

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: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[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 |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Informed Consent

| | | |
|----|--------------|--|
| 1. | Consent Was: | OBTAINED Date Written Consent Obtained Aug/11/2020 |
|----|--------------|--|

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Demography

| | | |
|----|---------------------------------|--|
| 1. | Subject ID | [11421073] |
| 2. | Birth Date: | (b) (6) 1958 |
| 3. | Sex: | FEMALE |
| 4. | Ethnicity: | NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN |
| 5. | Race: (Check X all that apply): | WHITE |
| 6. | Racial Designation: | |

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Aug/11/2020 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1142

Subject No: 11421073

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1142) University of Texas - Galveston

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1142

Subject No: 11421073

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1142) University of Texas - Galveston

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Disposition - Screening

| | | |
|----|---|-------------|
| 1. | Date of Completion/Discontinuation /Death | Aug/11/2020 |
| 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: 1142

Subject No: 11421073

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1142) University of Texas - Galveston

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[Form Comments](#)

[eCRF Audit Trail History](#)

Medical History Details

| | | |
|-----|--|---------------------------------|
| 1.a | Line/MH Number: | [1] |
| | Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies: | [History of smoking] |
| | Start Date: | UNK/UNK/1975 |
| | Ongoing: | NO End Date: UNK/UNK/2006 |

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Vital Signs

| | | |
|----|------------------|-------------|
| 1. | Date: | Aug/11/2020 |
| 2. | Weight: | [197.7] |
| 3. | Unit: | LB |
| 4. | Height: | [70.0] |
| 5. | Unit: | in |
| 6. | Body Mass Index: | [28.4] |

Vital Signs Details

| | | |
|-----|-----------------------|-------------|
| 7.a | Record Identifier: | 1 |
| | Temperature: | [97.6] |
| | Unit: | F |
| | Temperature Location: | ORAL CAVITY |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1142

Subject No: 11421073

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1142) University of Texas - Galveston

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[Form Comments](#)

[eCRF Audit Trail History](#)

Lab Urinalysis

| | | |
|----|---------------------------------------|--------------|
| 1. | Lab Panel: | URINALYSIS |
| 2. | Lab Sub-Panel: | PREGNANCY |
| 3. | Collection Date: | Aug/11/2020 |
| 4. | Laboratory Name and Address (Derived) | [STUDY SITE] |
| 5. | Specimen Type: | URINE |

Lab Result

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

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1142

Subject No: 11421073

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1142) University of Texas - Galveston

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Disposition

| | | |
|----|-----------------------|-------------|
| 1. | Randomization Date : | Aug/11/2020 |
| 2. | Randomization Number: | [225059] |
| 3. | Randomization Group: | [] |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Aug/11/2020 |
| 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 | [BM7YPPF] |
| 5.b | Sample ID | [BM7YPG] |
| 5.c | Sample ID | [BM7YPH] |
| 5.d | Sample ID | [BLCBB8] |
| 5.e | Sample ID | [BLCBB9] |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1142**Site Name:** (1142) University of Texas - Galveston**Subject No:** 11421073**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44[eCRF Audit Trail History](#)**Electronic Sample Tracking**

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Aug/11/2020 |
| 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 | [BM7YNV] |
|-----|-----------|----------|

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1142

Subject No: 11421073

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1142) University of Texas - Galveston

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[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/11/2020 10:28 |
| 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 |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1142

Subject No: 11421073

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1142) University of Texas - Galveston

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

Header Text: c4591001

Visit: V2_VAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Date of Visit

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

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

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

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | |
|-----|--|-------------------------------|
| 2.d | Symptom: | CHILLS |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.e | Symptom: | VOMITING |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.f | Symptom: | DIARRHEA |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.g | Symptom: | NEW OR WORSENERED MUSCLE PAIN |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.h | Symptom: | NEW OR WORSENERED JOINT PAIN |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 3. | Injection Site Location: | DELTOID MUSCLE |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1142

Subject No: 11421073

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1142) University of Texas - Galveston

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Vital Signs

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

Vital Signs Details

| | | |
|-----|-----------------------|-------------|
| 2.a | Record Identifier: | 1 |
| | Temperature: | [98.3] |
| | Unit: | F |
| | Temperature Location: | ORAL CAVITY |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1142

Subject No: 11421073

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1142) University of Texas - Galveston

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Lab Urinalysis

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

Lab Result

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

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|--|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Sep/1/2020 |
| 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 | [BP9TX7] |
|-----|-----------|----------|

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[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/1/2020 14:14 |
| 5. | Anatomical Location: | DELTOID MUSCLE |
| 6. | Body Side: | LEFT |
| 7. | Route: | INTRAMUSCULAR |
| 8. | Actual Dose: | [] |
| 9. | Unit: | |
| 10. | Timeframe Subject Was Observed | THE PROTOCOL SPECIFIED OBSERVATION PERIOD |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | YES |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1142 **Site Name:** (1142) University of Texas - Galveston

Subject No: 11421073 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

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

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

Site No: 1142 **Site Name:** (1142) University of Texas - Galveston

Subject No: 11421073 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

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

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

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

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

Site No: 1142 **Site Name:** (1142) University of Texas - Galveston

Subject No: 11421073 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

| | | |
|-----|--|-------------------------------|
| 2.d | Symptom: | CHILLS |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.e | Symptom: | VOMITING |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.f | Symptom: | DIARRHEA |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.g | Symptom: | NEW OR WORSENERED MUSCLE PAIN |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.h | Symptom: | NEW OR WORSENERED JOINT PAIN |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 3. | Injection Site Location: | DELTOID MUSCLE |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

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

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

Site No: 1142 **Site Name:** (1142) University of Texas - Galveston

Subject No: 11421073 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

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

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1142 **Site Name:** (1142) University of Texas - Galveston

Subject No: 11421073 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|--|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Oct/2/2020 |
| 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 | [BR91DP] |
|-----|-----------|----------|

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1142

Subject No: 11421073

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1142) University of Texas - Galveston

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Feb/24/2021 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Feb/24/2021 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BR4782] |
| 5.b | Sample ID | [BRWKH9] |
| 5.c | Sample ID | [BRWKGW] |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1142

Subject No: 11421073

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1142) University of Texas - Galveston

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

Date of Visit

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

Header Text: c4591001

Visit: V5_MONTH12_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1142

Subject No: 11421073

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1142) University of Texas - Galveston

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

Date of Visit

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

Header Text: c4591001

Visit: V6_MONTH24_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (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: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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 Version: 20-Feb-2021 02:17

Site No: 1142

Subject No: 11421073

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Not Started

Site Name: (1142) University of Texas - Galveston

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1142

Subject No: 11421073

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

Form Status: Not Started

Site Name: (1142) University of Texas - Galveston

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1142

Subject No: 11421073

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Status: Not Started

Site Name: (1142) University of Texas - Galveston

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (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: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Illness Details

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

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (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: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled **Form:** DATE OF VISIT
Visit

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

Site No: 1142 **Site Name:** (1142) University of Texas - Galveston

Subject No: 11421073 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

Date of Visit

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

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit **Form:** UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04 **Form Status:** Not Started

Site No: 1142 **Site Name:** (1142) University of Texas - Galveston

Subject No: 11421073 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

Unplanned Assessments

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

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Disposition - Treatment

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

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Disposition - Follow-Up

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

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

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

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

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Date of Visit

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

COVID-19 Repeat Swab

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

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

Site No: 1142 **Site Name:** (1142) University of Texas - Galveston

Subject No: 11421073 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

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

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| # | Category | AE Identifier | Adverse Event | Start Date | Is the Adverse Event Still Ongoing | Form Instance |
|----|---------------|---------------|---------------------------|------------------------|------------------------------------|---------------------------------|
| 1. | ADVERSE EVENT | 1 | Ascending Aortic Aneurysm | Jan/4/2021 U NK:UNK | YES | Repeating Pages |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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[Form Audit Trail](#)

Adverse Event Report

| | | |
|----|--|-----------------------------|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [1] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [Ascending Aortic Aneurysm] |
| 4. | Start Date Time: | Jan/4/2021 UNK:UNK |
| 5. | Is the adverse event still ongoing? | YES |
| 6. | Toxicity Grade: | 4 |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1142

Subject No: 11421073

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1142) University of Texas - Galveston

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

| | | |
|-----|---|--|
| 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). | YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES Other medically important serious event NO |
| 8. | Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log. | 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: [Unknown] |
| 10. | Latest Action Taken with Study Treatment: | NOT APPLICABLE |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | |
|-----|--|----------------------|
| 11. | Was a Concomitant Medication given? | NO |
| 12. | Was a Non-Drug Treatment given? | YES |
| 13. | What was the outcome of this adverse event?: | RECOVERING/RESOLVING |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO |
| 15. | Serious Adverse Event Number: For Pfizer Use Only | [2021015979] |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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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 | [] |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| # | 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: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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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: | // |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| # | 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: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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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? | |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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Radiation Treatment

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

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[Back to Form](#)

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Vital Signs

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

Vital Signs Details

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

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (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: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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: | |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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? | |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (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: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Contact Outcome

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** DATE OF VISIT
Unscheduled

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

Site No: 1142 **Site Name:** (1142) University of Texas - Galveston

Subject No: 11421073 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

Date of Visit

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

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: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1142 **Site Name:** (1142) University of Texas - Galveston

Subject No: 11421073 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

| Date of Visit | | |
|---------------|-----------------|-------------|
| 1. | Date of Visit | Dec/15/2020 |
| 2. | Erroneous Visit | |

Header Text: c4591001

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

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

Site No: 1142 **Site Name:** (1142) University of Texas - Galveston

Subject No: 11421073 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

[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 |
|----|---|---|

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Treatment Unblinded

| | | |
|----|--------------------------------|---|
| 1. | Date Treatment Unblinded : | Dec/16/2020 |
| 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: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Subject Status

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

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[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, Signed, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[Audit Trail](#)

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

- CRF_Sign

| Name | Signature Meaning | Date | Type | Action |
|--------------|-------------------|--|------|--------|
| Richard Rupp | Approved | Mar-09-2021 14:12:49 (UTC-06:00) Central Time (US & Canada) | BOOK | Signed |

Affidavit:

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

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

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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| Item | Date | User | Comment |
|------|---|---------------------|----------------|
| Form | Aug-11-2020 13:07:30 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not applicable |
| | | | Not Applicable |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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| Item | Date | User | Comment |
|------|--|-----------------------------------|--|
| Form | Feb-04-2021 17:46:43 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not applicable |
| Form | Aug-11-2020 13:08:26 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not applicable <hr/> Not Applicable |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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| Item | Date | User | Comment |
|------|---|---------------------|---|
| Form | Aug-11-2020 13:14:34 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Pt is a post-menopausal female over the age of 60. |

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[Back to Form](#)

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

- CRF_Sign

| Name | Signature Meaning | Date | Type | Action |
|--------------|-------------------|--|------|--------|
| Richard Rupp | Approved | Mar-09-2021 14:12:49 (UTC-06:00) Central Time (US & Canada) | BOOK | Signed |

Affidavit:

By my dated signature below, I, RichardRupp, 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 | Jan-27-2021 15:30:51 (UTC-06:00) Central Time (US & Canada) | | Edit - All signatures invalidated |
|---------|-----|--|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|--------------|----------|--|------|--------|
| Richard Rupp | Approved | Jan-22-2021 08:11:31 (UTC-06:00) Central Time (US & Canada) | BOOK | Signed |
|--------------|----------|--|------|--------|

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Affidavit:

By my dated signature below, I, RichardRupp, 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 | Dec-17-2020 16:08:22 (UTC-06:00) Central Time (US & Canada) | | Edit - All signatures invalidated |
|---------|-----|--|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|--------------|----------|--|------|--------|
| Richard Rupp | Approved | Oct-12-2020 11:48:28 (UTC-06:00) Central Time (US & Canada) | BOOK | Signed |
|--------------|----------|--|------|--------|

Affidavit:

By my dated signature below, I, RichardRupp, 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.

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|---------|-----|--|--|-----------------------------------|
| (b) (6) | N/A | Oct-02-2020 11:15:55 (UTC-06:00) Central Time (US & Canada) | | Edit - All signatures invalidated |
|---------|-----|--|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|--------------|----------|--|------|--------|
| Richard Rupp | Approved | Sep-16-2020 17:38:06 (UTC-06:00) Central Time (US & Canada) | BOOK | Signed |
|--------------|----------|--|------|--------|

Affidavit:

By my dated signature below, I, RichardRupp, 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.

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (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: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[Back to Form](#)

1. Select appropriate response - Protocol version

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Aug-11-2020 13:06:17 (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-11-2020 13:06:17 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: STAGE 3 COHORT S | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Consent Was:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Aug-11-2020 13:06:24 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: OBTAINED Date Written Cons ent Obtained Aug/11/2020 | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1142

Subject No: 11421073

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1142) University of Texas - Galveston

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[Back to Form](#)

1. Subject ID

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------|--------------------------------------|
| Aug-11-2020 13:06:06 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 11421073 | Item copied from previous form |

2. Birth Date:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|------------------------------------|---------------------|
| Aug-11-2020 13:06:02 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: (b) (6) 1958 | Enrollment Entry |

3. Sex:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Aug-11-2020 13:06:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: FEMALE | Initial Entry |

4. Ethnicity:

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

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|---|-----------------|---------------------|---|---------------|
| Aug-11-2020 13:06:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT HISPANIC O R LATINO(A) OR OF SPANISH ORI GIN | Initial Entry |
|---|-----------------|---------------------|---|---------------|

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------|---------------|
| Aug-11-2020 13:06:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: WHITE | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1142

Subject No: 11421073

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1142) University of Texas - Galveston

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Aug-11-2020 13:06:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/11/2020 | Initial Entry |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Date of Completion/Discontinuation/Death

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Aug-11-2020 13:07:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/11/2020 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Aug-11-2020 13:07:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SCREENING | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------------|---------------|
| Aug-11-2020 13:07:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1.a

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Feb-04-2021 17:51:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH 1 Number: Medical H History of istory Ter smoking m: Start Date UNK/UN : K/1975 Ongoing: NO End Date : UNK/U NK/200 6 | Initial Entry |

1.a Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Feb-04-2021 17:51:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 1 | Initial Entry |

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

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------------|--|---------------|
| Feb-04-2021 17:51:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: History of smoking | Initial Entry |

1.a Start Date:

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------------|------------------------------------|---------------|
| Feb-04-2021 17:51:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: UNK/UNK/1975 | Initial Entry |

1.a Ongoing:

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------------|---|---------------|
| Feb-04-2021 17:51:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: NO End Date: UNK/UNK/2006 | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Aug-11-2020 13:13:31 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/11/2020 | Initial Entry |

2. Weight:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------|---------------|
| Aug-11-2020 13:13:31 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 197.7 | Initial Entry |

3. Unit:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-11-2020 13:13:31 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LB | Initial Entry |

4. Height:

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

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|--|-----------------|---------------------|----------------------------|---------------|
| Aug-11-2020 13:13:31 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 70.0 | Initial Entry |
|--|-----------------|---------------------|----------------------------|---------------|

5. Unit:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-11-2020 13:13:31 (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-11-2020 13:13:31 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 28.4 | Initial Entry |

7.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Aug-11-2020 13:13:31 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Id 1 entifier:: Temperat 97.6 ure: | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | |
|--|--|--|---|
| | | | Temperat F ure Unit: Temperat ORAL ure Locati CAVIT on:: Y |
|--|--|--|---|

7.a Record Identifier:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Aug-11-2020 13:13:31 (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-11-2020 13:13:31 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 97.6 | Initial Entry |

7.a Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Aug-11-2020 13:13:31 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: F | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

7.a Temperature Location:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Aug-11-2020 13:13:31 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ORAL CAVITY | Initial Entry |

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: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Lab Panel:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Aug-11-2020 13:13:42 (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-11-2020 13:13:42 (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-11-2020 13:13:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/11/2020 | Initial Entry |

4. Laboratory Name and Address (Derived)

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

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (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: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Aug-11-2020 13:13:42 (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-11-2020 13:13:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: URINE | Initial Entry |

6.a

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Aug-11-2020 13:13:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor- 113 Defined I dentifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: Not Done NOT DON :: E | Initial Entry |

6.a Sponsor ID:

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (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: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------|---------------|
| Aug-11-2020 13:13:42 (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-11-2020 13:13:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Choriogonadotropin Beta_PX113 | Initial Entry |

6.a Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Aug-11-2020 13:13:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT DONE | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1142

Subject No: 11421073

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1142) University of Texas - Galveston

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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1. Randomization Date :

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Aug-11-2020 13:15:01 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/11/2020 | Initial Entry |

2. Randomization Number:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Aug-11-2020 14:55:24 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 225059 | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1142

Subject No: 11421073

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1142) University of Texas - Galveston

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Aug-11-2020 13:15:11 (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-11-2020 13:15:11 (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-11-2020 14:09:21 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Aug-11-2020 13:15:11 (UTC-06:00) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidat e | 'Sample Collected?' is Yes, however |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (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: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|---|-----------------|------------------|---|--|
| Central Time (US & Canada) | | | | no barcodes are entered. Please review and correct as appropriate. |
| Aug-11-2020 13:15:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Aug/11/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Aug-11-2020 14:09:21 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID BM7YP : F | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Aug-11-2020 14:09:21 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BM7YPF | Initial Entry |

5.b

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (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: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Aug-11-2020 14:09:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID BM7YP : G | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Aug-11-2020 14:09:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BM7YPG | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Aug-11-2020 14:09:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID BM7YP : H | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (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: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

5.c Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Aug-11-2020 14:09:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BM7YPH | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Aug-11-2020 14:10:13 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID BLCBB : 8 | Initial Entry |

5.d Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Aug-11-2020 14:10:13 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BLCBB8 | Initial Entry |

5.e

| Date | Location | User | Value | Reason |
|-------------------------|-----------------|---------------------|---------------------------------------|---------------|
| Aug-11-2020 14:10:21 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID BLCBB | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (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: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | | |
|--|--|------------------|---|---|--|
| (UTC-06:00) Central Time (US & Canada) | | (b) (4), (b) (6) | : | 9 | |
|--|--|------------------|---|---|--|

5.e Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Aug-11-2020 14:10:21 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BLCBB9 | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (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: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Aug-11-2020 13:15:19 (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-11-2020 13:15:19 (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-11-2020 14:11:08 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Aug-11-2020 13:15:19 (UTC-06:00) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidat e | 'Sample Collected?' is Yes, however |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (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: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|---|-----------------|------------------|---|--|
| Central Time (US & Canada) | | | | no barcodes are entered. Please review and correct as appropriate. |
| Aug-11-2020 13:15:19 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Aug/11/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Aug-11-2020 14:11:08 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample I BM7YN D: V | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Aug-11-2020 14:11:08 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BM7YNV | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1142

Subject No: 11421073

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1142) University of Texas - Galveston

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Aug-11-2020 13:15:38 (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-11-2020 13:15:38 (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-11-2020 13:15:38 (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 |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (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: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|---|-----------------|---------------------|---|---------------|
| Aug-11-2020 13:15:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/11/2020 10:28 | Initial Entry |
|---|-----------------|---------------------|---|---------------|

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Aug-11-2020 13:15:38 (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-11-2020 13:15:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LEFT | Initial Entry |

7. Route:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Aug-11-2020 13:15:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (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: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Aug-11-2020 13:15:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Aug-11-2020 13:15:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Select appropriate response - Reactogenicity diary collection

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Aug-11-2020 13:15:45 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES - REACTOGE NICITY E-DIARY COLLECTED FOR THIS SUBJECT | Initial Entry |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1142

Subject No: 11421073

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1142) University of Texas - Galveston

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|--|----------------------------------|---------------|
| Sep-01-2020 16:49:26 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] [Redacted] | Data Entry: Sep/1/2020 | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Sep-01-2020 16:49:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Sep-01-2020 16:49:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: F E V E R Were fever or s N ystemic sympto O ms present on t he last day the S ubject Diary wa s completed?: | Initial Entry |

2.a Symptom:

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

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|---|-----------------|--------------------------------|-----------------------------|---------------|
| Sep-01-2020 16:49:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Data Entry: FEVER | Initial Entry |
|---|-----------------|--------------------------------|-----------------------------|---------------|

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

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------------|--------------------------|---------------|
| Sep-01-2020 16:49:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Data Entry: NO | Initial Entry |

2.b

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------------|---|---------------|
| Sep-01-2020 16:49:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Data Entry: Symptom:: FA TI G U E Were fever or s N ystemic sympto O ms present on t he last day the Subject Diary was completed? : | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

2.b Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------------------|---------------|
| Sep-01-2020 16:49:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: FATIGUE | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Sep-01-2020 16:49:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.c

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Sep-01-2020 16:49:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: HE A D AC HE | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|--|--|--|---|--|
| | | | Were fever or systemic symptoms present on the last day the Subject Diary was completed?: | |
|--|--|--|---|--|

2.c Symptom:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------------|---------------|
| Sep-01-2020 16:49:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: HEADACHE | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Sep-01-2020 16:49:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.d

| Date | Location | User | Value | Reason |
|-------------------------|-----------------|------------------|-----------------------------------|---------------|
| Sep-01-2020 16:49:49 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: C | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|--|--|------------------|-----------------------------|---|
| (UTC-06:00) Central Time (US & Canada) | | (b) (4), (b) (6) | HI L L S N O | Were fever or systemic symptoms present on the last day the Subject Diary was completed?: |
|--|--|------------------|-----------------------------|---|

2.d Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Sep-01-2020 16:49:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> CHILLS | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Sep-01-2020 16:49:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

2.e

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

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|---|-----------------|--------------------------------|---|---------------|
| Sep-01-2020 16:49:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Data Entry: Symptom:: VO MI TI NG Were fever or s NO ystemic sympt oms present on the last day the Subject Diary was completed ?: | Initial Entry |
|---|-----------------|--------------------------------|---|---------------|

2.e Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------------|--------------------------------|---------------|
| Sep-01-2020 16:49:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Data Entry: VOMITING | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------------|--------------------------|---------------|
| Sep-01-2020 16:49:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Data Entry: NO | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

2.f

| Date | Location | User | Value | Reason |
|---|-----------------|--|--|---------------|
| Sep-01-2020 16:49:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] [Redacted] | Data Entry: Symptom:: DI A RR HE A Were fever or s N ystemic sympto O ms present on t he last day the Subject Diary was completed ?: | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY -
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History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

2.f Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|--|--------------------------------|---------------|
| Sep-01-2020 16:49:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] [REDACTED] | Data Entry: DIARRHEA | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|--|--------------------------|---------------|
| Sep-01-2020 16:49:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] [REDACTED] | Data Entry: NO | Initial Entry |

2.g

| Date | Location | User | Value | Reason |
|---|-----------------|--|--|---------------|
| Sep-01-2020 16:49:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] [REDACTED] | Data Entry: Symptom:: NEW OR W ORSE NED MUS CLE P AIN | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|--|--|--|---|----|
| | | | Were fever or systemic symptoms present on the last day the Subject Diary was completed?: | NO |
|--|--|--|---|----|

2.g Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Sep-01-2020 16:49:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR WORSENED MUSCLE PAIN | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-----------------------|---------------|
| Sep-01-2020 16:49:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.h

| Date | Location | User | Value | Reason |
|-------------|-----------------|------------------|--------------------|---------------|
| Sep-01-2020 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

16:49:49
(UTC-06:00)
Central Time (US
& Canada)

(b) (4), (b) (6)

Symptom:: NEW
OR W
ORSE
NED
JOIN
T PAI
N

**Were fever o NO
r systemic sy
mptoms pre
sent on the l
ast day the S
ubject Diary
was complet
ed?:**

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

2.h Symptom:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Sep-01-2020 16:49:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR WORSEN ED JOINT PAIN | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Sep-01-2020 16:49:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

3. Injection Site Location:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------------------|---------------|
| Sep-01-2020 16:49:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

4. Injection Site Body Side:

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

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|---|-----------------|--------------------------------|----------------------------|---------------|
| Sep-01-2020 16:49:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Data Entry: LEFT | Initial Entry |
|---|-----------------|--------------------------------|----------------------------|---------------|

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------------|--|---------------|
| Sep-01-2020 16:49:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Data Entry: Injection Site Reaction: REDNESS Were injection site reactions present on the last day the Subject Diary was completed?: | Initial Entry |

5.a Injection Site Reaction:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------------|-------------------------------|---------------|
| Sep-01-2020 16:49:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Data Entry: REDNESS | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Sep-01-2020 16:49:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Sep-01-2020 16:49:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Injection Site SW Reaction:: EL LI NG Were injection NO site reactions p resent on the l ast day the Su bject Diary wa s completed?: | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

5.b Injection Site Reaction:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Sep-01-2020 16:49:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: SWELLING | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Sep-01-2020 16:49:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Sep-01-2020 16:49:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Injection Site PAI Reaction:: N A T IN JEC TIO N SI TE | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|--|--|--|---|--|
| | | | Were injection site reactions present on the last day the Subject Diary was completed?: | |
|--|--|--|---|--|

5.c Injection Site Reaction:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Sep-01-2020 16:49:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: PAIN AT INJECTION SITE | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Sep-01-2020 16:49:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1142

Subject No: 11421073

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1142) University of Texas - Galveston

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[Back to Form](#)

1. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|----------------------------------|---------------|
| Sep-01-2020 16:50:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/1/2020 | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Sep-01-2020 16:50:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier:: Temperature: Temperature Unit: Temperature Location: Y | Initial Entry |

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|-------------------------|---------------|
| Sep-01-2020 16:50:04 (UTC-06:00) Central Time (US | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

& Canada)

2.a Temperature:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|----------------------------|---------------|
| Sep-01-2020 16:50:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 98.3 | Initial Entry |

2.a Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------------|---------------|
| Sep-01-2020 16:50:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: F | Initial Entry |

2.a Temperature Location:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-----------------------------------|---------------|
| Sep-01-2020 16:50:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ORAL CAVITY | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (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: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Lab Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Sep-01-2020 16:50:35 (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-01-2020 16:50:35 (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-01-2020 16:50:35 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] [Redacted] | Data Entry: Sep/1/2020 | Initial Entry |

4. Laboratory Name and Address (Derived)

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

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (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: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Sep-01-2020 16:50:35 (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-01-2020 16:50:35 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: URINE | Initial Entry |

6.a

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-01-2020 16:50:18 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor- 113 Defined I dentifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: Not Done NOT DON :: E | Initial Entry |

6.a Sponsor ID:

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (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: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------|---------------|
| Sep-01-2020 16:50:18 (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-01-2020 16:50:18 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Data Entry: Choriogonadotropin Beta_PX113 | Initial Entry |

6.a Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------------|--------------------------------|---------------|
| Sep-01-2020 16:50:18 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Data Entry: NOT DONE | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (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: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Sep-01-2020 16:50:26 (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-01-2020 16:50:26 (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-01-2020 18:23:14 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Sep-01-2020 16:50:26 (UTC-06:00) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (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: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|---|-----------------|------------------|--|--|
| Central Time (US & Canada) | | | | no barcodes are entered. Please review and correct as appropriate. |
| Sep-01-2020 16:50:26 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection : Sep/1/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Sep-01-2020 18:23:14 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP9TX7 | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Sep-01-2020 18:23:14 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BP9TX7 | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1142

Subject No: 11421073

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1142) University of Texas - Galveston

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Sep-01-2020 16:51:00 (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-01-2020 16:51:00 (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-01-2020 16:51:00 (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 |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (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: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|---|-----------------|--|--|---------------|
| Sep-01-2020 16:51:00 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] [Redacted] | Data Entry: Sep/1/2020 14:14 | Initial Entry |
|---|-----------------|--|--|---------------|

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Sep-01-2020 16:51:00 (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-01-2020 16:51:00 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] [Redacted] | Data Entry: LEFT | Initial Entry |

7. Route:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Sep-01-2020 16:51:00 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (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: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-01-2020 16:51:00 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|--|---------------------------|---------------|
| Sep-01-2020 16:51:00 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] [Redacted] | Data Entry: YES | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1142 **Site Name:** (1142) University of Texas - Galveston

Subject No: 11421073 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|--|----------------------------------|---------------|
| Oct-02-2020 11:15:55 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] [Redacted] | Data Entry: Oct/2/2020 | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

Site No: 1142 **Site Name:** (1142) University of Texas - Galveston

Subject No: 11421073 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

[Back to Form](#)

1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Oct-02-2020 11:16:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Oct-02-2020 11:16:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: F E V E R Were fever or s N ystemic sympto O ms present on t he last day the S ubject Diary wa s completed?: | Initial Entry |

2.a Symptom:

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

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

Site No: 1142 Site Name: (1142) University of Texas - Galveston

Subject No: 11421073 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|---|-----------------|--------------------------------|-----------------------------|---------------|
| Oct-02-2020 11:16:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Data Entry: FEVER | Initial Entry |
|---|-----------------|--------------------------------|-----------------------------|---------------|

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

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------------|--------------------------|---------------|
| Oct-02-2020 11:16:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Data Entry: NO | Initial Entry |

2.b

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------------|---|---------------|
| Oct-02-2020 11:16:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Data Entry: Symptom:: FA TI G U E Were fever or s N ystemic sympto O ms present on t he last day the Subject Diary was completed? : | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

Site No: 1142 **Site Name:** (1142) University of Texas - Galveston

Subject No: 11421073 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

2.b Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|--|-------------------------------|---------------|
| Oct-02-2020 11:16:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] [REDACTED] | Data Entry: FATIGUE | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|--|--------------------------|---------------|
| Oct-02-2020 11:16:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] [REDACTED] | Data Entry: NO | Initial Entry |

2.c

| Date | Location | User | Value | Reason |
|---|-----------------|--|---|---------------|
| Oct-02-2020 11:16:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] [REDACTED] | Data Entry: Symptom:: HE A D AC HE | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

Site No: 1142 **Site Name:** (1142) University of Texas - Galveston

Subject No: 11421073 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

| | | | | |
|--|--|--|---|--|
| | | | Were fever or systemic symptoms present on the last day the Subject Diary was completed?: | |
|--|--|--|---|--|

2.c Symptom:

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------------|--------------------------------|---------------|
| Oct-02-2020 11:16:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Data Entry: HEADACHE | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------------|--------------------------|---------------|
| Oct-02-2020 11:16:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Data Entry: NO | Initial Entry |

2.d

| Date | Location | User | Value | Reason |
|-------------------------|-----------------|--------------------------------|-----------------------------------|---------------|
| Oct-02-2020 11:16:11 | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Data Entry: Symptom:: C | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

Site No: 1142 Site Name: (1142) University of Texas - Galveston

Subject No: 11421073 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|--|--|------------------|-----------------------------|---|
| (UTC-06:00) Central Time (US & Canada) | | (b) (4), (b) (6) | HI L L S N O | Were fever or systemic symptoms present on the last day the Subject Diary was completed?: |
|--|--|------------------|-----------------------------|---|

2.d Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Oct-02-2020 11:16:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> CHILLS | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Oct-02-2020 11:16:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

2.e

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

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

Site No: 1142 Site Name: (1142) University of Texas - Galveston

Subject No: 11421073 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|---|-----------------|--------------------------------|---|---------------|
| Oct-02-2020 11:16:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Data Entry: Symptom:: VO MI TI NG Were fever or s NO ystemic sympt oms present on the last day the Subject Diary was completed ?: | Initial Entry |
|---|-----------------|--------------------------------|---|---------------|

2.e Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------------|--------------------------------|---------------|
| Oct-02-2020 11:16:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Data Entry: VOMITING | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------------|--------------------------|---------------|
| Oct-02-2020 11:16:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Data Entry: NO | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

Site No: 1142 **Site Name:** (1142) University of Texas - Galveston

Subject No: 11421073 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

2.f

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Oct-02-2020 11:16:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: DI A RR HE A Were fever or s N ystemic sympto O ms present on t he last day the Subject Diary was completed ?: | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

Site No: 1142 **Site Name:** (1142) University of Texas - Galveston

Subject No: 11421073 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

2.f Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-02-2020 11:16:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: DIARRHEA | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Oct-02-2020 11:16:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.g

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Oct-02-2020 11:16:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: NEW OR W ORSE NED MUS CLE P AIN | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

Site No: 1142 **Site Name:** (1142) University of Texas - Galveston

Subject No: 11421073 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

| | | | | |
|--|--|--|--|--|
| | | | Were fever or systemic symptoms present on the last day the Subject Diary was completed?: | |
|--|--|--|--|--|

2.g Symptom:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Oct-02-2020 11:16:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR WORSENED MUSCLE PAIN | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Oct-02-2020 11:16:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.h

| Date | Location | User | Value | Reason |
|-------------|-----------------|------------------|--------------------|---------------|
| Oct-02-2020 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

Site No: 1142 **Site Name:** (1142) University of Texas - Galveston

Subject No: 11421073 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

| | | | | |
|--|--|------------------|--|--|
| 11:16:11 (UTC-06:00) Central Time (US & Canada) | | (b) (4), (b) (6) | Symptom:: NEW OR W ORSE NED JOIN T PAI N Were fever o NO r systemic sy mptoms pre sent on the l ast day the S ubject Diary was complet ed?: | |
|--|--|------------------|--|--|

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

Site No: 1142 **Site Name:** (1142) University of Texas - Galveston

Subject No: 11421073 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

2.h Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Oct-02-2020 11:16:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR WORSE NED JOINT PAIN | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Oct-02-2020 11:16:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

3. Injection Site Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Oct-02-2020 11:16:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

4. Injection Site Body Side:

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

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

Site No: 1142 **Site Name:** (1142) University of Texas - Galveston

Subject No: 11421073 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

| | | | | |
|---|-----------------|--|----------------------------|---------------|
| Oct-02-2020 11:16:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] [REDACTED] | Data Entry: LEFT | Initial Entry |
|---|-----------------|--|----------------------------|---------------|

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|--|--|---------------|
| Oct-02-2020 11:16:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] [REDACTED] | Data Entry: Injection Site Reaction: REDNESS Were injection site reactions present on the last day the Subject Diary was completed?: NO | Initial Entry |

5.a Injection Site Reaction:

| Date | Location | User | Value | Reason |
|---|-----------------|--|-------------------------------|---------------|
| Oct-02-2020 11:16:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] [REDACTED] | Data Entry: REDNESS | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

Site No: 1142 **Site Name:** (1142) University of Texas - Galveston

Subject No: 11421073 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

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

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Oct-02-2020 11:16:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Oct-02-2020 11:16:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Injection Site SW Reaction:: EL LI NG Were injection NO site reactions p resent on the l ast day the Su bject Diary wa s completed?: | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

Site No: 1142 Site Name: (1142) University of Texas - Galveston

Subject No: 11421073 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 11:44

5.b Injection Site Reaction:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-02-2020 11:16:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: SWELLING | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Oct-02-2020 11:16:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Oct-02-2020 11:16:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Injection Site PAI Reaction:: N A T IN JEC TIO N SI TE | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

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

Site No: 1142 **Site Name:** (1142) University of Texas - Galveston

Subject No: 11421073 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

| | | | | |
|--|--|--|--|--|
| | | | Were injection site reactions present on the last day the Subject Diary was completed?: | |
|--|--|--|--|--|

5.c Injection Site Reaction:

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------------|--|---------------|
| Oct-02-2020 11:16:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Data Entry: PAIN AT INJECTION SITE | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------------|--------------------------|---------------|
| Oct-02-2020 11:16:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Data Entry: NO | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1142 **Site Name:** (1142) University of Texas - Galveston

Subject No: 11421073 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Oct-02-2020 11:16:24 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Oct-02-2020 11:16:24 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|-----------------|---|
| Oct-05-2020 13:55:22 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Oct-03-2020 07:02:37 (UTC-06:00) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | 'Sample Collected?' is Yes, however |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001
Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1142 **Site Name:** (1142) University of Texas - Galveston
Subject No: 11421073 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

| | | | | |
|---|-----------------|------------------------|--|--|
| Central Time (US & Canada) | | | | no barcodes are entered. Please review and correct as appropriate. |
| Oct-02-2020 11:16:24 (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. |
| Oct-02-2020 11:16:24 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection : Oct/2/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Oct-05-2020 13:55:22 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID BR91D : P | Initial Entry |

5.a Sample ID

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

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1142 **Site Name:** (1142) University of Texas - Galveston

Subject No: 11421073 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

| | | | | |
|---|-----------------|--------------------------------|------------------------------|---------------|
| Oct-05-2020 13:55:22 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: BR91DP | Initial Entry |
|---|-----------------|--------------------------------|------------------------------|---------------|

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1142

Subject No: 11421073

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1142) University of Texas - Galveston

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|--|-----------------------------------|---------------|
| Feb-24-2021 09:47:10 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] [Redacted] | Data Entry: Feb/24/2021 | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1142

Subject No: 11421073

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1142) University of Texas - Galveston

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Feb-24-2021 09:47:23 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Feb-24-2021 09:47:23 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--------------------|---|
| Feb-24-2021 16:27:13 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Feb-24-2021 09:47:23 (UTC-06:00) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|---|-----------------|------------------|---|--|
| Central Time (US & Canada) | | | | no barcodes are entered. Please review and correct as appropriate. |
| Feb-24-2021 09:47:23 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection : Feb/24/2021 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Feb-24-2021 16:27:13 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BR4782 | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Feb-24-2021 16:27:13 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BR4782 | Initial Entry |

5.b

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Feb-24-2021 16:27:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID BRWKH : 9 | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Feb-24-2021 16:27:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BRWKH9 | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Feb-24-2021 16:27:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID BRWKG : W | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1142

Subject No: 11421073

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1142) University of Texas - Galveston

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Feb-24-2021 16:27:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BRWKGW | Initial Entry |

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Date of Completion/Discontinuation/Death :

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------------|----------------------------------|---------------|
| Oct-06-2020 16:45:22 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: Oct/2/2020 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------------|---------------|
| Oct-06-2020 16:45:22 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: VACCINATION | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------------|---------------------------------|---------------|
| Oct-06-2020 16:45:22 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: COMPLETED | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------------|--------------|--------|
| Jan-12-2021 09:26:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Form Created | |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Category:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Jan-12-2021 09:26:52 (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 |
|--|-----------------|-------------------------|-------------------------|---------------|
| Jan-12-2021 09:26:52 (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-07-2021 03:28:02 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Giselle Castillo (b) (4) | Query 2: Closed | Response satisfies query |
| Feb-04-2021 17:51:47 (UTC-06:00) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | Changed data per query |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|--|-----------------|--------------------------------|-------------------|--|
| Central Time (US & Canada) | | | | |
| Feb-04-2021 16:45:08 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Giselle Castillo (b) (4) | Query 2: Opened | CLINICAL_ Per source, the subject has history of smoking, which prompted the need of screening. This information is not recorded in MedHx of CRF. Pls revise and update accordingly. Thanks |
| Jan-14-2021 18:23:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Giselle Castillo (b) (4) | Query 1: Closed | Response satisfies query |
| Jan-13-2021 10:53:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | No additional conditions. Screening only. |
| Jan-13-2021 08:16:37 (UTC-06:00) | ACV0PFEINFP6000 | Giselle Castillo (b) (4) | Query 1: Opened | CLINICAL_ Per report, subject went to |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|---|-----------------|------------------|---|---|
| Central Time (US & Canada) | | | | "an incidental screening for lung cancer". Are there any additional conditions or MedHx that precipitated this screening?. If so, please update this form. thank you. |
| Jan-12-2021 09:26:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Ascending Aortic Aneurysm | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Jan-12-2021 09:26:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/4/2021 UNK:UNK | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|-------------|-----------------|------------------|--------------------|---------------|
| Jan-12-2021 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|--|--|------------------|-----|--|
| 09:26:52 (UTC-06:00) Central Time (US & Canada) | | (b) (4), (b) (6) | YES | |
|--|--|------------------|-----|--|

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------------|---------------|
| Jan-12-2021 09:26:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 4 | Initial Entry |

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--------------------|-------------------------------|
| Jan-12-2021 20:22:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Jan-12-2021 09:26:52 (UTC-06:00) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | For AE Ascending Aortic |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|---|-----------------|------------------|--|---|
| Central Time (US & Canada) | | | | Aneurysm: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank. |
| Jan-12-2021 09:26:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <p>Data Entry: YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolonged hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant d</p> | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete**Site No:** 1142**Site Name:** (1142) University of Texas - Galveston**Subject No:** 11421073**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44

| | | | | |
|--|--|--|---|--|
| | | | isability/incapacity ? | |
| | | | NO | |
| | | | Is this serious event life threatening? | |
| | | | YES | |
| | | | Other medically important serious event | |
| | | | NO | |

8. Is this adverse event the result of a study Medication Error?*If Yes, record the type of medication error on the Medication Error Log.*

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------------|--------------------------|---------------|
| Jan-12-2021 09:26:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: NO | Initial Entry |

9. Is this event related to study treatment:

| Date | Location | User | Value | Reason |
|--|-----------------|-----------------------------------|-----------------|--------------------------|
| Jan-15-2021 00:53:07 (UTC-06:00) Central Time | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Query 1: Closed | Response satisfies query |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|---|-----------------|---------------------------|---|---|
| (US & Canada) | | | | |
| Jan-13-2021 10:59:05 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Query resolution |
| Jan-13-2021 10:59:05 (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> Unknown | Query resolution |
| Jan-12-2021 22:12:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | DM: Kindly consider updating 'If Not Related to study treatment(s)' missing field. Thank you. |
| Jan-12-2021 09:26:52 (UTC-06:00) Central Time | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT RELATED | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

(US & Canada)

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Jan-12-2021 09:26:52 (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 |
|---|-----------------|------------------|--------------------------|---------------|
| Jan-12-2021 09:26:52 (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 |
|---|-----------------|------------------|---------------------------|---------------|
| Jan-12-2021 09:26:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

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

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

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|---|-----------------|------------------|--|---------------|
| Jan-12-2021 09:26:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RECOVERING/RES OLVING | Initial Entry |
|---|-----------------|------------------|--|---------------|

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

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Jan-12-2021 09:26:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

15. Serious Adverse Event Number: For Pfizer Use Only

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|----------------------------------|---------------|
| Jan-12-2021 20:22:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 2021015979 | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History
Unscheduled

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1142 **Site Name:** (1142) University of Texas - Galveston

Subject No: 11421073 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|--|-----------------------------------|---------------|
| Jan-27-2021 15:30:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] [Redacted] | Data Entry: Dec/15/2020 | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

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

Site No: 1142 **Site Name:** (1142) University of Texas - Galveston

Subject No: 11421073 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--|---|
| Mar-04-2021 14:27:10 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | data updated |
| Mar-04-2021 11:28:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Transcription Error |
| Mar-04-2021 11:28:42 (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 | Transcription Error |
| Mar-03-2021 21:12:03 (UTC-06:00) Central Time (US | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | DM: Participant is eligible and confirmed to |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

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

Site No: 1142 **Site Name:** (1142) University of Texas - Galveston

Subject No: 11421073 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

| | | | | |
|---|-----------------|--------------------------------|---|--|
| & Canada) | | | | have received Placebo, but Date Written Consent Obtained is missing in Informed Consent - Further Vaccination CRF. Please review and update as appropriate. |
| Jan-27-2021 15:30:58 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: Participant is willi ng to return for Va ccination 3 Participant is: eligible per loc al/national reco mmendations a nd confirmed t o have receive d only placebo at Vaccination 1/2 | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Date Treatment Unblinded :

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-----------------------------------|---------------|
| Dec-17-2020 16:08:22 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Dec/16/2020 | Initial Entry |

2. Primary Reason for Unblinding:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Dec-17-2020 16:08:22 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ASSESS ELIGIBILI TY FOR ADDITION AL VACCINATION | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (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: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Subject Status

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Oct-06-2020 16:45:22 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: FOLLOW-UP | Initial Entry |
| Aug-11-2020 13:15:01 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ENROLLED/RANDOMIZED | Initial Entry |
| Aug-11-2020 13:07:56 (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 |
|--|-----------------|------------------|-----------------|--------------------------|
| Jan-12-2021 20:23:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Jan-12-2021 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: | Changed data per query |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (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:** 1142**Site Name:** (1142) University of Texas - Galveston**Subject No:** 11421073**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44

| | | | | |
|--|-----------------|--|-----------------------------------|---|
| 09:27:10 (UTC-06:00) Central Time (US & Canada) | | (b) (4), (b) (6) | Answered | |
| Jan-11-2021 06:17:14 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] [REDACTED] | Query 1: Opened | SAE RECON:AER#2021015979 Ascending Aortic Aneurysm(onset date:04Jan2021)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form. |
| Oct-06-2020 16:45:22 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Oct/2/2020 | Initial Entry |
| Aug-11-2020 13:15:01 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Aug/11/2020 | Initial Entry |
| Aug-11-2020 13:07:56 (UTC-06:00) Central Time | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Aug/11/2020 | Initial Entry |

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1142

Site Name: (1142) University of Texas - Galveston

Subject No: 11421073

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1142

Subject No: 11421073

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1142) University of Texas - Galveston

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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1. Casebook Signature

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------------|--|---------------|
| Sep-16-2020 17:37:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Richard Rupp (b) (4) | Data Entry: Click Here to Enable | Initial Entry |

090177e196ae3e30\Final\Final On: 01-Apr-2021 04:48 (GMT)