|
| Aug-26-2020 12:09:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

2.e

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

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

| | | | | |
|---|-----------------|------------------------------|--|---------------|
| Aug-26-2020 12:09:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Symptom:: VO MI TI NG Were fever or sy NO stemic symptom s present on the last day the Subj ect Diary was co mpleted?: | Initial Entry |
|---|-----------------|------------------------------|--|---------------|

2.e Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------|---------------|
| Aug-26-2020 12:09:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: VOMITING | Initial Entry |

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------|---------------|
| Aug-26-2020 12:09:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

2.f

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|---|---------------|
| Aug-26-2020 12:09:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | <p>Data Entry:</p> <p>Symptom:: DI AR RH EA</p> <p>Were fever or sy NO stemic symptom s present on the l ast day the Subj ect Diary was co mpleted?:</p> | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES - eCRF Audit Trail
History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

2.f Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------|---------------|
| Aug-26-2020 12:09:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: DIARRHEA | Initial Entry |

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------|---------------|
| Aug-26-2020 12:09:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

2.g

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--|---------------|
| Aug-26-2020 12:09:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Symptom:: NEW OR W ORSE NED MUSC LE PA IN | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

| | | | | |
|--|--|--|---|--|
| | | | Were fever or NO r systemic sy mptoms pres ent on the las t day the Sub ject Diary wa s completed? : | |
|--|--|--|---|--|

2.g Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|---|---------------|
| Aug-26-2020 12:09:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NEW OR WORSENE D MUSCLE PAIN | Initial Entry |

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------|---------------|
| Aug-26-2020 12:09:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

2.h

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

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES - eCRF Audit Trail
History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

| | | | | |
|--|------------------------|---------------------------------------|--|----------------------|
| <p>Aug-26-2020 12:09:20 (UTC-05:00) Eastern Time (US & Canada)</p> | <p>ACV0PFEINFP6000</p> | <p>Laura Pace (pfe.lpace)</p> | <p>Data Entry: Symptom:: NEW OR W ORSE NED J OINT PAIN Were fever or NO systemic sym ptoms presen t on the last d ay the Subjec t Diary was c ompleted?:</p> | <p>Initial Entry</p> |
|--|------------------------|---------------------------------------|--|----------------------|

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY -
SYMPTOM RESOLVED DATES - eCRF Audit Trail
History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

2.h Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--|---------------|
| Aug-26-2020 12:09:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NEW OR WORSENE D JOINT PAIN | Initial Entry |

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------|---------------|
| Aug-26-2020 12:09:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

3. Injection Site Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Aug-26-2020 12:09:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

4. Injection Site Body Side:

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

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

| | | | | |
|---|-----------------|------------------------------|----------------------------|---------------|
| Aug-26-2020 12:09:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: LEFT | Initial Entry |
|---|-----------------|------------------------------|----------------------------|---------------|

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--|---------------|
| Aug-26-2020 12:09:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Injection Site Reaction: RE D NE SS Were injection site reactions present on the last day the Subject Diary was completed?: N O | Initial Entry |

5.a Injection Site Reaction:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|-------------------------------|---------------|
| Aug-26-2020 12:09:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: REDNESS | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

5.a Were injection site reactions present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Aug-26-2020 12:09:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Aug-26-2020 12:09:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Injection Site Reaction: SW EL LI NG Were injection site reactions present on the last day the Subject Diary was completed?: NO | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

5.b Injection Site Reaction:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------|---------------|
| Aug-26-2020 12:09:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: SWELLING | Initial Entry |

5.b Were injection site reactions present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Aug-26-2020 12:09:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Aug-26-2020 12:09:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Injection Site Reaction:: PAIN AT I NJE CTIO N SI TE | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

| | | | | |
|--|--|--|---|--|
| | | | Were injection site reactions present on the last day the Subject Diary was completed?: | |
|--|--|--|---|--|

5.c Injection Site Reaction:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Aug-26-2020 12:09:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: PAIN AT INJECTION SITE | Initial Entry |

5.c Were injection site reactions present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Aug-26-2020 12:09:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1007

Subject No: 10071124

Generated By: pfe.lewissc

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|-----------------------------------|---------------|
| Aug-26-2020 12:08:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Aug/26/2020 | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Aug-26-2020 12:08:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Record Identifier:: 1 Temperature: 36.8 Temperature Unit: Temperature Location:: ORAL CAVITY | Initial Entry |

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|-------------------------|---------------|
| Aug-26-2020 12:08:16 (UTC-05:00) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: 1 | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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

2.a Temperature:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------|---------------|
| Aug-26-2020 12:08:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: 36.8 | Initial Entry |

2.a Unit:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|-------------------------|---------------|
| Aug-26-2020 12:08:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: C | Initial Entry |

2.a Temperature Location:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|-----------------------------------|---------------|
| Aug-26-2020 12:08:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: ORAL CAVITY | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Lab Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------------|---------------|
| Aug-26-2020 12:07:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Not Applicable | Initial Entry |

2. Lab Sub-Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------------|---------------|
| Aug-26-2020 12:07:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Not Applicable | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------------|---------------|
| Aug-26-2020 12:07:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Not Applicable | Initial Entry |

4. Laboratory Name and Address (Derived)

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------------|---------------|
| Aug-26-2020 12:07:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Not Applicable | Initial Entry |

5. Specimen Type:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------------|---------------|
| Aug-26-2020 12:07:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Not Applicable | Initial Entry |

6.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|---|---------------|
| Aug-26-2020 12:07:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Sponsor-Defi Not Ap ned Identifie plicabl r: e Test:: Not Ap plicabl e Result:: Not Ap plicabl e | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

| | | | | |
|--|--|--|----------------------------------|--|
| | | | Not Done:: Not Applicable | |
|--|--|--|----------------------------------|--|

6.a Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------------|---------------|
| Aug-26-2020 12:07:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Not Applicable | Initial Entry |

6.a Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------------|---------------|
| Aug-26-2020 12:07:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Not Applicable | Initial Entry |

6.a Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------------|---------------|
| Aug-26-2020 12:07:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Not Applicable | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

6.a Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------------|---------------|
| Aug-26-2020 12:07:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Not Applicable | Initial Entry |

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Aug-26-2020 12:07:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Aug-26-2020 12:07:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--------------------|---------------------------|
| Aug-26-2020 13:46:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Aug-26-2020 12:07:55 | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (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: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

| | | | | |
|---|-----------------|---------------------------|---|--|
| (UTC-05:00) Eastern Time (US & Canada) | | | | Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Aug-26-2020 12:07:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: YES Date of Collection: Aug/26/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------------------|--|---------------|
| Aug-26-2020 13:46:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Jesse LePage (pfe.jlepage) | Data Entry: Sample ID BP75G : 9 | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------------------|------------------------------|---------------|
| Aug-26-2020 13:46:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Jesse LePage (pfe.jlepage) | Data Entry: BP75G9 | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071124

Generated By: pfe.lewissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Aug-26-2020 16:44:42 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------------|---------------|
| Aug-26-2020 16:44:42 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BLINDED THERAPY | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Aug-26-2020 16:44:42 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INJECTION | Initial Entry |

4. Dose Date Time:

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

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

| | | | | |
|---|-----------------|------------------------------|---|---------------|
| Aug-26-2020 16:44:42 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Aug/26/2020 12:16 | Initial Entry |
|---|-----------------|------------------------------|---|---------------|

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Aug-26-2020 16:44:42 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|----------------------------|---------------|
| Aug-26-2020 16:44:42 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: LEFT | Initial Entry |

7. Route:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Aug-26-2020 16:44:42 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Aug-26-2020 16:44:42 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------|---------------|
| Aug-26-2020 16:44:42 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: YES | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|-----------------------------------|---------------|
| Sep-23-2020 11:10:59 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Sep/23/2020 | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071124**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------|---------------|
| Sep-23-2020 11:12:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--|---------------|
| Sep-23-2020 11:12:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Symptom:: F E V E R Were fever or sys N temic symptoms O present on the las t day the Subject Diary was compl eted?: | Initial Entry |

2.a Symptom:

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

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:12

| | | | | |
|---|-----------------|------------------------------|-----------------------------|---------------|
| Sep-23-2020 11:12:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: FEVER | Initial Entry |
|---|-----------------|------------------------------|-----------------------------|---------------|

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------|---------------|
| Sep-23-2020 11:12:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

2.b

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--|---------------|
| Sep-23-2020 11:12:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Symptom:: FA TI G U E Were fever or sys N temic symptoms O present on the la st day the Subjec t Diary was com pleted?: | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:12

2.b Symptom:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|-------------------------------|---------------|
| Sep-23-2020 11:12:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: FATIGUE | Initial Entry |

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Sep-23-2020 11:12:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

2.c

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Sep-23-2020 11:12:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Symptom:: HE AD AC HE | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124 **Subject Initials:** ---

Generated By: pfe.lewissc **Generated Time (GMT):** 29-Mar-2021 04:12

| | | | | |
|--|--|--|--|--|
| | | | Were fever or sy NO stemic symptom s present on the l ast day the Subj ect Diary was co mpleted?: | |
|--|--|--|--|--|

2.c Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------|---------------|
| Sep-23-2020 11:12:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: HEADACHE | Initial Entry |

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------|---------------|
| Sep-23-2020 11:12:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

2.d

| Date | Location | User | Value | Reason |
|-------------------------|-----------------|---------------|--|---------------|
| Sep-23-2020 11:12:01 | ACV0PFEINFP6000 | Laura Pace | Data Entry: Symptom:: C | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071124**Subject Initials:** ---**Generated By:** pfe.lpace**Generated Time (GMT):** 29-Mar-2021 04:12

| | | | | |
|--|--|-------------|-------------------------|---|
| (UTC-05:00) Eastern Time (US & Canada) | | (pfe.lpace) | HI L LS N O | Were fever or systemic symptoms present on the last day the Subject Diary was completed?: |
|--|--|-------------|-------------------------|---|

2.d Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|------------------------------|---------------|
| Sep-23-2020 11:12:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: CHILLS | Initial Entry |

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------|---------------|
| Sep-23-2020 11:12:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

2.e

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

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124 **Subject Initials:** ---

Generated By: pfe.lewissc **Generated Time (GMT):** 29-Mar-2021 04:12

| | | | | |
|---|-----------------|------------------------------|---|---------------|
| Sep-23-2020 11:12:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Symptom:: VO MI TI NG Were fever or sy stemic symptom s present on the last day the Subj ect Diary was co mpleted?: | Initial Entry |
|---|-----------------|------------------------------|---|---------------|

2.e Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------|---------------|
| Sep-23-2020 11:12:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: VOMITING | Initial Entry |

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------|---------------|
| Sep-23-2020 11:12:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:12

2.f

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|---|---------------|
| Sep-23-2020 11:12:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Symptom:: DI AR RH EA Were fever or sy NO stemic symptom s present on the l ast day the Subj ect Diary was co mpleted?: | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:12

2.f Symptom:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------|---------------|
| Sep-23-2020 11:12:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: DIARRHEA | Initial Entry |

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Sep-23-2020 11:12:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

2.g

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Sep-23-2020 11:12:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Symptom:: NEW OR W ORSE NED MUSC LE PA IN | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:12

| | | | | |
|--|--|--|---|--|
| | | | Were fever or systemic symptoms present on the last day the Subject Diary was completed? : | |
|--|--|--|---|--|

2.g Symptom:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Sep-23-2020 11:12:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NEW OR WORSENE D MUSCLE PAIN | Initial Entry |

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Sep-23-2020 11:12:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

2.h

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

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124 **Subject Initials:** ---

Generated By: pfe.lewissc **Generated Time (GMT):** 29-Mar-2021 04:12

| | | | | |
|--|------------------------|---------------------------------------|--|----------------------|
| <p>Sep-23-2020 11:12:01 (UTC-05:00) Eastern Time (US & Canada)</p> | <p>ACV0PFEINFP6000</p> | <p>Laura Pace (pfe.lpace)</p> | <p>Data Entry: Symptom:: NEW OR W ORSE NED J OINT PAIN Were fever or NO systemic sym ptoms presen t on the last d ay the Subjec t Diary was c ompleted?:</p> | <p>Initial Entry</p> |
|--|------------------------|---------------------------------------|--|----------------------|

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:12

2.h Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--|---------------|
| Sep-23-2020 11:12:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NEW OR WORSENE D JOINT PAIN | Initial Entry |

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------|---------------|
| Sep-23-2020 11:12:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

3. Injection Site Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Sep-23-2020 11:12:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

4. Injection Site Body Side:

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

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:12

| | | | | |
|---|-----------------|------------------------------|----------------------------|---------------|
| Sep-23-2020 11:12:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: LEFT | Initial Entry |
|---|-----------------|------------------------------|----------------------------|---------------|

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--|---------------|
| Sep-23-2020 11:12:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Injection Site Reaction: RE D NE SS Were injection site reactions present on the last day the Subject Diary was completed?: N O | Initial Entry |

5.a Injection Site Reaction:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|-------------------------------|---------------|
| Sep-23-2020 11:12:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: REDNESS | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:12

5.a Were injection site reactions present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Sep-23-2020 11:12:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Sep-23-2020 11:12:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Injection Site Reaction: SW EL LI NG Were injection site reactions present on the last day the Subject Diary was completed?: NO | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:12

5.b Injection Site Reaction:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------|---------------|
| Sep-23-2020 11:12:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: SWELLING | Initial Entry |

5.b Were injection site reactions present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Sep-23-2020 11:12:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Sep-23-2020 11:12:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Injection Site Reaction:: PAIN AT I NJE CTIO N SI TE | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:12

| | | | | |
|--|--|--|--|--|
| | | | Were injection NO site reactions present on the last day the Subject Diary was completed?: | |
|--|--|--|--|--|

5.c Injection Site Reaction:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--|---------------|
| Sep-23-2020 11:12:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: PAIN AT INJECTION SITE | Initial Entry |

5.c Were injection site reactions present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--------------------------|---------------|
| Sep-23-2020 11:12:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (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: 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:12

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Sep-23-2020 11:11:21 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Sep-23-2020 11:11:21 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--------------------|---------------------------|
| Sep-23-2020 11:42:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Sep-23-2020 11:11:21 | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (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:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical Center**Subject No:** 10071124**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12

| | | | | |
|---|-----------------|---------------------------|---|--|
| (UTC-05:00) Eastern Time (US & Canada) | | | | Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Sep-23-2020 11:11:21 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: YES Date of Collection: Sep/23/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------------------|---|---------------|
| Sep-23-2020 11:42:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Jesse LePage (pfe.jlepage) | Data Entry: Sample ID BPYTS : S | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------------------|------------------------------|---------------|
| Sep-23-2020 11:42:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Jesse LePage (pfe.jlepage) | Data Entry: BPYTSS | Initial Entry |

5.b

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: 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:12

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------------------|--|---------------|
| Sep-23-2020 11:42:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Jesse LePage (pfe.jlepage) | Data Entry: Sample I BMPSB D: H | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------------------|------------------------------|---------------|
| Sep-23-2020 11:42:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Jesse LePage (pfe.jlepage) | Data Entry: BMPSBH | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------------------|---|---------------|
| Sep-23-2020 11:42:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Jesse LePage (pfe.jlepage) | Data Entry: Sample ID BMPSB : J | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (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: 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:12

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------------------|------------------------------|---------------|
| Sep-23-2020 11:42:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Jesse LePage (pfe.jlepage) | Data Entry: BMPSBJ | Initial Entry |

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124 **Subject Initials:** ---

Generated By: pfe.lewissc **Generated Time (GMT):** 29-Mar-2021 04:12

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1. Date of Completion/Discontinuation/Death :

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|-----------------------------------|---------------|
| Sep-23-2020 11:12:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Sep/23/2020 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------------|---------------|
| Sep-23-2020 11:12:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: VACCINATION | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|---------------------------------|---------------|
| Sep-23-2020 11:12:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: COMPLETED | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071124

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------|--------|
| Feb-14-2021 20:49:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Form Created | |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------|--------|
| Feb-14-2021 20:50:45 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Form Created | |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------|--------|
| Feb-14-2021 20:54:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Form Created | |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------|--------|
| Feb-14-2021 20:55:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Form Created | |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------|--------|
| Feb-14-2021 20:57:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Form Created | |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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1. Category:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Feb-14-2021 20:49:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------|---------------|
| Feb-14-2021 20:49:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 1 | Initial Entry |

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

| Date | Location | User | Value | Reason |
|--|-----------------|------------------------------|---|---------------|
| Feb-14-2021 20:49:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: generalized myalgia | Initial Entry |

4. Start Date Time:

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (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, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-14-2021 20:49:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Feb/9/2021 18:00 | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-14-2021 20:49:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO End Date Time: Feb/10/2021 18:00 | Initial Entry |

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|-------------------------|---------------|
| Feb-14-2021 20:49:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: 1 | Initial Entry |

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Feb-14-2021 20:49:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Feb-14-2021 20:49:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

9. Is this event related to study treatment:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|-------------------------------|---------------|
| Feb-14-2021 20:49:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: RELATED | Initial Entry |

10. Latest Action Taken with Study Treatment:

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

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (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, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

| | | | | |
|---|-----------------|------------------------------|--------------------------------------|---------------|
| Feb-14-2021 20:49:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NOT APPLICABLE | Initial Entry |
|---|-----------------|------------------------------|--------------------------------------|---------------|

11. Was a Concomitant Medication given?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------|---------------|
| Feb-14-2021 20:49:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------|---------------|
| Feb-14-2021 20:49:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|------------------------------|--|---------------|
| Feb-14-2021 20:49:43 (UTC-05:00) Eastern Time (US | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: RECOVERED/RESOLVED | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (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, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

& Canada)

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

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------|---------------|
| Feb-14-2021 20:49:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (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, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Feb-14-2021 20:50:45 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Feb-14-2021 20:50:45 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 2 | Initial Entry |

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|------------------------------|---------------|
| Feb-14-2021 20:50:45 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: chills | Initial Entry |

4. Start Date Time:

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (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, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-14-2021 20:50:45 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Feb/9/2021 18:00 | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-14-2021 20:50:45 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO End Date Time: Feb/10/2021 18:00 | Initial Entry |

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|-------------------------|---------------|
| Feb-14-2021 20:50:45 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: 1 | Initial Entry |

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (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, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Feb-14-2021 20:50:45 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Feb-14-2021 20:50:45 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

9. Is this event related to study treatment:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|-------------------------------|---------------|
| Feb-14-2021 20:50:45 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: RELATED | Initial Entry |

10. Latest Action Taken with Study Treatment:

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

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (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, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

| | | | | |
|---|-----------------|------------------------------|--------------------------------------|---------------|
| Feb-14-2021 20:50:45 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NOT APPLICABLE | Initial Entry |
|---|-----------------|------------------------------|--------------------------------------|---------------|

11. Was a Concomitant Medication given?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------|---------------|
| Feb-14-2021 20:50:45 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------|---------------|
| Feb-14-2021 20:50:45 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|------------------------------|--|---------------|
| Feb-14-2021 20:50:45 (UTC-05:00) Eastern Time (US | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: RECOVERED/RESOLVED | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (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, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

& Canada)

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

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------|---------------|
| Feb-14-2021 20:50:45 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (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, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Feb-14-2021 20:54:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Feb-14-2021 20:54:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 3 | Initial Entry |

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--|---------------|
| Feb-14-2021 20:54:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: axillary lymphadenopa thy | Initial Entry |

4. Start Date Time:

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (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, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-14-2021 20:54:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Feb/10/2021 UNK:UNK | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|-----------------|
| Feb-21-2021 11:26:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO End Date Time: Feb/12/2021 UNK:UNK | New Information |
| Feb-14-2021 20:54:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: YES | Initial Entry |

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|-------------------------|---------------|
| Feb-14-2021 20:54:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: 1 | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (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, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Feb-14-2021 20:54:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Feb-14-2021 20:54:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

9. Is this event related to study treatment:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|-------------------------------|---------------|
| Feb-14-2021 20:54:02 (UTC-05:00) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: RELATED | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (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, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Eastern Time (US & Canada)

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------------|---------------|
| Feb-14-2021 20:54:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Feb-14-2021 20:54:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Feb-14-2021 20:54:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

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

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (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, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---|
| Feb-21-2021 11:26:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Feb-21-2021 11:26:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: RECOVERED/RE SOLVED | New Information |
| Feb-21-2021 11:26:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | For AE axillary lymphadenopathy: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present. |
| Feb-14-2021 20:54:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NOT RECOVERED/NOT RESOLVED | Transcription Error |
| Feb-14-2021 20:54:02 (UTC-05:00) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: RECOVERED/RE SOLVED | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (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, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Eastern Time (US & Canada)

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Feb-14-2021 20:54:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (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, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Feb-14-2021 20:55:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Feb-14-2021 20:55:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 4 | Initial Entry |

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------|---------------|
| Feb-14-2021 20:55:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: headache | Initial Entry |

4. Start Date Time:

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (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, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-14-2021 20:55:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Feb/9/2021 18:00 | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-14-2021 20:55:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO End Date Time: Feb/10/2021 18:00 | Initial Entry |

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|-------------------------|---------------|
| Feb-14-2021 20:55:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: 2 | Initial Entry |

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (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, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Feb-14-2021 20:55:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Feb-14-2021 20:55:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

9. Is this event related to study treatment:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|-------------------------------|---------------|
| Feb-14-2021 20:55:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: RELATED | Initial Entry |

10. Latest Action Taken with Study Treatment:

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

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (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, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

| | | | | |
|---|-----------------|------------------------------|--------------------------------------|---------------|
| Feb-14-2021 20:55:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NOT APPLICABLE | Initial Entry |
|---|-----------------|------------------------------|--------------------------------------|---------------|

11. Was a Concomitant Medication given?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------|---------------|
| Feb-14-2021 20:55:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------|---------------|
| Feb-14-2021 20:55:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|------------------------------|--|---------------|
| Feb-14-2021 20:55:53 (UTC-05:00) Eastern Time (US | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: RECOVERED/RESOLVED | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (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, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

& Canada)

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

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------|---------------|
| Feb-14-2021 20:56:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (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, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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1. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Feb-14-2021 20:57:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Feb-14-2021 20:57:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 5 | Initial Entry |

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|---|---------------|
| Feb-14-2021 20:57:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: injection site pain | Initial Entry |

4. Start Date Time:

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (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, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-14-2021 20:57:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Feb/10/2021 UNK:UNK | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-14-2021 20:57:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO End Date Time: Feb/11/2021 UNK:UNK | Initial Entry |

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|-------------------------|---------------|
| Feb-14-2021 20:57:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: 1 | Initial Entry |

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization;

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (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, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Feb-14-2021 20:57:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Feb-14-2021 20:57:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

9. Is this event related to study treatment:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|-------------------------------|---------------|
| Feb-14-2021 20:57:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: RELATED | Initial Entry |

10. Latest Action Taken with Study Treatment:

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (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, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------------|---------------|
| Feb-14-2021 20:57:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Feb-14-2021 20:57:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Feb-14-2021 20:57:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-14-2021 20:57:15 (UTC-05:00) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: RECOVERED/RESOLVED | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (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, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Eastern Time (US & Canada)

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Feb-14-2021 20:57:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History
Unscheduled

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|-----------------------------------|---------------|
| Jan-19-2021 09:49:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Jan/13/2021 | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen, Verified

Site No: 1007 **Site Name:** (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124 **Subject Initials:** ---

Generated By: pfe.lewissc **Generated Time (GMT):** 29-Mar-2021 04:12

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

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|---|---------------|
| Jan-19-2021 09:49:42 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2 | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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1. Date Treatment Unblinded :

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|-----------------------------------|---------------|
| Jan-19-2021 09:49:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Jan/14/2021 | Initial Entry |

2. Primary Reason for Unblinding:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|---|---------------|
| Jan-19-2021 09:49:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: ASSESS ELIGIBILIT Y FOR ADDITIONA L VACCINATION | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071124

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|-----------------------------------|---------------|
| Jan-19-2021 09:49:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Jan/19/2021 | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER
VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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1. Consent Was:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|---|---------------|
| Jan-19-2021 11:23:56 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: OBTAINED Date Written Consent Obtained Jan/19/2021 | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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1. Date of Completion/Discontinuation/Death :

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|-----------------------------------|---------------|
| Jan-19-2021 11:24:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Jan/19/2021 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Jan-19-2021 11:24:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: REPEAT SCREENING 1 | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|---------------------------------|---------------|
| Jan-19-2021 11:24:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: COMPLETED | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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1. Lab Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------------|---------------|
| Jan-19-2021 11:24:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Not Applicable | Initial Entry |

2. Lab Sub-Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------------|---------------|
| Jan-19-2021 11:24:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Not Applicable | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------------|---------------|
| Jan-19-2021 11:24:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Not Applicable | Initial Entry |

4. Laboratory Name and Address (Derived)

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------------|---------------|
| Jan-19-2021 11:24:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Not Applicable | Initial Entry |

5. Specimen Type:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------------|---------------|
| Jan-19-2021 11:24:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Not Applicable | Initial Entry |

6.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Jan-19-2021 11:24:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Sponsor-Defined Identifier: Not Applicable Test: Not Applicable Result: Not Applicable | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

| | | | | |
|--|--|--|----------------------------------|--|
| | | | Not Done:: Not Applicable | |
|--|--|--|----------------------------------|--|

6.a Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------------|---------------|
| Jan-19-2021 11:24:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Not Applicable | Initial Entry |

6.a Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------------|---------------|
| Jan-19-2021 11:24:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Not Applicable | Initial Entry |

6.a Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------------|---------------|
| Jan-19-2021 11:24:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Not Applicable | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
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Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

6.a Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------------|---------------|
| Jan-19-2021 11:24:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Not Applicable | Initial Entry |

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1007

Subject No: 10071124

Generated By: pfe.lewissc

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Jan-19-2021 11:24:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Jan-19-2021 11:24:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--------------------|---------------------------|
| Jan-19-2021 11:57:52 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Jan-19-2021 11:24:47 | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1007**Site Name:** (1007) Cincinnati Children's Hospital Medical
Center**Subject No:** 10071124**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12

| | | | | |
|---|-----------------|---------------------------|---|--|
| (UTC-05:00) Eastern Time (US & Canada) | | | | Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Jan-19-2021 11:24:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: YES Date of Collection: Jan/19/2021 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------------------|--|---------------|
| Jan-19-2021 11:57:52 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Morgan Messeder (pfe.mmesseder) | Data Entry: Sample I BRB8N D: B | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------------------|------------------------------|---------------|
| Jan-19-2021 11:57:52 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Morgan Messeder (pfe.mmesseder) | Data Entry: BRB8NB | Initial Entry |

5.b

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

| Date | Location | User | Value | Reason |
|--|-----------------|------------------------------------|--|---------------|
| Jan-19-2021 11:57:59 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Morgan Messeder (pfe.mmesseder) | Data Entry: Sample I BNWM D: N8 | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|------------------------------------|------------------------------|---------------|
| Jan-19-2021 11:57:59 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Morgan Messeder (pfe.mmesseder) | Data Entry: BNWMN8 | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|--|-----------------|------------------------------------|---|---------------|
| Jan-19-2021 11:58:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Morgan Messeder (pfe.mmesseder) | Data Entry: Sample BNWM ID: NC | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------------------|------------------------------|---------------|
| Jan-19-2021 11:58:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Morgan Messeder (pfe.mmesseder) | Data Entry: BNWMNC | Initial Entry |

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Jan-19-2021 11:24:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Jan-19-2021 11:24:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--------------------|---------------------------|
| Jan-19-2021 11:30:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Jan-19-2021 11:24:55 | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

| | | | | |
|---|-----------------|---------------------------|---|--|
| (UTC-05:00) Eastern Time (US & Canada) | | | | Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Jan-19-2021 11:24:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: YES Date of Collection: Jan/19/2021 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------------------|--|---------------|
| Jan-19-2021 11:30:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Jesse LePage (pfe.jlepage) | Data Entry: Sample ID BRB8N : 9 | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------------------|------------------------------|---------------|
| Jan-19-2021 11:30:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Jesse LePage (pfe.jlepage) | Data Entry: BRB8N9 | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1007

Subject No: 10071124

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------|---------------|
| Jan-19-2021 11:25:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------|---------------|
| Jan-19-2021 11:25:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BNT162b2 | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Jan-19-2021 11:25:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INJECTION | Initial Entry |

4. Dose Date Time:

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

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

| | | | | |
|---|-----------------|------------------------------|---|---------------|
| Jan-19-2021 11:25:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Jan/19/2021 10:46 | Initial Entry |
|---|-----------------|------------------------------|---|---------------|

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Jan-19-2021 11:25:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|----------------------------|---------------|
| Jan-19-2021 11:25:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: LEFT | Initial Entry |

7. Route:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Jan-19-2021 11:25:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

8. Actual Dose:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Jan-19-2021 11:25:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 30.0 | Initial Entry |

9. Unit:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------|---------------|
| Jan-19-2021 11:25:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ug | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Jan-19-2021 11:25:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 30 MINUTES | Initial Entry |

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

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

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1007

Subject No: 10071124

Generated By: pfe.lewissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

| | | | | |
|---|-----------------|------------------------------|---------------------------|---------------|
| Jan-19-2021 11:25:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: YES | Initial Entry |
|---|-----------------|------------------------------|---------------------------|---------------|

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071124

Generated By: pfe.lewissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|----------------------------------|---------------|
| Feb-09-2021 13:11:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Feb/9/2021 | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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1. Lab Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------------|---------------|
| Feb-09-2021 13:11:50 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Not Applicable | Initial Entry |

2. Lab Sub-Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------------|---------------|
| Feb-09-2021 13:11:50 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Not Applicable | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------------|---------------|
| Feb-09-2021 13:11:50 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Not Applicable | Initial Entry |

4. Laboratory Name and Address (Derived)

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------------|---------------|
| Feb-09-2021 13:11:50 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Not Applicable | Initial Entry |

5. Specimen Type:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------------|---------------|
| Feb-09-2021 13:11:50 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Not Applicable | Initial Entry |

6.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|---|---------------|
| Feb-09-2021 13:11:50 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Sponsor-Defi Not Ap ned Identifie plicabl r: e Test:: Not Ap plicabl e Result:: Not Ap plicabl e | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

| | | | | |
|--|--|--|----------------------------------|--|
| | | | Not Done:: Not Applicable | |
|--|--|--|----------------------------------|--|

6.a Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------------|---------------|
| Feb-09-2021 13:11:50 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Not Applicable | Initial Entry |

6.a Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------------|---------------|
| Feb-09-2021 13:11:50 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Not Applicable | Initial Entry |

6.a Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------------|---------------|
| Feb-09-2021 13:11:50 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Not Applicable | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

6.a Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------------|---------------|
| Feb-09-2021 13:11:50 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Not Applicable | Initial Entry |

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Feb-09-2021 13:12:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Feb-09-2021 13:12:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--------------------|---------------------------|
| Feb-09-2021 13:22:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Feb-09-2021 13:12:07 | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

| | | | | |
|---|-----------------|---------------------------|--|--|
| (UTC-05:00) Eastern Time (US & Canada) | | | | Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Feb-09-2021 13:12:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: YES Date of Collection: Feb/9/2021 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------------------|--|---------------|
| Feb-09-2021 13:22:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Morgan Messeder (pfe.mmesseder) | Data Entry: Sample I BRB94 D: Y | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------------------|------------------------------|---------------|
| Feb-09-2021 13:22:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Morgan Messeder (pfe.mmesseder) | Data Entry: BRB94Y | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1007

Subject No: 10071124

Generated By: pfe.lewissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------|---------------|
| Feb-09-2021 14:23:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------|---------------|
| Feb-09-2021 14:23:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BNT162b2 | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Feb-09-2021 14:23:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INJECTION | Initial Entry |

4. Dose Date Time:

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

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

| | | | | |
|---|-----------------|------------------------------|--|---------------|
| Feb-09-2021 14:23:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Feb/9/2021 13:37 | Initial Entry |
|---|-----------------|------------------------------|--|---------------|

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Feb-09-2021 14:23:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|----------------------------|---------------|
| Feb-09-2021 14:23:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: LEFT | Initial Entry |

7. Route:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Feb-09-2021 14:23:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

8. Actual Dose:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Feb-09-2021 14:23:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 30.0 | Initial Entry |

9. Unit:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------|---------------|
| Feb-09-2021 14:23:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ug | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Feb-09-2021 14:23:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 30 MINUTES | Initial Entry |

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

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

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1007

Subject No: 10071124

Generated By: pfe.lewissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

| | | | | |
|---|-----------------|------------------------------|---------------------------|---------------|
| Feb-09-2021 14:23:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: YES | Initial Entry |
|---|-----------------|------------------------------|---------------------------|---------------|

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1007

Subject No: 10071124

Generated By: pfe.lewissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|----------------------------------|---------------|
| Mar-10-2021 09:26:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Mar/9/2021 | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071124

Generated By: pfe.levissc

Form: CONTACT OUTCOME - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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1. Contact Type:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Mar-10-2021 09:26:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: TELEPHONE VISIT | Initial Entry |

2. Was contact made?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|---|---------------|
| Mar-10-2021 09:26:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: YES Date of Contact: Mar/9/2021 | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit
Trail History

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|----------------------------------|---------------|
| Mar-10-2021 09:26:52 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Mar/9/2021 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Mar-10-2021 09:26:52 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: OPEN LABEL TREAT MENT | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|---------------------------------|---------------|
| Mar-10-2021 09:26:52 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: COMPLETED | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Subject Status

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-23-2020 11:12:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: FOLLOW-UP | Initial Entry |
| Aug-05-2020 11:50:32 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ENROLLED/RANDOMIZED | Initial Entry |
| Aug-05-2020 11:45:51 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SCREENED | Initial Entry |

2. Subject Status Date

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------------|---------------|
| Sep-23-2020 11:12:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sep/23/2020 | Initial Entry |
| Aug-05-2020 | ACV0PFEINFP6000 | auto calc | Data Entry: | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1007

Site Name: (1007) Cincinnati Children's Hospital Medical Center

Subject No: 10071124

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 04:12

| | | | | |
|---|-----------------|-------------------------|----------------------------------|---------------|
| 11:50:32 (UTC-05:00) Eastern Time (US & Canada) | | (autocalc) | Aug/5/2020 | |
| Aug-05-2020 11:45:51 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Aug/5/2020 | Initial Entry |

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1007

Subject No: 10071124

Generated By: pfe.levissc

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1007) Cincinnati Children's Hospital Medical
Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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1. Casebook Signature

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--|---------------|
| Sep-10-2020 07:20:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Laura Pace (pfe.lpace) | Data Entry: Click Here to Enable | Initial Entry |

090177e196ae402b\Final\Final On: 01-Apr-2021 05:32 (GMT)