

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: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Cohort Selection

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Informed Consent

| | | |
|----|--------------|--|
| 1. | Consent Was: | OBTAINED Date Written Consent Obtained Aug/19/2020 |
|----|--------------|--|

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Demography

| | | |
|----|---------------------------------|--|
| 1. | Subject ID | [10421129] |
| 2. | Birth Date: | (b) (6) /1990 |
| 3. | Sex: | FEMALE |
| 4. | Ethnicity: | NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN |
| 5. | Race: (Check X all that apply): | BLACK OR AFRICAN AMERICAN |
| 6. | Racial Designation: | |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Aug/19/2020 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition - Screening

| | | |
|----|--|-------------|
| 1. | Date of Completion/Discontinuation/Death | Aug/19/2020 |
| 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: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Form Comments

Medical History Details

| | | |
|----|--|--------------------------|
| 1. | Line/MH Number: | Not Done _____ [] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | Not Done _____ [] |
| | Start Date: | Not Done _____ // |
| | Ongoing: | Not Done _____ |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vital Signs

| | | |
|----|------------------|-------------|
| 1. | Date: | Aug/19/2020 |
| 2. | Weight: | [234.2] |
| 3. | Unit: | LB |
| 4. | Height: | [67.0] |
| 5. | Unit: | in |
| 6. | Body Mass Index: | [36.7] |

Vital Signs Details

| | | |
|-----|-----------------------|-------------|
| 7.a | Record Identifier: | 1 |
| | Temperature: | [97.9] |
| | Unit: | F |
| | Temperature Location: | ORAL CAVITY |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Lab Urinalysis

| | | |
|----|---------------------------------------|--------------|
| 1. | Lab Panel: | URINALYSIS |
| 2. | Lab Sub-Panel: | PREGNANCY |
| 3. | Collection Date: | Aug/19/2020 |
| 4. | Laboratory Name and Address (Derived) | [STUDY SITE] |
| 5. | Specimen Type: | URINE |

Lab Result

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

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition

| | | |
|----|-----------------------|-------------|
| 1. | Randomization Date : | Aug/19/2020 |
| 2. | Randomization Number: | [55000] |
| 3. | Randomization Group: | [] |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Aug/19/2020 |
| 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 | [BP3MCK] |
| 5.b | Sample ID | [BP3MCL] |
| 5.c | Sample ID | [BP3MCM] |
| 5.d | Sample ID | [BPLCW1] |
| 5.e | Sample ID | [BPLCW2] |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Aug/19/2020 |
| 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 | [BN5R6G] |
|-----|-----------|----------|

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[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/19/2020 10:09 |
| 5. | Anatomical Location: | DELTOID MUSCLE |
| 6. | Body Side: | LEFT |
| 7. | Route: | INTRAMUSCULAR |
| 8. | Actual Dose: | [] |
| 9. | Unit: | |
| 10. | Timeframe Subject Was Observed | THE PROTOCOL SPECIFIED OBSERVATION PERIOD |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | YES |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Vital Signs

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

Vital Signs Details

| | | |
|-----|-----------------------|-------------|
| 2.a | Record Identifier: | 1 |
| | Temperature: | [97.4] |
| | Unit: | F |
| | Temperature Location: | ORAL CAVITY |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Lab Urinalysis

| | | |
|----|---------------------------------------|--------------|
| 1. | Lab Panel: | URINALYSIS |
| 2. | Lab Sub-Panel: | PREGNANCY |
| 3. | Collection Date: | Sep/9/2020 |
| 4. | Laboratory Name and Address (Derived) | [STUDY SITE] |
| 5. | Specimen Type: | URINE |

Lab Result

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

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BN5RDX] |
|-----|-----------|----------|

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Vaccination

| | | |
|-----|---|---|
| 1. | Was there a temporary delay of vaccination? | NO |
| 2. | Treatment Name | [BLINDED THERAPY] |
| 3. | Formulation: | INJECTION |
| 4. | Dose Date Time: | Sep/9/2020 08:52 |
| 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 |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Form Comments](#)

[eCRF Audit Trail History](#)

Date of Visit

| | | | Comments |
|----|-----------------|-------------------------|--------------------------|
| 1. | Date of Visit | Not Done _____ // | Comments |
| 2. | Erroneous Visit | Not Done _____ | Comments |

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Form Comments](#)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

| | | |
|----|-----------|--------------------------|
| 5. | Sample ID | Not Done _____ [] |
|----|-----------|--------------------------|

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

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

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

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

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

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

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

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

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

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: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52 **Form Status:** Not Started

Site No: 1042 **Site Name:** (1042) HealthFirst Medical Group

Subject No: 10421129 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 04:44

Illness Details

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

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

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: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Sep/10/2020

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/10/2020

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Unplanned Assessments

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

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Sep/10/2020

Form: CONTACT OUTCOME - UNPLANNED

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Contact Outcome

| | | |
|----|-------------------|---|
| 1. | Contact Type: | TELEPHONE VISIT |
| 2. | Was contact made? | YES Date of Contact: Sep/10/2020 Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION |
| 3. | Comments: | [] |

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

Form Status: Incomplete, Queries, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition - Treatment

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

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Data Complete, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

Disposition - Follow-Up

| | | | |
|----|--|--------------------------------|--------------------------|
| 1. | Date of Completion/Discontinuation/Death : | Not Applicable _____ // | Comments |
| 2. | Phase of Disposition: | Not Applicable _____ | Comments |
| 3. | Status: | Not Applicable _____ | Comments |
| 4. | Specify Status: | Not Applicable _____ [] | Comments |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

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

COVID-19 Repeat Swab

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

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (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: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

| # | Category | AE Identifier | Adverse Event | Start Date | Is the Adverse Event Still Ongoing | Form Instance |
|----|---------------|---------------|---------------------------|-------------------|------------------------------------|---------------------------------|
| 1. | ADVERSE EVENT | 1 | Exposure during Pregnancy | Aug/19/2020 10:09 | YES | Repeating Pages |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Answered Queries

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

Adverse Event Report

| | | | |
|-----|---|--|--------------------------|
| 1. | Category: | ADVERSE EVENT | |
| 2. | AE ID: | [1] | |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [Exposure during Pregnancy] | |
| 4. | Start Date Time: | Aug/19/2020 10:09 | |
| 5. | Is the adverse event still ongoing? | YES | |
| 6. | Toxicity Grade: | Not Applicable | Comments |
| 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: | NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Birth Control Failure] | |
| 10. | Latest Action Taken with Study Treatment: | NOT APPLICABLE | |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Answered Queries

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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Medication Error

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

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

| # | 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: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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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: | // |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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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? | |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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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: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Vital Signs

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

Vital Signs Details

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

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (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: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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: | |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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? | |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Contact Outcome

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form Version: 14-Jan-2021 02:29

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE

Form Status: Not Started

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Informed Consent - Asymptomatic Surveillance

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Verified

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[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 and NOT confirmed to have received only placebo at Vaccination 1/2 |
|----|---|--|

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Treatment Unblinded

| | | |
|----|--------------------------------|---|
| 1. | Date Treatment Unblinded : | Feb/4/2021 |
| 2. | Primary Reason for Unblinding: | ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION |

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Withdrawal Of Consent

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

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Subject Status

| | | |
|----|---------------------|---------------------|
| 1. | Subject Status | ENROLLED/RANDOMIZED |
| 2. | Subject Status Date | Aug/19/2020 |

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[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, Verified

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Audit Trail](#)

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

- CRF_Sign
- CRF_Sign_1

| Name | Signature Meaning | Date | Type | Action |
|------|-------------------|------|------|--------|
|------|-------------------|------|------|--------|

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|--------------------------------|----------|
| Form | Aug-19-2020 15:32:46 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Done |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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| Item | Date | User | Comment |
|------|---|--------------------------------|----------|
| Form | Aug-19-2020 15:33:51 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Done |

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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| Item | Date | User | Comment |
|------|---|--------------------------------|----------|
| Form | Nov-09-2020 12:00:47 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Done |

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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| Item | Date | User | Comment |
|------|---|--------------------------------|----------|
| 1 | Nov-09-2020 12:00:47 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Done |

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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| Item | Date | User | Comment |
|------|---|--------------------------------|----------|
| 2 | Nov-09-2020 12:00:47 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Done |

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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| Item | Date | User | Comment |
|------|---|--------------------------------|----------|
| Form | Mar-05-2021 07:21:47 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Done |

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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| Item | Date | User | Comment |
|------|---|--------------------------------|----------|
| 1 | Mar-05-2021 07:21:47 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Done |

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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| Item | Date | User | Comment |
|------|---|--------------------------------|----------|
| 2 | Mar-05-2021 07:21:47 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Done |

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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| Item | Date | User | Comment |
|------|---|--------------------------------|----------|
| 3 | Mar-05-2021 07:21:47 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Done |

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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| Item | Date | User | Comment |
|------|---|--------------------------------|----------|
| 4 | Mar-05-2021 07:21:47 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Done |

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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| Item | Date | User | Comment |
|------|---|------------------|---------------------------|
| Form | Mar-02-2021 07:29:10 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Waiting for subject visit |
| | | | Not Applicable |

Header Text: c4591001

Visit: Follow-Up

Form Version: 15-Sep-2020 21:53

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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| Item | Date | User | Comment |
|------|---|--------------------------------|---|
| 1 | Mar-02-2021 07:29:10 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Waiting for subject visit <hr/> Not Applicable |

Header Text: c4591001

Visit: Follow-Up

Form Version: 15-Sep-2020 21:53

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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| Item | Date | User | Comment |
|------|---|--------------------------------|---|
| 2 | Mar-02-2021 07:29:10 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Waiting for subject visit <hr/> Not Applicable |

Header Text: c4591001

Visit: Follow-Up

Form Version: 15-Sep-2020 21:53

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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| Item | Date | User | Comment |
|------|---|--------------------------------|---|
| 3 | Mar-02-2021 07:29:10 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Waiting for subject visit <hr/> Not Applicable |

Header Text: c4591001

Visit: Follow-Up

Form Version: 15-Sep-2020 21:53

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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| Item | Date | User | Comment |
|------|---|--------------------------------|---|
| 4 | Mar-02-2021 07:29:10 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Waiting for subject visit <hr/> Not Applicable |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Comments

Form Status: Data Complete, Answered Queries

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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| Item | Date | User | Comment |
|------|---|--------------------------------|----------------|
| 6 | Feb-23-2021 07:33:50 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

- CRF_Sign
- CRF_Sign_1

| Name | Signature Meaning | Date | Type | Action |
|---------|-------------------|---|------|-----------------------------------|
| (b) (6) | N/A | Feb-12-2021 11:45:27 (UTC-06:00) Central Time (US & Canada) | | Edit - All signatures invalidated |

Affidavit:

N/A

| | | | | |
|---------------|----------|---|------|--------|
| William Seger | Approved | Nov-10-2020 14:42:36 (UTC-06:00) Central Time (US & Canada) | BOOK | Signed |
|---------------|----------|---|------|--------|

Affidavit:

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

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

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

| | | | | |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Nov-10-2020 08:15:12 (UTC-06:00) Central Time (US & Canada) | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|---------|----------|---|------|--------|
| (b) (6) | Approved | Nov-09-2020 16:47:41 (UTC-06:00) Central Time (US & Canada) | BOOK | Signed |
|---------|----------|---|------|--------|

Affidavit:

By my dated signature below, I, (b) (6), 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.

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (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: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Select appropriate response - Protocol version

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Aug-19-2020 15:29:53 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 24 JUL 2020 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------------------|---------------|
| Aug-19-2020 15:29:53 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: STAGE 3 COHORTS | Initial Entry |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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I. Consent Was:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Aug-19-2020 15:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: OBTAINED Date Written Consent Obtained Aug/19/2020 | Initial Entry |

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Subject ID

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------|-----------------------------------|
| Aug-19-2020 15:29:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 10421129 | Item copied from previous form |

2. Birth Date:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|------------------|
| Aug-19-2020 15:29:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: (b) (6) /1990 | Enrollment Entry |

3. Sex:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Aug-19-2020 15:32:14 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: FEMALE | Initial Entry |

4. Ethnicity:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Aug-19-2020 15:32:14 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Aug-19-2020 15:32:14 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BLACK OR AFRICAN AMERI CAN | Initial Entry |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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I. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Aug-19-2020 15:32:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/19/2020 | Initial Entry |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Completion/Discontinuation/Death

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Aug-19-2020 15:33:05 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/19/2020 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Aug-19-2020 15:33:05 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SCREENING | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------------|---------------|
| Aug-19-2020 15:33:05 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Aug-19-2020 15:35:05 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/19/2020 | Initial Entry |

2. Weight:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------|---------------|
| Aug-19-2020 15:35:05 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 234.2 | Initial Entry |

3. Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Aug-19-2020 15:35:05 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LB | Initial Entry |

4. Height:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------|---------------|
| Aug-19-2020 15:35:05 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 67.0 | Initial Entry |

5. Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Aug-19-2020 15:35:05 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: in | Initial Entry |

6. Body Mass Index:

| Date | Location | User | Value | Reason |
|----------------------|-----------------|-----------|--------------------|---------------|
| Aug-19-2020 15:35:05 | ACV0PFEINFP6000 | auto calc | Data Entry: | Initial Entry |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

| | | | | |
|--|--|------------|------|--|
| (UTC-06:00) Central Time (US & Canada) | | (autocalc) | 36.7 | |
|--|--|------------|------|--|

7.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Aug-19-2020 15:35:05 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier: 1 : Temperature: 97.9 Temperature Unit F : Temperature Location: ORAL CAVITY | Initial Entry |

7.a Record Identifier:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Aug-19-2020 15:35:05 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

7.a Temperature:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------|---------------|
| Aug-19-2020 15:35:05 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 97.9 | Initial Entry |

7.a Unit:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Aug-19-2020 15:35:05 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: F | Initial Entry |

7.a Temperature Location:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Aug-19-2020 15:35:05 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ORAL CAVITY | Initial Entry |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (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: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

1. Lab Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Aug-19-2020 15:36:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: URINALYSIS | Initial Entry |

2. Lab Sub-Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Aug-19-2020 15:36:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: PREGNANCY | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Aug-19-2020 15:36:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/19/2020 | Initial Entry |

4. Laboratory Name and Address (Derived)

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Aug-19-2020 15:36:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: STUDY SITE | Initial Entry |

5. Specimen Type:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Aug-19-2020 15:36:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: URINE | Initial Entry |

6.a

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

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (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: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

| | | | | |
|---|-----------------|-------------------------|--|---------------|
| Aug-19-2020 15:36:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done:: | Initial Entry |
|---|-----------------|-------------------------|--|---------------|

6.a Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------|---------------|
| Aug-19-2020 15:36:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 113 | Initial Entry |

6.a Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Aug-19-2020 15:36:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Choriogonadotropin Beta_PX113 | Initial Entry |

6.a Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Aug-19-2020 15:36:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEGATIVE | Initial Entry |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Randomization Date :

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Aug-19-2020 15:36:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/19/2020 | Initial Entry |

2. Randomization Number:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------|---------------|
| Aug-19-2020 15:36:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 55000 | Initial Entry |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Aug-19-2020 15:38:53 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Aug-19-2020 15:38:53 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|---|
| Aug-19-2020 15:40:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Aug-19-2020 15:38:53 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Aug-19-2020 15:38:53 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Aug/19/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Aug-19-2020 15:40:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP3MCK | Initial Entry |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (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: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Aug-19-2020 15:40:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BP3MCK | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Aug-19-2020 15:40:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP3MCL | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Aug-19-2020 15:40:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BP3MCL | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Aug-19-2020 15:41:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP3MCM | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Aug-19-2020 15:41:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BP3MCM | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Aug-19-2020 15:41:55 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BPLCW1 | Initial Entry |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (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: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.d Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Aug-19-2020 15:41:55 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BPLCW1 | Initial Entry |

5.e

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Aug-19-2020 15:42:05 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BPLCW2 | Initial Entry |

5.e Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Aug-19-2020 15:42:05 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BPLCW2 | Initial Entry |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (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:** 1042**Site Name:** (1042) HealthFirst Medical Group**Subject No:** 10421129**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Data Origin**

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Aug-19-2020 15:42:29 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Aug-19-2020 15:42:29 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------------|---|---|
| Aug-19-2020 15:42:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Aug-19-2020 15:42:29 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Aug-19-2020 15:42:29 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: YES Date of Collection: Aug/19/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------------|--|---------------|
| Aug-19-2020 15:42:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: Sample ID: BN5R6G | Initial Entry |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Aug-19-2020 15:42:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BN5R6G | Initial Entry |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Aug-19-2020 15:37:18 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Aug-19-2020 15:37:18 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BLINDED THERAPY | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Aug-19-2020 15:37:18 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INJECTION | Initial Entry |

4. Dose Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Aug-19-2020 15:37:18 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/19/2020 10:09 | Initial Entry |

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Aug-19-2020 15:37:18 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|----------------------|-----------------|---------------------|--------------------|---------------|
| Aug-19-2020 15:37:18 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (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: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

| | | | | |
|--|--|---------------------|------|--|
| (UTC-06:00) Central Time (US & Canada) | | (b) (4), (b) (6) | LEFT | |
|--|--|---------------------|------|--|

7. Route:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Aug-19-2020 15:37:18 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Aug-19-2020 15:37:18 (UTC-06:00) Central 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-19-2020 15:37:18 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Select appropriate response - Reactogenicity diary collection

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------------|--|---------------|
| Aug-19-2020 15:37:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: NO - REACTOGENICITY E-DI ARY NOT COLLECTED FOR T HIS SUBJECT | Initial Entry |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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I. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Sep-09-2020 17:18:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/9/2020 | Initial Entry |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Sep-09-2020 17:19:07 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/9/2020 | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-09-2020 17:19:07 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier 1 : Temperature: 97.4 Temperature Unit F : Temperature Loc ORAL CAV ation: ITY | Initial Entry |

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Sep-09-2020 17:19:07 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

2.a Temperature:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------|---------------|
| Sep-09-2020 17:19:07 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 97.4 | Initial Entry |

2.a Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Sep-09-2020 17:19:07 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: F | Initial Entry |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

2.a Temperature Location:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|-----------------------------------|---------------|
| Sep-09-2020 17:19:07 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ORAL CAVITY | Initial Entry |

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: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Lab Panel:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Sep-09-2020 17:19:39 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: URINALYSIS | Initial Entry |

2. Lab Sub-Panel:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Sep-09-2020 17:19:39 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: PREGNANCY | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------------|---------------|
| Sep-09-2020 17:19:39 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/9/2020 | Initial Entry |

4. Laboratory Name and Address (Derived)

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Sep-09-2020 17:19:39 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: STUDY SITE | Initial Entry |

5. Specimen Type:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Sep-09-2020 17:19:39 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: URINE | Initial Entry |

6.a

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

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (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: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

| | | | | |
|---|-----------------|-------------------------|--|---------------|
| Sep-09-2020 17:19:39 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done:: | Initial Entry |
|---|-----------------|-------------------------|--|---------------|

6.a Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------|---------------|
| Sep-09-2020 17:19:39 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 113 | Initial Entry |

6.a Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-09-2020 17:19:39 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Choriogonadotropin Beta_PX113 | Initial Entry |

6.a Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Sep-09-2020 17:19:39 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEGATIVE | Initial Entry |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (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:** 1042**Site Name:** (1042) HealthFirst Medical Group**Subject No:** 10421129**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Data Origin**

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Sep-09-2020 17:19:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Sep-09-2020 17:19:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--|---|
| Sep-09-2020 17:51:13 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Sep-09-2020 17:19:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Sep-09-2020 17:19:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Sep/9/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--|---------------|
| Sep-09-2020 17:51:13 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BN5RDX | 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: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|------------------------------|---------------|
| Sep-09-2020 17:51:13 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BN5RDX | Initial Entry |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Sep-09-2020 17:20:45 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Sep-09-2020 17:20:45 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BLINDED THERAPY | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Sep-09-2020 17:20:45 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INJECTION | Initial Entry |

4. Dose Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-09-2020 17:20:45 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/9/2020 08:52 | Initial Entry |

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Sep-09-2020 17:20:45 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|----------------------|-----------------|------------------|--------------------|---------------|
| Sep-09-2020 17:20:45 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (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: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

| | | | | |
|--|--|---------------------|------|--|
| (UTC-06:00) Central Time (US & Canada) | | (b) (4), (b) (6) | LEFT | |
|--|--|---------------------|------|--|

7. Route:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Sep-09-2020 17:20:45 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Sep-09-2020 17:20:45 (UTC-06:00) Central 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 |
|--|-----------------|---------------------|---------------------------|---------------|
| Sep-09-2020 17:20:45 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-09-2020 12:00:47 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

2. Erroneous Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-09-2020 12:00:47 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Mar-05-2021 07:21:47 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Mar-05-2021 07:21:47 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Mar-05-2021 07:21:47 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Mar-05-2021 07:21:47 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/10/2020

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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I. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-17-2020 12:22:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/10/2020 | Initial Entry |

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/10/2020

Form: UNPLANNED VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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I. Assessments

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---------------------------------------|---|
| Sep-17-2020 12:23:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Sep-17-2020 12:22:55 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate. |
| Sep-17-2020 12:22:55 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: CONTACT OUTCOME | Initial Entry |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/10/2020

Form Version: 22-Apr-2020 21:04

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Contact Type:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Sep-17-2020 12:23:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: TELEPHONE VISIT | Initial Entry |

2. Was contact made?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-17-2020 12:23:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Contact: Sep/10/2020 Contact Outcome: VISIT NOT REQUIRED, IN VESTIGATOR DECISION | Initial Entry |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Incomplete, Queries, Verified

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date of Completion/Discontinuation/Death :

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|-----------------|
| Mar-02-2021 07:27:54 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | New Information |
| Nov-09-2020 11:59:10 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/19/2020 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------------|-----------------|
| Mar-02-2021 07:27:54 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: | New Information |
| Nov-09-2020 11:59:10 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: VACCINATION | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------|---|
| Mar-12-2021 16:05:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Hayley Wyper (b) (4) | Query 2: Reissued:Opened | CLINQUERY: Please complete this page for this subject who was initially LTFU but has returned to the study in the open label phase. Per CCRs status OTHER should be used and clarify prior LTFU subject has re-joined trial for revaccination phase. |
| Mar-05-2021 16:43:05 (UTC-06:00) Central | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | waiting for subject visit |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Incomplete, Queries, Verified

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

| | | | | |
|---|-----------------|---------------------------|--------------------------|--|
| Time (US & Canada) | | | | |
| Mar-04-2021 11:30:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Hayley Wyper (b) (4) | Query 2: Reissued:Opened | CLINQUERY: Page needed for snapshot - please complete page to reflect reason and date for missed Visit 3. |
| Mar-03-2021 07:29:41 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | Will enter data after subject comes for visit 4 |
| Mar-02-2021 13:59:19 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Hayley Wyper (b) (4) | Query 2: Reissued:Opened | CLINQUERY: EOT still needs to be done since the time has passed to complete the Visit 3. Please capture date and status to match to missing the Visit 3 in October. Please review prior query in chain for instruction on switching a previous LTFU status |
| Mar-02-2021 07:28:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Answered | New Information |
| Mar-02-2021 07:28:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | New Information |
| Mar-01-2021 05:11:39 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Hayley Wyper (b) (4) | Query 2: Opened | CLINQUERY: Please update this status (and specify status) field for this subject who has returned to the study in the open label phase. Per CCRs status OTHER should be used and |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Incomplete, Queries, Verified

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

| | | | | |
|--|-----------------|-------------------------|---|--|
| | | | | clarify prior LTFU subject has re-joined trial for revaccination phase |
| Nov-10-2020 09:39:35 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Ahmed Hassan (b) (4) | Query 1: Closed | Response satisfies query |
| Nov-10-2020 08:15:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Changed data per query |
| Nov-10-2020 05:52:24 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Ahmed Hassan (b) (4) | Query 1: Opened | Clin: Subject is listed to be lost to follow up, however, the FUP page is blank. Please review/update as appropriate. Thanks |
| Nov-09-2020 11:59:10 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LOST TO FOLLOW-UP | Initial Entry |

4. Specify Status:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|-----------------|
| Mar-02-2021 07:28:22 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | New Information |
| Nov-09-2020 11:59:10 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Lost to follow up after unsuccessful attempts to make contact. | Initial Entry |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001**Visit:** Follow-Up - Unscheduled**Form Version:** 15-Sep-2020 21:53**Site No:** 1042**Subject No:** 10421129**Generated By:** (b) (4)**Form:** DISPOSITION - FOLLOW-UP - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1042) HealthFirst Medical Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Date of Completion/Discontinuation/Death :**

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---|
| Mar-02-2021 11:11:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Mar-02-2021 07:29:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Changed data per query |
| Mar-02-2021 07:29:10 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |
| Mar-01-2021 23:51:34 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | DM: Kindly consider to update this form if require else mark as Not applicable by selecting form level comment. Thank you. |
| Feb-23-2021 15:50:17 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | New Information |
| Feb-23-2021 15:33:58 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/19/2020 | Initial Entry |
| Feb-12-2021 15:27:07 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Transcription Error |
| Nov-10-2020 08:15:12 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/19/2020 | Initial Entry |

2. Phase of Disposition:

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

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

| | | | | |
|---|-----------------|-------------------------|--------------------------------------|---------------------|
| Mar-02-2021 07:29:10 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Not Applicable | Initial Entry |
| Feb-23-2021 15:50:17 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: | New Information |
| Feb-23-2021 15:33:58 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: FOLLOW-UP | Initial Entry |
| Feb-12-2021 15:27:07 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: | Transcription Error |
| Nov-10-2020 08:15:12 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: FOLLOW-UP | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------------|--------------------------------------|---|
| Mar-02-2021 07:29:10 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Data Entry: Not Applicable | Initial Entry |
| Feb-27-2021 13:37:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Hayley Wyper (b) (4) | Query 2: Closed | Response satisfies query |
| Feb-25-2021 12:55:58 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Query 2: Answered | Subject was never really lost to follow up. They are still in the study |
| Feb-24-2021 06:35:47 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Hayley Wyper (b) (4) | Query 2: Opened | CLINQUERY: Subject was originally reported as Lost to Follow Up both at EOT and FUP (end of study). Please clarify clearing of form - has the subject returned to study? |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001**Visit:** Follow-Up - Unscheduled**Form Version:** 15-Sep-2020 21:53**Site No:** 1042**Subject No:** 10421129**Generated By:** (b) (4)**Form:** DISPOSITION - FOLLOW-UP - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1042) HealthFirst Medical Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44

| | | | | |
|---|-----------------|-----------------------------------|---|--|
| Feb-23-2021 15:50:28 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: | New Information |
| Feb-23-2021 15:34:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Feb-23-2021 15:33:58 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | Response to "Status" is LOST TO FOLLOW-UP but "Specify Status" is missing. |
| Feb-23-2021 15:33:58 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: LOST TO FOLLOW-UP | Initial Entry |
| Feb-12-2021 15:27:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: | Transcription Error |
| Nov-10-2020 08:15:12 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: LOST TO FOLLOW-UP | Initial Entry |

4. Specify Status:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------------|--|---------------------|
| Mar-02-2021 07:29:10 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: Not Applicable | Initial Entry |
| Feb-23-2021 15:50:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: | Transcription Error |
| Feb-23-2021 15:34:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: Subject is lost to follow up after unsuccessful attempts to make c ontact and follow up. | Initial Entry |
| Feb-12-2021 15:27:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: | Transcription Error |
| Nov-10-2020 08:15:12 (UTC-06:00) Central | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: Lost to follow up after unsuccess | Initial Entry |

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Time (US & Canada)

ful attempts to make contact.

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

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Form Status:

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| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--------------|--------|
| Feb-12-2021 11:45:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Category:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Feb-12-2021 11:45:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------|---------------|
| Feb-12-2021 11:45:27 (UTC-06:00) Central 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-25-2021 17:29:29 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Response satisfies query |
| Feb-25-2021 12:57:19 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | Changed data per query |
| Feb-23-2021 19:47:34 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | Clinical Event term is EDP; however, PG safety report term is still Pregnancy. Please submit a PG safety update with the EDP term [per 3 Nov EDP guidance (study communication)]. |
| Feb-23-2021 19:46:23 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | reissuing |
| Feb-23-2021 13:47:09 (UTC-06:00) Central | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Candid ate | Pending SDB update |

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Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

| | | | | |
|--|-----------------|---------------------------|---|--|
| Time (US & Canada) | | | | |
| Feb-23-2021 13:39:05 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Update was submitted |
| Feb-23-2021 13:33:14 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Open ed | SAE RECON1: Thanks for the response. Please confirm submission of follow up SAE form to update the term in safety database. |
| Feb-23-2021 07:33:12 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | New Information |
| Feb-23-2021 07:33:12 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Exposure during Pregnan cy | New Information |
| Feb-15-2021 05:08:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | SAE RECON:AER#2021123853, the term in both database was recorded as 'pregnancy'. Per 3 Nov EDP guidance (study communication), term should be recorded as Exposure during pregnancy. Please confirm and update accordingly |
| Feb-12-2021 11:45:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Pregnancy | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------|---|
| Mar-12-2021 07:05:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | exposure during pregnancy would be the day and time |

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Generated By: (b) (4)

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Form Status: Data Complete, Answered Queries

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

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| | | | | |
|--|-----------------|---------------------------|--------------------------|---|
| | | | | they were first vaccinated |
| Mar-11-2021 20:49:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Opened | Clinical - there was no alteration in PG start date in 10Mar21 update. The new estimated date of conception (24Jul20) should be used as PG start date, in both AE and PG Safety report; please update both locations. |
| Mar-10-2021 16:30:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | updated |
| Mar-08-2021 07:00:13 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Opened | Clinical - Thank you; however, Safety unit does not have this updated start date of (19Aug2020). Please submit an update with this date ASAP |
| Mar-05-2021 07:23:24 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | THis has already been submitted in a follow-up report |
| Mar-04-2021 17:26:43 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Opened | Clinical - thank you; please submit the updated start date (is this also the updated date of conception) to the SAE report |
| Mar-02-2021 11:33:21 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 4: Closed | Close Auto Query |

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Header Text: c4591001

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Subject No: 10421129

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

| | | | | |
|---|-----------------|---------------------------|---|---|
| Mar-02-2021 11:33:21 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/19/2020 10:09 | New Information |
| Mar-02-2021 11:32:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 4: Opened | For AE Exposure during Pregnancy : Start Date is the same as a Vaccination Date, but time is not provided. Please review and update as appropriate. |
| Mar-02-2021 11:32:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 3: Closed | Close Auto Query |
| Mar-02-2021 11:32:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Closed | Close Auto Query |
| Mar-02-2021 11:32:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/19/2020 UNK:UNK | New Information |
| Mar-02-2021 11:31:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 3: Opened | For Exposure during Pregnancy : Start date 24/Jul/2020 is before VID1VX1L visit date 19/Aug /2020. Please review and update as appropriate. |
| Mar-02-2021 11:31:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Opened | Start date is before Consent Date 19/Aug/2020. |
| Mar-02-2021 11:31:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | New Information |
| Mar-02-2021 11:31:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jul/24/2020 UNK:UNK | New Information |

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Generated By: (b) (4)

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Form Status: Data Complete, Answered Queries

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Subject Initials: ---

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| | | | | |
|---|-----------------|---------------------|--|--|
| Mar-02-2021 10:35:59 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | Clinical - please clarify if there is an estimated date of Conception on 24Jul2020 (currently showing in event narrative; this would be 2 days after LMP on 22Jul2020). If correct, please update start date to date of Conception (or, LMP) in AE & PG report |
| Feb-12-2021 11:45:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/UNK/2020 UNK:UNK | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|-------------------|--|
| Feb-23-2021 19:43:07 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Closed | Response satisfies query |
| Feb-23-2021 15:49:34 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Answered | Original value is correct |
| Feb-23-2021 15:33:58 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 3: Opened | 'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate. |
| Feb-16-2021 14:58:24 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | incorrect location to query |
| Feb-15-2021 21:55:12 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | CLINL CAL As per CRF CG 8.50.2.5, an "Exposure |

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Subject Initials: ---

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| | | | | |
|---|-----------------|------------------------|---------------------------|---|
| | | | | During Pregnancy” is not an SAE [despite using similar forms to report pregnancy]; only abnormal outcomes of pregnancy are evaluated for serious criteria |
| Feb-12-2021 15:27:07 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Feb-12-2021 11:45:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | 'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate. |
| Feb-12-2021 11:45:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|--------------------------------------|--------------------------|
| Feb-23-2021 14:42:21 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Feb-23-2021 07:33:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |
| Feb-23-2021 07:33:39 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | New Information |
| Feb-23-2021 07:33:39 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | New Information |

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Subject Initials: ---

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| | | | | |
|---|-----------------|---------------------|-------------------------|---|
| Feb-15-2021 21:53:07 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | Clinical As per CRF CG 8.50.2.5, the toxicity grade for "Exposure During Pregnancy" is reported as Not Applicable |
| Feb-12-2021 11:45:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 3 | Initial Entry |

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|-------------------|-----------------------------|
| Feb-23-2021 14:42:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Closed | Response satisfies query |
| Feb-23-2021 13:33:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Response satisfies query |
| Feb-23-2021 07:34:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 4: Deleted | Close Auto Query |
| Feb-23-2021 07:34:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 3: Answered | New Information |
| Feb-23-2021 07:34:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Answered | New Information |

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Subject No: 10421129

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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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-23-2021 07:34:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | New Information |
| Feb-23-2021 07:33:12 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 4: Candidate | For AE Exposure during Pregnancy : Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank. |
| Feb-16-2021 14:58:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Opened | CLINLCA As per CRF CG 8.50.2.5, an "Exposure During Pregnancy" is not an SAE [despite using similar forms to report pregnancy]; only abnormal outcomes of pregnancy are evaluated for serious criteria |
| Feb-15-2021 05:09:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | SAE RECON: AER#2021123853,'EXPOSURE DURING PREGNANCY' event was appropriately reported to safety; however, seriousness criteria is met there is an abnormal pregnancy outcome/protocol section 8.3.5.1. Please update seriousness criteria accordingly. |
| Feb-15-2021 05:08:19 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Deleted | Query can be addressed internally |

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Generated By: (b) (4)

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| | | | | |
|---|-----------------|---------------------------|---|--|
| Canada) | | | | |
| Feb-12-2021 11:45:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | For AE Pregnancy : Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank. |
| Feb-12-2021 11:45:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Is this serious event associated with cong enital anomaly or bir th defect? NO Did this serious even t result in death? NO Did this serious even t require or prolong h ospitalization? NO Did this serious even t result in persistent or significant disabili ty/incapacity? NO Is this serious event l ife threatening? NO Other medically imp ortant serious event YES | Initial Entry |

8. Is this adverse event the result of a study Medication Error?

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Subject No: 10421129

Generated By: (b) (4)

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Subject Initials: ---

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If Yes, record the type of medication error on the Medication Error Log.

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Feb-12-2021 11:45:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

9. Is this event related to study treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------|--|
| Feb-23-2021 19:41:37 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Response satisfies query |
| Feb-23-2021 16:46:22 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | Not related to study drug. Only the exposure is. |
| Feb-23-2021 14:44:22 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | requeried |
| Feb-23-2021 14:43:59 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | Clinical - please clarify; is the intention to state that pregnancy was related to 'Drug Ineffective' for BNT study vaccine. |
| Feb-23-2021 07:35:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Original value is correct |
| Feb-18-2021 09:32:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | CLINICAL - Event is Not Related to study drug; however, PG safety report (2021123853) states related to BOTH Depo-Provera and study drug due to 'Drug Ineffective'. Please review |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

| | | | | |
|---|-----------------|------------------|---|--|
| | | | | Relatedness to study drug, and update where applicable |
| Feb-12-2021 11:45:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Birth Control Failure | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Feb-12-2021 11:45:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Feb-12-2021 11:45:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Feb-12-2021 11:45:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-----------------|--------------------------|
| Feb-23-2021 19:42:18 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Response satisfies query |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

| | | | | |
|---|-----------------|---------------------------|-------------------------------|---|
| Feb-23-2021 07:35:28 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | Original value is correct |
| Feb-23-2021 07:33:12 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Opened | For AE Exposure during Pregnancy : Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes". |
| Feb-15-2021 08:34:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Feb-12-2021 15:29:02 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Original value is correct |
| Feb-12-2021 11:45:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | For AE Pregnancy : Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes". |
| Feb-12-2021 11:45:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNKNOWN | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Feb-12-2021 11:45:27 (UTC-06:00) Central | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

| | |
|--------------------|------------------|
| Time (US & Canada) | (b) (4), (b) (6) |
|--------------------|------------------|

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Verified

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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I. Date of Visit

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---|
| Mar-09-2021 15:03:26 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Rei ssued: Candi date | waiting for subject visit |
| Mar-08-2021 16:57:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: An swere d | still missing visit |
| Mar-08-2021 10:16:45 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Rei ssued: Opene d | DM: Thank you for your response, please update missing visit per query response. |
| Mar-05-2021 16:43:22 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: An swere d | waiting for subject visit |
| Mar-04-2021 23:53:39 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Rei ssued: Opene d | DM1: Thanks for your response. DOV is entered for Revax Contact but Disposition Treatment at END_OF_TRT visit is null. Please consider to update as appropriate. |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Verified

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

| | | | | |
|--|---|------------------------------------|--|---|
| Mar-04-2021 10:00:29 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Query 1: An swere d | Subject coming in for visit 4 today |
| Mar-03-2021 04:35:28 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY (b) (4) [REDACTED] | Query 1: Op ened | DMW7582548;DOV is entered for Revax Contact but Disposition Treatment at END_OF_TRT visit is null. Please review and update as appropriate. |
| Mar-02-2021 18:31:45 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry : Feb/4/ 2021 | Initial Entry |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|---|---------------|
| Mar-02-2021 18:32:00 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2 | Initial Entry |

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Date Treatment Unblinded :

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Mar-02-2021 18:31:23 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/4/2021 | Initial Entry |

2. Primary Reason for Unblinding:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Mar-02-2021 18:31:23 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION | Initial Entry |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1042

Subject No: 10421129

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1042) HealthFirst Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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1. Subject Status

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------------|
| Mar-02-2021 07:28:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ENROLLED/RANDOMIZED | New Information |
| Feb-23-2021 15:50:28 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DISCONTINUED | New Information |
| Feb-23-2021 15:33:58 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DISCONTINUED | Initial Entry |
| Feb-12-2021 15:27:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DISCONTINUED | Transcription Error |
| Nov-10-2020 08:15:12 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DISCONTINUED | Initial Entry |
| Nov-09-2020 11:59:10 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DISCONTINUED | Initial Entry |
| Aug-19-2020 15:36:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ENROLLED/RANDOMIZED | Initial Entry |
| Aug-19-2020 15:33:05 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SCREENED | Initial Entry |

2. Subject Status Date

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|-------------------|--|
| Mar-05-2021 08:12:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Response satisfies query |
| Mar-04-2021 09:56:29 (UTC-06:00) Central | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | Visit 3 not done, pending for visit 4 |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (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: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

| Time (US & Canada) | | | | |
|---|-----------------|-------------------------|-----------------------------------|--|
| Mar-02-2021 10:51:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Reissued:Opened | DM: Please complete the Disposition - Treatment (EOT) CRF if the subject received at least 1 vaccination and Visit 2 or Visit 3 was not performed (Note: Status should not be COMPLETED). See FAQ #3 in CRFCGs for further instructions. |
| Mar-02-2021 07:31:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | Changed data per query |
| Mar-02-2021 07:28:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Aug/19/2020 | New Information |
| Mar-02-2021 07:27:54 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Aug/19/2020 | New Information |
| Mar-01-2021 11:18:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Reissued:Opened | DM: Please update data per query response provided. Thank you. |
| Feb-26-2021 07:32:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | waiting for page to be unlocked |
| Feb-26-2021 06:03:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Reissued:Opened | DM 2: Per the response "Subject is still in the study" please verify and update data as appropriate on EOT page as on EOT page "Lost to follow up" reason is |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (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: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

| | | | | |
|--|-----------------|-------------------------|-----------------------------------|--|
| | | | | provided. Thank you. |
| Feb-25-2021 23:15:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Feb-25-2021 14:56:28 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | Subject is still in the study |
| Feb-25-2021 08:22:07 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Reissued:Opened | DM 1: Thanks for the response, however data is missing for FUP visit. Please review and update as appropriate, else clarify. |
| Feb-24-2021 13:15:19 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | Original value is correct |
| Feb-24-2021 08:50:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Reissued:Opened | Per site comment "Changed data per query", however data is missing for FUP visit. Please review and update as appropriate. Else clarify. |
| Feb-23-2021 16:46:53 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | Changed data per query |
| Feb-23-2021 15:50:28 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Oct/19/2020 | New Information |
| Feb-23-2021 15:50:17 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Oct/19/2020 | New Information |
| Feb-23-2021 15:33:58 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Oct/19/2020 | Initial Entry |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (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: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

| | | | | |
|---|-----------------|-------------------------|-----------------------------------|--|
| Feb-15-2021 02:34:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | DM: Subject is lost to follow up. If correct, update FUP visit or else clarify. Thank you. |
| Feb-12-2021 15:28:17 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Changed data per query |
| Feb-12-2021 15:27:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Oct/19/2020 | Transcription Error |
| Feb-12-2021 15:27:07 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Oct/19/2020 | Transcription Error |
| Feb-12-2021 09:54:45 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | Clinical PG Safety report (#2021123853) received for subject's pregnancy with start date ??Aug2020. Please enter event on the Adverse Event form, following pregnancy reporting guidelines |
| Nov-10-2020 08:15:12 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Oct/19/2020 | Initial Entry |
| Nov-09-2020 11:59:10 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Oct/19/2020 | Initial Entry |
| Aug-19-2020 15:36:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Aug/19/2020 | Initial Entry |
| Aug-19-2020 15:33:05 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Aug/19/2020 | Initial Entry |

090177e196ae3e46\Final\Final On: 01-Apr-2021 04:50 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1042

Site Name: (1042) HealthFirst Medical Group

Subject No: 10421129

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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I. Casebook Signature

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Nov-09-2020 16:40:22 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Click Here to Enable | Initial Entry |