## 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.

<table>
<thead>
<tr>
<th></th>
<th>Select appropriate response - Protocol version</th>
<th>24 JUL 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Select appropriate response - What cohort does the subject belong to?</td>
<td>STAGE 3 COHORTS</td>
</tr>
</tbody>
</table>
**Informed Consent**

<table>
<thead>
<tr>
<th></th>
<th>Consent Was:</th>
<th>OBTAINED</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Date Written Consent Obtained</td>
<td>Aug/21/2020</td>
</tr>
</tbody>
</table>
**Demography**

1. Subject ID: [11111139]
2. Birth Date: (b) (6) 1973
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:
Date of Visit

1. Date of Visit Aug/21/2020
2. Erroneous Visit
### Form Comments

<table>
<thead>
<tr>
<th>Inclusion Criteria Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description of Inclusion Criterion Not Met</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Exclusion Criteria Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description of Exclusion Criterion Met</td>
</tr>
</tbody>
</table>
### Disposition - Screening

1. **Date of Completion/Discontinuation/Death**: Aug/21/2020
2. **Phase of Disposition**: SCREENING
3. **Status**: COMPLETED
4. **Specify Status**: [ ]
### Medical History Details

<table>
<thead>
<tr>
<th>Line/MH Number</th>
<th>Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies</th>
<th>Start Date</th>
<th>Ongoing</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>[nearsighted]</td>
<td>UNK/UNK/1983</td>
<td>YES</td>
</tr>
<tr>
<td>2</td>
<td>[asthma]</td>
<td>UNK/UNK/2017</td>
<td>YES</td>
</tr>
<tr>
<td>3</td>
<td>[acne]</td>
<td>UNK/UNK/1987</td>
<td>YES</td>
</tr>
<tr>
<td>4</td>
<td>[overweight]</td>
<td>UNK/UNK/2010</td>
<td>YES</td>
</tr>
<tr>
<td>Line/MH Number:</td>
<td>[5]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------------</td>
<td>-----</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:</td>
<td>[anxiety]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Start Date:</td>
<td>UNK/UNK/2001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ongoing:</td>
<td>YES</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Line/MH Number:</th>
<th>[6]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:</td>
<td>[benign thyroid nodule]</td>
</tr>
<tr>
<td>Start Date:</td>
<td>UNK/UNK/2017</td>
</tr>
<tr>
<td>Ongoing:</td>
<td>YES</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Line/MH Number:</th>
<th>[7]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:</td>
<td>[Heart benign physiologic murmur]</td>
</tr>
<tr>
<td>Start Date:</td>
<td>Dec/5/2017</td>
</tr>
<tr>
<td>Ongoing:</td>
<td>YES</td>
</tr>
</tbody>
</table>
**Vital Signs**

1. **Date:** Aug/21/2020
2. **Weight:** [290.0]
3. **Unit:** LB
4. **Height:** [65.0]
5. **Unit:** in
6. **Body Mass Index:** [48.3]

**Vital Signs Details**

7.a **Record Identifier:** 1
   **Temperature:** [97.1]
   **Unit:** F
   **Temperature Location:** FOREHEAD
# Lab Urinalysis

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Lab Panel: URINALYSIS</td>
</tr>
<tr>
<td>2.</td>
<td>Lab Sub-Panel: PREGNANCY</td>
</tr>
<tr>
<td>3.</td>
<td>Collection Date: Aug/21/2020</td>
</tr>
<tr>
<td>4.</td>
<td>Laboratory Name and Address (Derived): [STUDY SITE]</td>
</tr>
<tr>
<td>5.</td>
<td>Specimen Type: URINE</td>
</tr>
</tbody>
</table>

## Lab Result

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>6.a</td>
<td>Sponsor ID: [113]</td>
</tr>
<tr>
<td></td>
<td>Test: Choriogonadotropin Beta_PX113</td>
</tr>
<tr>
<td></td>
<td>Result: NEGATIVE</td>
</tr>
<tr>
<td></td>
<td>Not Done:</td>
</tr>
</tbody>
</table>
**eCRF Audit Trail History**

<table>
<thead>
<tr>
<th>Disposition</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Randomization Date:</td>
<td>Aug/21/2020</td>
</tr>
<tr>
<td>2. Randomization Number:</td>
<td>[55011]</td>
</tr>
<tr>
<td>3. Randomization Group:</td>
<td>[ ]</td>
</tr>
</tbody>
</table>
### eCRF Audit Trail History

**Electronic Sample Tracking**

1. **Data Origin** | SITE
2. **Sample Type** | SERUM
3. **Sample Collected?** | YES  
   **Date of Collection:** Aug/21/2020
4. **If no sample was collected or sample was not collected according to protocol, please provide reason:** [ ]

**Aliquot**

Please enter barcode for each aliquot.

<table>
<thead>
<tr>
<th></th>
<th>Sample ID</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5.a</td>
<td>Sample ID</td>
<td>[BP5CHG]</td>
</tr>
<tr>
<td>5.b</td>
<td>Sample ID</td>
<td>[BP5CHH]</td>
</tr>
<tr>
<td>5.c</td>
<td>Sample ID</td>
<td>[BP5CHJ]</td>
</tr>
<tr>
<td>5.d</td>
<td>Sample ID</td>
<td>[BLD2V9]</td>
</tr>
<tr>
<td>5.e</td>
<td>Sample ID</td>
<td>[BLD2VB]</td>
</tr>
</tbody>
</table>
### eCRF Audit Trail History

**Electronic Sample Tracking**

<table>
<thead>
<tr>
<th>1. Data Origin</th>
<th>SITE</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Sample Type</td>
<td>NASAL_SWAB</td>
</tr>
<tr>
<td>3. Sample Collected?</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td>Date of Collection: Aug/21/2020</td>
</tr>
<tr>
<td>4. If no sample was collected or sample was not collected according to protocol, please provide reason:</td>
<td>[]</td>
</tr>
</tbody>
</table>

**Aliquot**

Please enter barcode for each aliquot.

<table>
<thead>
<tr>
<th>5.a Sample ID</th>
<th>[BP5CH8]</th>
</tr>
</thead>
</table>

---

***Confidential***
<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Was there a temporary delay of vaccination?</td>
<td>NO</td>
</tr>
<tr>
<td>2. Treatment Name</td>
<td>[BLINDED THERAPY]</td>
</tr>
<tr>
<td>3. Formulation</td>
<td>INJECTION</td>
</tr>
<tr>
<td>4. Dose Date Time</td>
<td>Aug/21/2020 10:43</td>
</tr>
<tr>
<td>5. Anatomical Location</td>
<td>DELTOID MUSCLE</td>
</tr>
<tr>
<td>6. Body Side</td>
<td>LEFT</td>
</tr>
<tr>
<td>7. Route</td>
<td>INTRAMUSCULAR</td>
</tr>
<tr>
<td>8. Actual Dose</td>
<td>[]</td>
</tr>
<tr>
<td>9. Unit</td>
<td></td>
</tr>
<tr>
<td>10. Timeframe Subject Was Observed</td>
<td>THE PROTOCOL SPECIFIED OBSERVATION PERIOD</td>
</tr>
<tr>
<td>11. Was the subject observed for at least the protocol specified observation period after investigational product administration?</td>
<td>YES</td>
</tr>
</tbody>
</table>
Reactogenicity Diary

1. Select appropriate response - Reactogenicity diary collection

NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
<table>
<thead>
<tr>
<th>Date of Visit</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Visit</td>
<td>Sep/8/2020</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
<tr>
<td>Vital Signs Details</td>
<td></td>
</tr>
<tr>
<td>---------------------</td>
<td></td>
</tr>
<tr>
<td>2.a</td>
<td>Record Identifier:</td>
</tr>
<tr>
<td></td>
<td>Temperature:</td>
</tr>
<tr>
<td></td>
<td>Unit:</td>
</tr>
<tr>
<td></td>
<td>Temperature Location:</td>
</tr>
</tbody>
</table>

**Vital Signs**

1. Date: Sep/8/2020
Header Text: c4591001
Visit: V2_VAX2_L
Form Version: 21-Aug-2020 02:49
Site No: 1111
Subject No: 11111139
Generated By: (b) (4)

**eCRF Audit Trail History**

<table>
<thead>
<tr>
<th>Lab Urinalysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Lab Panel:</td>
</tr>
<tr>
<td>2. Lab Sub-Panel:</td>
</tr>
<tr>
<td>3. Collection Date:</td>
</tr>
<tr>
<td>4. Laboratory Name and Address (Derived)</td>
</tr>
<tr>
<td>5. Specimen Type:</td>
</tr>
</tbody>
</table>

**Lab Result**

<table>
<thead>
<tr>
<th>6.a</th>
<th>Sponsor ID:</th>
<th>[113]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test:</td>
<td>Choriogonadotropin Beta_PX113</td>
<td></td>
</tr>
<tr>
<td>Result:</td>
<td>NEGATIVE</td>
<td></td>
</tr>
</tbody>
</table>

Not Done:
### eCRF Audit Trail History

**Electronic Sample Tracking**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Data Origin</td>
</tr>
<tr>
<td>2.</td>
<td>Sample Type</td>
</tr>
<tr>
<td>3.</td>
<td>Sample Collected?</td>
</tr>
<tr>
<td>4.</td>
<td>If no sample was collected or sample was not collected according to protocol, please provide reason:</td>
</tr>
</tbody>
</table>

**Aliquot**

Please enter barcode for each aliquot.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5.a</td>
<td>Sample ID</td>
</tr>
</tbody>
</table>

---

*Header Text:* c4591001  
*Visit:* V2_VAX2_L  
*Form Version:* 22-Apr-2020 21:03  
*Form:* ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
*Site No:* 1111  
*Site Name:* (1111) Fleming Island Center for Clinical Research  
*Subject No:* 11111139  
*Generated By:* (b) (4)  
*Generated Time (GMT):* 29-Mar-2021 10:58

---

*Data Origin:* SITE  
*Sample Type:* NASAL_SWAB  
*Sample Collected?:* YES  
*Date of Collection:* Sep/8/2020  

---

*Final On:* 01-Apr-2021 04:51 (GMT)
### eCRF Audit Trail History

#### Vaccination

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Was there a temporary delay of vaccination?</td>
</tr>
<tr>
<td>2.</td>
<td>Treatment Name</td>
</tr>
<tr>
<td>3.</td>
<td>Formulation:</td>
</tr>
<tr>
<td>4.</td>
<td>Dose Date Time:</td>
</tr>
<tr>
<td>5.</td>
<td>Anatomical Location:</td>
</tr>
<tr>
<td>6.</td>
<td>Body Side:</td>
</tr>
<tr>
<td>7.</td>
<td>Route:</td>
</tr>
<tr>
<td>8.</td>
<td>Actual Dose:</td>
</tr>
<tr>
<td>9.</td>
<td>Unit:</td>
</tr>
<tr>
<td>10.</td>
<td>Timeframe Subject Was Observed</td>
</tr>
<tr>
<td>11.</td>
<td>Was the subject observed for at least the protocol specified observation period after investigational product administration?</td>
</tr>
<tr>
<td>Date of Visit</td>
<td>Oct/6/2020</td>
</tr>
<tr>
<td>--------------</td>
<td>------------</td>
</tr>
<tr>
<td>1. Date of Visit</td>
<td>Oct/6/2020</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>
### eCRF Audit Trail History

#### Electronic Sample Tracking

1. **Data Origin**: SITE
2. **Sample Type**: SERUM
3. **Sample Collected?**: YES  
   *Date of Collection: Oct/6/2020*
4. If no sample was collected or sample was not collected according to protocol, please provide reason: [ ]

#### Aliquot

Please enter barcode for each aliquot.

<table>
<thead>
<tr>
<th>Sample ID</th>
<th>Barcode</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.a</td>
<td>BP9RMS</td>
</tr>
<tr>
<td>5.b</td>
<td>BP9RMT</td>
</tr>
<tr>
<td>5.c</td>
<td>BP9RMV</td>
</tr>
<tr>
<td>5.d</td>
<td>BNW9M9</td>
</tr>
<tr>
<td>5.e</td>
<td>BNW9MB</td>
</tr>
<tr>
<td>Date of Visit</td>
<td></td>
</tr>
<tr>
<td>--------------</td>
<td></td>
</tr>
<tr>
<td>1. Date of Visit</td>
<td>//</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>COVID-19 Illness Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. COVID-19 Illness Visit:</td>
</tr>
</tbody>
</table>

**Header Text:** c4591001
**Visit:** POT_COVID_ILL - New Unscheduled Visit
**Form:** DATE OF VISIT - ILLNESS ONSET
**Form Version:** 22-Apr-2020 21:03
**Site No:** 1111
**Subject No:** 11111139
**Generated By:** (b) (4)
**Site Name:** (1111) Fleming Island Center for Clinical Research
**Subject Initials:** ---
**Generated Time (GMT):** 29-Mar-2021 10:58

**Date of Visit**

1. Date of Visit
2. Erroneous Visit

**COVID-19 Illness Visit**

3. COVID-19 Illness Visit:
## Signs and Symptoms

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Date of Assessment: //</td>
</tr>
<tr>
<td>2.</td>
<td>Date of First Symptom Started: //</td>
</tr>
<tr>
<td>3.</td>
<td>Symptoms Ongoing?</td>
</tr>
</tbody>
</table>

## Symptoms

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>4.</td>
<td>Symptoms:</td>
</tr>
<tr>
<td></td>
<td>Was symptom present?</td>
</tr>
</tbody>
</table>

## Symptoms - Other

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5.</td>
<td>Symptoms - Other Text: [ ]</td>
</tr>
<tr>
<td>Electronic Sample Tracking</td>
<td></td>
</tr>
<tr>
<td>----------------------------</td>
<td></td>
</tr>
<tr>
<td>1. Data Origin</td>
<td></td>
</tr>
<tr>
<td>2. Sample Type</td>
<td></td>
</tr>
<tr>
<td>3. Sample Collected?</td>
<td></td>
</tr>
<tr>
<td>4. If no sample was collected or sample was not collected according to protocol, please provide reason: [ ]</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Aliquot</th>
</tr>
</thead>
<tbody>
<tr>
<td>Please enter barcode for each aliquot.</td>
</tr>
<tr>
<td>5. Sample ID</td>
</tr>
<tr>
<td><strong>Electronic Sample Tracking</strong></td>
</tr>
<tr>
<td>-----------------------------</td>
</tr>
<tr>
<td>1. Data Origin</td>
</tr>
<tr>
<td>2. Sample Type</td>
</tr>
<tr>
<td>3. Sample Collected?</td>
</tr>
<tr>
<td>4. If no sample was collected or sample was not collected according to protocol, please provide reason: [ ]</td>
</tr>
</tbody>
</table>

**Aliquot**

Please enter barcode for each aliquot.

<table>
<thead>
<tr>
<th>5. Sample ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ]</td>
</tr>
<tr>
<td>Health Care Utilization</td>
</tr>
<tr>
<td>-------------------------</td>
</tr>
<tr>
<td>1. Physician or Healthcare Professional:</td>
</tr>
<tr>
<td>Occurrence of Visits or Contacts:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Health Care Utilization Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Other Type of Practitioner Specify: [ ]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Health Care Utilization</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. Has the subject been hospitalized due to potential COVID-19 illness?</td>
</tr>
</tbody>
</table>
**Header Text:** c4591001  
**Visit:** POT_COVID_ILL - New Unscheduled Visit  
**Form Version:** 06-Jul-2020 21:52  
**Site No:** 1111  
**Subject No:** 11111139  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:58

## Illness Details

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Category of Clinical Event:</td>
</tr>
<tr>
<td>2.</td>
<td>Was a diagnosis obtained for Potential COVID-19 Illness?</td>
</tr>
<tr>
<td>3.</td>
<td>Toxicity Grade:</td>
</tr>
</tbody>
</table>
Date of Visit

1. Date of Visit  //

2. Erroneous Visit

COVID-19 Illness Visit

3. COVID-19 Illness Visit:
## 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 [ ]

---

FDA-CBER-2021-5683-0930009

Page 30 of 159
<table>
<thead>
<tr>
<th>Date of Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Visit</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
</tr>
</tbody>
</table>

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1111

**Site Name:** (1111) Fleming Island Center for Clinical Research

**Subject No:** 11111139

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:58
Unplanned Assessments

1. Assessments
**Header Text:** e4591001  
**Visit:** End of Treatment - Unscheduled  
**Form Version:** 15-Sep-2020 21:55  
**Site No:** 1111  
**Subject No:** 11111139  
**Generated By:** (b) (4)  
**Site Name:** (1111) Fleming Island Center for Clinical Research  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:58

**eCRF Audit Trail History**

### Disposition - Treatment

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Completion/Discontinuation/Death</td>
<td>Oct/6/2020</td>
</tr>
<tr>
<td>2. Phase of Disposition</td>
<td>VACCINATION</td>
</tr>
<tr>
<td>3. Status</td>
<td>COMPLETED</td>
</tr>
<tr>
<td>4. Specify Status</td>
<td>[ ]</td>
</tr>
</tbody>
</table>
### Disposition - Follow-Up

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Date of Completion/Discontinuation/Death: //</td>
</tr>
<tr>
<td>2</td>
<td>Phase of Disposition:</td>
</tr>
<tr>
<td>3</td>
<td>Status:</td>
</tr>
<tr>
<td>4</td>
<td>Specify Status: [ ]</td>
</tr>
<tr>
<td>Date of Visit</td>
<td></td>
</tr>
<tr>
<td>---------------</td>
<td>--</td>
</tr>
<tr>
<td>1. Date of Visit</td>
<td>//</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>COVID-19 Repeat Swab</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>3. COVID-19 Repeat Swab:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td><strong>Electronic Sample Tracking</strong></td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td>Data Origin</td>
</tr>
<tr>
<td>2.</td>
<td>Sample Type</td>
</tr>
<tr>
<td>3.</td>
<td>Sample Collected?</td>
</tr>
<tr>
<td>4.</td>
<td>If no sample was collected or sample was not collected according to protocol, please provide reason: [ ]</td>
</tr>
<tr>
<td><strong>Aliquot</strong></td>
<td></td>
</tr>
<tr>
<td>Please enter barcode for each aliquot.</td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>Sample ID [ ]</td>
</tr>
<tr>
<td>#</td>
<td>Category</td>
</tr>
<tr>
<td>----</td>
<td>---------------</td>
</tr>
<tr>
<td>1.</td>
<td>ADVERSE EVENT</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Adverse Event Report

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Category:</td>
<td>ADVERSE EVENT</td>
</tr>
<tr>
<td>2. AE ID:</td>
<td>[1]</td>
</tr>
<tr>
<td>3. Adverse Event: (If possible specify diagnosis, not individual symptoms)</td>
<td>[Left axillary lymph node swelling]</td>
</tr>
<tr>
<td>4. Start Date Time:</td>
<td>Jan/13/2021 UNK:UNK</td>
</tr>
<tr>
<td>5. Is the adverse event still ongoing?</td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td>End Date Time: Jan/16/2021 UNK:UNK</td>
</tr>
<tr>
<td>6. Toxicity Grade:</td>
<td>1</td>
</tr>
<tr>
<td>7. Is the adverse event serious?</td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td>If Yes, NOTIFY PFIZER IMMEDIATELY.</td>
</tr>
<tr>
<td></td>
<td>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).</td>
</tr>
<tr>
<td>8. Is this adverse event the result of a study Medication Error?</td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td>If Yes, record the type of medication error on the Medication Error Log.</td>
</tr>
<tr>
<td>9. Is this event related to study treatment:</td>
<td>RELATED</td>
</tr>
<tr>
<td>10. Latest Action Taken with Study Treatment:</td>
<td>NOT APPLICABLE</td>
</tr>
<tr>
<td>11. Was a Concomitant Medication given?</td>
<td>NO</td>
</tr>
<tr>
<td>Question</td>
<td>Answer</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>12. Was a Non-Drug Treatment given?</td>
<td>NO</td>
</tr>
<tr>
<td>13. What was the outcome of this adverse event?</td>
<td>RECOVERED/RESOLVED</td>
</tr>
<tr>
<td>14. Did the adverse event cause the subject to be discontinued from the study?</td>
<td>NO</td>
</tr>
<tr>
<td>15. Serious Adverse Event Number: For Pfizer Use Only</td>
<td>[ ]</td>
</tr>
<tr>
<td>#</td>
<td>Category</td>
</tr>
<tr>
<td>----</td>
<td>----------</td>
</tr>
<tr>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

Site Name: (1111) Fleming Island Center for Clinical Research
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 10:58
### 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** [ ]
<table>
<thead>
<tr>
<th>#</th>
<th>Sponsor-Defined Identifier</th>
<th>Category for Medication</th>
<th>Concomitant Medications Pre-specified</th>
<th>Name of Medication</th>
<th>Start Date</th>
<th>Form Instance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Repeating Pages</td>
</tr>
</tbody>
</table>
### Concomitant Medications

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td><strong>What is the medication identifier?</strong> [ ]</td>
</tr>
<tr>
<td>2.</td>
<td><strong>Category:</strong></td>
</tr>
</tbody>
</table>
| 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). [ ] |
<p>| 5. | <strong>Date:</strong> // |</p>
<table>
<thead>
<tr>
<th>#</th>
<th>Sponsor-Defined Identifier</th>
<th>Category for Medication</th>
<th>Concomitant Medications Pre-specified</th>
<th>Name of Medication</th>
<th>Dose Description</th>
<th>Form Instance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Repeating Pages</td>
</tr>
</tbody>
</table>
### 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?**
<table>
<thead>
<tr>
<th>#</th>
<th>Category</th>
<th>Treatment Identifier</th>
<th>Con Non-Drug Treatments Pre-specified</th>
<th>Treatment Date</th>
<th>Form Instance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Repeating Pages</td>
</tr>
</tbody>
</table>
## Radiation Treatment

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>1.</td>
<td>Category:</td>
</tr>
<tr>
<td>2.</td>
<td>What is the treatment Identifier? [ ]</td>
</tr>
<tr>
<td>3.</td>
<td>Concomitant Non-drug Treatment Pre-specified:</td>
</tr>
<tr>
<td>4.</td>
<td>Treatment: [ ]</td>
</tr>
<tr>
<td>5.</td>
<td>Start Date: //</td>
</tr>
<tr>
<td>6.</td>
<td>Ongoing?</td>
</tr>
<tr>
<td>#</td>
<td>Transfusion Type</td>
</tr>
<tr>
<td>---</td>
<td>-----------------</td>
</tr>
<tr>
<td>1.</td>
<td>Repeating Pages</td>
</tr>
</tbody>
</table>
### Back to Form

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Transfusion Type:</td>
</tr>
<tr>
<td>2.</td>
<td>Date of Transfusion: //</td>
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</tbody>
</table>

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**Header Text:** c4591001  
**Visit:** Logs - Unscheduled  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1111  
**Subject No:** 11111139  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:58
Date of Visit

1. Date of Visit //

2. Erroneous Visit
**Vital Signs**

1. **Date:** //

---

**Vital Signs Details**

2.  
   - **Record Identifier:**  
   - **Temperature:** [ ]  
   - **Unit:**  
   - **Temperature Location:**
<table>
<thead>
<tr>
<th>Lab Urinalysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Lab Panel:</td>
</tr>
<tr>
<td>2. Lab Sub-Panel:</td>
</tr>
<tr>
<td>3. Collection Date: //</td>
</tr>
<tr>
<td>4. Laboratory Name and Address (Derived) [ ]</td>
</tr>
<tr>
<td>5. Specimen Type:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lab Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>6. Sponsor ID: [ ]</td>
</tr>
<tr>
<td>Test:</td>
</tr>
<tr>
<td>Result:</td>
</tr>
<tr>
<td>Not Done:</td>
</tr>
<tr>
<td>Vaccination</td>
</tr>
<tr>
<td>---------------------------------------------------------------------------</td>
</tr>
<tr>
<td>1.</td>
</tr>
<tr>
<td>2.</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>3.</td>
</tr>
<tr>
<td>4.</td>
</tr>
<tr>
<td>5.</td>
</tr>
<tr>
<td>6.</td>
</tr>
<tr>
<td>7.</td>
</tr>
<tr>
<td>8.</td>
</tr>
<tr>
<td>9.</td>
</tr>
<tr>
<td>10.</td>
</tr>
<tr>
<td>11.</td>
</tr>
<tr>
<td>Contact Outcome</td>
</tr>
<tr>
<td>-----------------</td>
</tr>
<tr>
<td>1. Contact Type:</td>
</tr>
<tr>
<td>2. Was contact made?</td>
</tr>
<tr>
<td>3. Comments:</td>
</tr>
<tr>
<td>Contact Outcome</td>
</tr>
<tr>
<td>-----------------</td>
</tr>
<tr>
<td>1. Contact Type:</td>
</tr>
<tr>
<td>2. Was contact made?</td>
</tr>
<tr>
<td>3. Comments: [ ]</td>
</tr>
</tbody>
</table>
**Header Text:** c4591001  
**Visit:** Potential ReVax Initial Contact - Unscheduled  
**Form:** DATE OF VISIT  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1111  
**Subject No:** 11111139  
**Generated By:** (b) (4)  
**Form Status:** Data Complete, Frozen, Verified  
**Site Name:** (1111) Fleming Island Center for Clinical Research  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:58

**eCRF Audit Trail History**

<table>
<thead>
<tr>
<th>Date of Visit</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Visit</td>
<td>Dec/16/2020</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
<tr>
<td>Question</td>
<td>Response</td>
</tr>
<tr>
<td>----------</td>
<td>----------</td>
</tr>
<tr>
<td>1. Select appropriate response - Is participant willing to return for Vaccination 3?</td>
<td>Participant is willing to return for Vaccination 3. Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2</td>
</tr>
</tbody>
</table>
## eCRF Audit Trail History

<table>
<thead>
<tr>
<th>Date of Visit</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Visit</td>
<td>Dec/21/2020</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>
## Informed Consent - Further Vaccination

<table>
<thead>
<tr>
<th></th>
<th>Consent Was:</th>
<th>OBTAINED</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Date Written Consent Obtained</td>
<td>Dec/21/2020</td>
</tr>
</tbody>
</table>
### 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
## Disposition - Screening for Further Vaccination

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Date of Completion/Discontinuation/Death:</td>
</tr>
<tr>
<td>2.</td>
<td>Phase of Disposition:</td>
</tr>
<tr>
<td>3.</td>
<td>Status:</td>
</tr>
<tr>
<td>4.</td>
<td>Specify Status:</td>
</tr>
</tbody>
</table>

**eCRF Audit Trail History**

- **Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION
- **Form Version:** 10-Dec-2020 02:31
- **Form Status:** Data Complete, Frozen, Verified
- **Site No:** 1111
- **Site Name:** (1111) Fleming Island Center for Clinical Research
- **Subject No:** 11111139
- **Generated By:** (b) (4)
- **Generated Time (GMT):** 29-Mar-2021 10:58

**FDA-CBER-2021-5683-0930040**
### eCRF Audit Trail History

#### Lab Urinalysis

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Lab Panel:</td>
<td>URINALYSIS</td>
</tr>
<tr>
<td>2. Lab Sub-Panel:</td>
<td>PREGNANCY</td>
</tr>
<tr>
<td>3. Collection Date:</td>
<td>Dec/21/2020</td>
</tr>
<tr>
<td>4. Laboratory Name and Address (Derived)</td>
<td>[STUDY SITE]</td>
</tr>
<tr>
<td>5. Specimen Type:</td>
<td>URINE</td>
</tr>
</tbody>
</table>

#### Lab Result

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>6.a Sponsor ID:</td>
<td>[113]</td>
</tr>
<tr>
<td>Test:</td>
<td>Choriogonadotropin BetaPX113</td>
</tr>
<tr>
<td>Result:</td>
<td>NEGATIVE</td>
</tr>
<tr>
<td>Not Done:</td>
<td></td>
</tr>
</tbody>
</table>
### eCRF Audit Trail History

**Electronic Sample Tracking**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Data Origin</td>
</tr>
<tr>
<td>2.</td>
<td>Sample Type</td>
</tr>
<tr>
<td>3.</td>
<td>Sample Collected?</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>If no sample was collected or sample was not collected according to protocol, please provide reason:</td>
</tr>
</tbody>
</table>

### Aliquot

Please enter barcode for each aliquot.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5.a</td>
<td>Sample ID</td>
</tr>
<tr>
<td>5.b</td>
<td>Sample ID</td>
</tr>
<tr>
<td>5.c</td>
<td>Sample ID</td>
</tr>
<tr>
<td>5.d</td>
<td>Sample ID</td>
</tr>
<tr>
<td>5.e</td>
<td>Sample ID</td>
</tr>
</tbody>
</table>
**eCRF Audit Trail History**

**Electronic Sample Tracking**

1. **Data Origin** | SITE
2. **Sample Type** | NASAL_SWAB
3. **Sample Collected?** | YES  
   **Date of Collection:**  
   Dec/21/2020
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** | [BRJC75]
## eCRF Audit Trail History

### Vaccination

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Was there a temporary delay of vaccination?</td>
</tr>
<tr>
<td>2.</td>
<td>Treatment Name</td>
</tr>
<tr>
<td>3.</td>
<td>Formulation:</td>
</tr>
<tr>
<td>4.</td>
<td>Dose Date Time:</td>
</tr>
<tr>
<td>5.</td>
<td>Anatomical Location:</td>
</tr>
<tr>
<td>6.</td>
<td>Body Side:</td>
</tr>
<tr>
<td>7.</td>
<td>Route:</td>
</tr>
<tr>
<td>8.</td>
<td>Actual Dose:</td>
</tr>
<tr>
<td>9.</td>
<td>Unit:</td>
</tr>
<tr>
<td>10.</td>
<td>Timeframe Subject Was Observed</td>
</tr>
<tr>
<td>11.</td>
<td>Was the subject observed for at least the protocol specified observation period after investigational product administration?</td>
</tr>
</tbody>
</table>
### Treatment Unblinded

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Date Treatment Unblinded : Dec/16/2020</td>
</tr>
<tr>
<td>2.</td>
<td>Primary Reason for Unblinding: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION</td>
</tr>
<tr>
<td>Withdrawal Of Consent</td>
<td></td>
</tr>
<tr>
<td>-----------------------</td>
<td></td>
</tr>
<tr>
<td>1. Withdrawal of Consent Date: //</td>
<td></td>
</tr>
</tbody>
</table>
## Death Details

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

## Cause of Death

2. Cause of Death Status:

   Cause of Death: [ ]
**Header Text:** c4591001  
**Visit:** V102_VAX4  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1111  
**Subject No:** 11111139  
**Generated By:** (b) (4)  

**Form:** DATE OF VISIT  
**Form Status:** Data Complete, Frozen, Verified  
**Site Name:** (1111) Fleming Island Center for Clinical Research  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:58

### eCRF Audit Trail History

#### Date of Visit

<table>
<thead>
<tr>
<th></th>
<th>Date of Visit</th>
<th>Generated Time (GMT)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Date of Visit</td>
<td>Jan/11/2021</td>
</tr>
<tr>
<td>2.</td>
<td>Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>
**Header Text:** c4591001  
**Visit:** V102_VAX4  
**Form Version:** 10-Dec-2020 02:23  
**Site No:** 1111  
**Subject No:** 11111139  
**Generated By:** (b) (4)  
**Form:** LAB URINALYSIS - PREGNANCY TEST  
**Form Status:** Data Complete, Frozen, Verified  
**Site Name:** (1111) Fleming Island Center for Clinical Research  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:58

### eCRF Audit Trail History

#### Lab Urinalysis

<p>| | |</p>
<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Lab Panel: URINALYSIS</td>
</tr>
<tr>
<td>2.</td>
<td>Lab Sub-Panel: PREGNANCY</td>
</tr>
<tr>
<td>3.</td>
<td>Collection Date: Jan/11/2021</td>
</tr>
<tr>
<td>4.</td>
<td>Laboratory Name and Address (Derived): [STUDY SITE]</td>
</tr>
<tr>
<td>5.</td>
<td>Specimen Type: URINE</td>
</tr>
</tbody>
</table>

#### Lab Result

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>6.a</td>
<td>Sponsor ID: [113]</td>
</tr>
<tr>
<td></td>
<td>Test: Choriogonadotropin Beta_PX113</td>
</tr>
<tr>
<td></td>
<td>Result: NEGATIVE</td>
</tr>
<tr>
<td></td>
<td>Not Done:</td>
</tr>
</tbody>
</table>

---

090177e196ae3e4b\Final\Final On: 01-Apr-2021 04:51 (GMT)
**Electronic Sample Tracking**

1. **Data Origin**
   - SITE

2. **Sample Type**
   - NASAL_SWAB

3. **Sample Collected?**
   - YES
   - **Date of Collection:**
     - Jan/11/2021

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**
   - [BRJCBW]

---

**eCRF Audit Trail History**
### eCRF Audit Trail History

**Vaccination**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Was there a temporary delay of vaccination?</td>
</tr>
<tr>
<td>2.</td>
<td>Treatment Name</td>
</tr>
<tr>
<td>3.</td>
<td>Formulation:</td>
</tr>
<tr>
<td>4.</td>
<td>Dose Date Time:</td>
</tr>
<tr>
<td>5.</td>
<td>Anatomical Location:</td>
</tr>
<tr>
<td>6.</td>
<td>Body Side:</td>
</tr>
<tr>
<td>7.</td>
<td>Route:</td>
</tr>
<tr>
<td>8.</td>
<td>Actual Dose:</td>
</tr>
<tr>
<td>9.</td>
<td>Unit:</td>
</tr>
<tr>
<td>10.</td>
<td>Timeframe Subject Was Observed</td>
</tr>
<tr>
<td>11.</td>
<td>Was the subject observed for at least the protocol specified observation period after investigational product administration?</td>
</tr>
<tr>
<td>Date of Visit</td>
<td>1. Date of Visit</td>
</tr>
<tr>
<td>---------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
<tr>
<td>Contact Outcome</td>
<td></td>
</tr>
<tr>
<td>-----------------</td>
<td></td>
</tr>
<tr>
<td><strong>1.</strong> Contact Type:</td>
<td>TELEPHONE VISIT</td>
</tr>
<tr>
<td><strong>2.</strong> Was contact made?</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td>Date of Contact:</td>
</tr>
<tr>
<td></td>
<td>Feb/8/2021</td>
</tr>
<tr>
<td><strong>3.</strong> Comments:</td>
<td>[ ]</td>
</tr>
<tr>
<td>Date of Visit</td>
<td></td>
</tr>
<tr>
<td>--------------</td>
<td>--</td>
</tr>
<tr>
<td>1. Date of Visit //</td>
<td></td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>
### Contact Outcome

1. **Contact Type:**

2. **Was contact made?**

3. **Comments:** [ ]

---

**Header Text:** c4591001  
**Visit:** V104_MONTH6  
**Form Version:** 22-Apr-2020 21:04  
**Site No:** 1111  
**Subject No:** 11111139  
**Generated By:** (b) (4)  
**Site Name:** (1111) Fleming Island Center for Clinical Research  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:58
<table>
<thead>
<tr>
<th>Date of Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Visit //</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
</tr>
</tbody>
</table>
Contact Outcome

1. Contact Type: 

2. Was contact made? 

3. Comments: [ ]
**Disposition - Treatment**

1. **Date of Completion/Discontinuation/Death:** Feb/8/2021
2. **Phase of Disposition:** OPEN LABEL TREATMENT
3. **Status:** COMPLETED
4. **Specify Status:** [ ]
### eCRF Audit Trail History

<table>
<thead>
<tr>
<th>Subject Status</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Subject Status</td>
<td>FOLLOW-UP</td>
</tr>
<tr>
<td>2. Subject Status Date</td>
<td>Oct/6/2020</td>
</tr>
</tbody>
</table>
**eCRF Audit Trail History**

**Casebook Signature Form**

<table>
<thead>
<tr>
<th></th>
<th>Casebook Signature</th>
<th>Click Here to Enable</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Audit Trail**

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

<table>
<thead>
<tr>
<th>Name</th>
<th>Signature Meaning</th>
<th>Date</th>
<th>Type</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Michael Stephens</td>
<td>Approved</td>
<td>Feb-25-2021 09:27:46 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>BOOK</td>
<td>Signed</td>
</tr>
</tbody>
</table>

**Affidavit:**

By my dated signature below, I, Michael Stephens, 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.
<table>
<thead>
<tr>
<th>Item</th>
<th>Date</th>
<th>User</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form</td>
<td>Aug-21-2020 12:58:09 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>(b) (4), (b) (6)</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Item</td>
<td>Date</td>
<td>User</td>
<td>Comment</td>
</tr>
<tr>
<td>-------</td>
<td>-------------------------------------------</td>
<td>---------------</td>
<td>------------------</td>
</tr>
<tr>
<td>Form</td>
<td>Dec-21-2020 14:24:44 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>(b) (4), (b) (6)</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>
This form requires signing by a member of each of the following signature groups:

- **CRF_Sign**

<table>
<thead>
<tr>
<th>Name</th>
<th>Signature Meaning</th>
<th>Date</th>
<th>Type</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Michael Stephens</td>
<td>Approved</td>
<td>Feb-25-2021 09:27:46 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>BOOK</td>
<td>Signed</td>
</tr>
</tbody>
</table>

**Affidavit:**

By my dated signature below, I, Michael Stephens, 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.

<table>
<thead>
<tr>
<th>(b) (6)</th>
<th>N/A</th>
<th>Feb-23-2021 12:35:44 (UTC-05:00) Eastern Time (US &amp; Canada)</th>
<th></th>
<th>Edit - All signatures invalidated</th>
</tr>
</thead>
</table>

**Affidavit:**

N/A

| Michael Stephens | Approved | Feb-10-2021 13:52:19 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |

**Affidavit:**

By my dated signature below, I, Michael Stephens, 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.

<table>
<thead>
<tr>
<th>(b) (6)</th>
<th>N/A</th>
<th>Feb-09-2021 13:55:32 (UTC-05:00) Eastern Time (US &amp; Canada)</th>
<th></th>
<th>Edit - All signatures invalidated</th>
</tr>
</thead>
</table>

**Affidavit:**

N/A
**Affidavit:**
By my dated signature below, I, Michael Stephens, 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.
Affidavit:
By my dated signature below, I, Michael Stephens, 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.
### 1. Select appropriate response - Protocol version

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aug-21-2020 12:57:29</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4),</td>
<td>Data Entry:</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern</td>
<td></td>
<td>(b) (6)</td>
<td>24 JUL 2020</td>
<td></td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aug-21-2020 12:57:29</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4),</td>
<td>Data Entry:</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern</td>
<td></td>
<td>(b) (6)</td>
<td>STAGE 3 COHORTS</td>
<td></td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 1. Consent Was:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aug-21-2020 12:57:34 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Date Written Consent Obtained Aug/21/2020</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>
## 1. Subject ID

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aug-21-2020 12:57:20 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: 11111139</td>
<td>Item copied from previous form</td>
</tr>
</tbody>
</table>

## 2. Birth Date:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aug-21-2020 12:57:17 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: (b) (6)/1973</td>
<td>Enrollment Entry</td>
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## 3. Sex:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aug-21-2020 12:57:48 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: FEMALE</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

## 4. Ethnicity:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aug-21-2020 12:57:48 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NOT HISPANIC OR LATINO(A OR OF SPANISH ORIGIN</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aug-21-2020 12:57:48 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: WHITE</td>
<td>Initial Entry</td>
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</table>
## 1. Date of Visit

<table>
<thead>
<tr>
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<th>Location</th>
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<th>Reason</th>
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<tbody>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: Aug/21/2020</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 1. Date of Completion/Discontinuation/Death

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aug-21-2020 12:58:25 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Aug/21/2020</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

### 2. Phase of Disposition:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aug-21-2020 12:58:25 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: SCREENING</td>
<td>Initial Entry</td>
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### 3. Status:

<table>
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<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aug-21-2020 12:58:25 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: COMPLETED</td>
<td>Initial Entry</td>
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</table>
### 1.a Medical History Term:

<table>
<thead>
<tr>
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<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aug-21-2020 12:59:21</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td><strong>Medical History Term:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(autocalc)</td>
<td><strong>nearsighted</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>Start Date:</strong></td>
<td>UNK/UNK/1983</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>Ongoing:</strong></td>
<td>YES</td>
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</tbody>
</table>

### 1.a Line/MH Number:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aug-21-2020 12:59:21</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td><strong>Data Entry:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(autocalc)</td>
<td>1</td>
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</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aug-21-2020 12:59:21</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong></td>
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</tr>
<tr>
<td></td>
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<td></td>
<td><strong>nearsighted</strong></td>
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### 1.a Start Date:

<table>
<thead>
<tr>
<th>Date</th>
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<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Aug-21-2020 12:59:21</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong></td>
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<td></td>
<td></td>
<td><strong>UNK/UNK/1983</strong></td>
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### 1.a Ongoing:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aug-21-2020 12:59:21</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>YES</strong></td>
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### 1.b

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Aug-21-2020 12:59:39</td>
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<td>Initial Entry</td>
</tr>
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<td></td>
<td></td>
<td>(autocalc)</td>
<td>Medical History Term:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>asthma</td>
<td></td>
</tr>
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<td></td>
<td></td>
<td></td>
<td>Start Date: UNK/UNK/2017</td>
<td></td>
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<tr>
<td></td>
<td></td>
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<td>Ongoing: YES</td>
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</table>

#### 1.b Line/MH Number:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aug-21-2020 12:59:39</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td>2</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern</td>
<td></td>
<td>(autocalc)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
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</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aug-21-2020 12:59:39</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: asthma</td>
<td>Initial Entry</td>
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### 1.c

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***Confidential***

FDA-CBER-2021-5683-0930075
**Medical History Term:** anxiety
**Start Date:** UNK/UNK/2001
**Ongoing:** YES

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**Form Status:** Data Complete, Locked, Frozen, Verified
**Site No:** 1111
**Site Name:** (1111) Fleming Island Center for Clinical Research
**Subject No:** 11111139
**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 10:58

**Start Date:** Dec/5/2017
**Ongoing:** YES

FDA-CBER-2021-5683-0930078
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### 1.g Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

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**Back to Form**
### 7.a

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### 2. Sample Type

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### 3. Sample Collected?

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

**Generated Time (GMT):** 29-Mar-2021 10:58

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**Subject Initials:** ---

**Site Name:** (1111) Fleming Island Center for Clinical Research

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**Header Text:** c4591001

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**Visit:** V1_DAY1_VAX1_L

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

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**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
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### 5.a Sample ID

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

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### 2. Treatment Name

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### 3. Formulation:

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### 4. Dose Date Time:

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### 5. Anatomical Location:

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### 6. Body Side:

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### 7. Route:

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### 10. Timeframe Subject Was Observed

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

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### 1. Select appropriate response - Reactogenicity diary collection

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<td><strong>Data Entry:</strong> NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT</td>
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**Back to Form**
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<tr>
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<td>window (-1 day) from Date of visit</td>
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<td>(21/Aug/2020) at VID1VXIL visit. Please</td>
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<td>reconcile and update accordingly, else</td>
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<td>confirm date is</td>
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<td>(UTC-05:00) Eastern Time</td>
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1. Date:

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2.a

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2.a Temperature:

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2.a Temperature Location:
Header Text: c4591001
Visit: V2_VAX2_L
Form Version: 21-Aug-2020 02:51
Site No: 1111
Subject No: 11111139
Generated By: (b) (4)

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1. Lab Panel:

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3. Collection Date:

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4. Laboratory Name and Address (Derived)

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6.a
### 6.a Sponsor ID:

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### 6.a Test:

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### 6.a Result:

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<td>NEGATIVE</td>
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### 1. Data Origin

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<td><strong>Data Entry:</strong> SITE</td>
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### 2. Sample Type

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### 3. Sample Collected?

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### 5.a

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1. Was there a temporary delay of vaccination?

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2. Treatment Name

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3. Formulation:

<table>
<thead>
<tr>
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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Sep-08-2020 12:31:52</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td>Data Entry:</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern</td>
<td></td>
<td>(autocalc)</td>
<td>INJECTION</td>
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<td>Time (US &amp; Canada)</td>
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4. Dose Date Time:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-08-2020 12:31:52</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4)</td>
<td>Data Entry:</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern</td>
<td></td>
<td>(b) (6)</td>
<td>Sep/8/2020 10:48</td>
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</tr>
<tr>
<td>Time (US &amp; Canada)</td>
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</table>

5. Anatomical Location:

<table>
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<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-08-2020 12:31:52</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td>Data Entry:</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern</td>
<td></td>
<td>(autocalc)</td>
<td>DELTOID MUSCLE</td>
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</tr>
<tr>
<td>Time (US &amp; Canada)</td>
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6. Body Side:

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<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-08-2020 12:31:52</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4)</td>
<td>Data Entry:</td>
<td>Initial Entry</td>
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<tr>
<td>(UTC-05:00) Eastern</td>
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<td>(b) (6)</td>
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<tr>
<td>Time (US &amp; Canada)</td>
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### 7. Route:

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<th>User</th>
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<th>Reason</th>
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<tbody>
<tr>
<td>Sep-08-2020 12:31:52</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td>Data Entry: INTRAMUSCULAR</td>
<td>Initial Entry</td>
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<tr>
<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
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<td>(autocalc)</td>
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### 10. Timeframe Subject Was Observed

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Sep-08-2020 12:31:52</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td>Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD</td>
<td>Initial Entry</td>
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<tr>
<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td></td>
<td>(autocalc)</td>
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</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Sep-08-2020 12:31:52</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: YES</td>
<td>Initial Entry</td>
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<tr>
<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
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</table>
### 1. Date of Visit

<table>
<thead>
<tr>
<th>Date</th>
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<th>Reason</th>
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<tbody>
<tr>
<td>Oct-06-2020 10:55:36 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4); (b) (6)</td>
<td>Data Entry: Oct/6/2020</td>
<td>Initial Entry</td>
</tr>
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</table>
## 1. Data Origin

<table>
<thead>
<tr>
<th>Date</th>
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<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Oct-06-2020 14:45:17 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> SITE</td>
<td>Initial Entry</td>
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## 2. Sample Type

<table>
<thead>
<tr>
<th>Date</th>
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<th>User</th>
<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Oct-06-2020 14:45:17 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> SERUM</td>
<td>Initial Entry</td>
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## 3. Sample Collected?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Oct-06-2020 14:45:26 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Deleted</td>
<td>Close Auto Query</td>
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<tr>
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<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Candidate</td>
<td>'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.</td>
</tr>
<tr>
<td>Oct-06-2020 14:45:17 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> YES Date of Collection: Oct/6/2020</td>
<td>Initial Entry</td>
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## 5.a

<table>
<thead>
<tr>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Sample ID: BP9RMS</td>
<td>Initial Entry</td>
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### 5.a Sample ID

<table>
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<tbody>
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<td>Data Entry: BP9RMS</td>
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### 5.b Sample ID

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<tr>
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<td>Initial Entry</td>
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### 5.c Sample ID

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### 5.d Sample ID

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<tr>
<td>Oct-06-2020 14:45:59</td>
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<td>Data Entry: Sample ID: BNW9M9</td>
<td>Initial Entry</td>
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### 5.d Sample ID

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### 5.e

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<th>Reason</th>
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<tr>
<td>Oct-06-2020 14:46:10</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Sample ID: BNW9MB</td>
<td>Initial Entry</td>
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### 5.e Sample ID

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<td>(b) (4), (b) (6)</td>
<td>Data Entry: BNW9MB</td>
<td>Initial Entry</td>
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### 1. Date of Completion/Discontinuation/Death:

<table>
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<tbody>
<tr>
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<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> October 6, 2020</td>
<td>Initial Entry</td>
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<td>10:55:29</td>
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### 2. Phase of Disposition:

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<tbody>
<tr>
<td>Oct-06-2020</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> VACCINATION</td>
<td>Initial Entry</td>
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<td>10:55:29</td>
<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
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### 3. Status:

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<th>Reason</th>
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<tbody>
<tr>
<td>Oct-06-2020</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> COMPLETED</td>
<td>Initial Entry</td>
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<td>User</td>
<td>Value</td>
<td>Reason</td>
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<td>Feb-23-2021 12:35:44</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Form Created</td>
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</table>
### 1. Category:

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<tr>
<td>Feb-23-2021 12:35:44</td>
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<td>Data Entry: ADVERSE EVENT</td>
<td>Initial Entry</td>
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### 2. AE ID:

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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
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<td>Feb-23-2021 12:35:44</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc(autocalc)</td>
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<td>Initial Entry</td>
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### 3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

<table>
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<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Feb-23-2021 12:35:44</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Left axillary lymph node swelling</td>
<td>Initial Entry</td>
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### 4. Start Date Time:

<table>
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<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Feb-23-2021 12:35:44</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Jan/13/2021 UNK:UNK</td>
<td>Initial Entry</td>
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</table>

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

<table>
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<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Feb-23-2021 12:35:44</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>NO</td>
<td>Initial Entry</td>
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</table>

### 6. Toxicity Grade:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
</table>
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).

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-23-2021 12:35:44 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
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</table>

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.**

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-23-2021 12:35:44 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

9. Is this event related to study treatment:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
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<tbody>
<tr>
<td>Feb-23-2021 12:35:44 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: RELATED</td>
<td>Initial Entry</td>
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10. Latest Action Taken with Study Treatment:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
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<tbody>
<tr>
<td>Feb-23-2021 12:35:44 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NOT APPLICABLE</td>
<td>Initial Entry</td>
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11. Was a Concomitant Medication given?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
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</table>

**Page 131 of 159**
<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Feb-23-2021 12:35:44 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

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

14. **Did the adverse event cause the subject to be discontinued from the study?**
### Date of Visit

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Dec-21-2020 14:24:01 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
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<td><strong>Data Entry:</strong> Dec/16/2020</td>
<td>Initial Entry</td>
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**Form:** DATE OF VISIT - eCRF Audit Trail History  
**Form Status:** Data Complete, Frozen, Verified  
**Site Name:** (1111) Fleming Island Center for Clinical Research  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:58
1. Select appropriate response - Is participant willing to return for Vaccination 3?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
</table>
| Dec-21-2020 14:24:13  | ACV0PFEINFP6000| (b) (4); (b) (6) | Data Entry: Participant is willing to return for Vaccination 3  
Participant is eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2 | Initial Entry |
| (UTC-05:00) Eastern Time (US & Canada) |              |             | Data Entry: Participant is willing to return for Vaccination 3  
Participant is eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2 | Initial Entry |
### 1. Date of Visit

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<td>Dec-21-2020 14:24:29</td>
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<td>Time (US &amp; Canada)</td>
<td>(b) (6)</td>
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### 1. Consent Was:

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<td>Data Entry: OBTAINED Date Written Consent Obtained Dec/21/2020</td>
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### 1. Date of Completion/Discontinuation/Death:

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### 2. Phase of Disposition:

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<tr>
<td>Dec-21-2020 14:25:24 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
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### 3. Status:

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### 1. Lab Panel:

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<td>Dec-21-2020 14:25:52</td>
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### 2. Lab Sub-Panel:

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### 3. Collection Date:

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### 4. Laboratory Name and Address (Derived)

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### 5. Specimen Type:

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### 6.a Sponsor ID:

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### 6.a Test:

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### 1. Data Origin

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<tr>
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### 2. Sample Type

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### 3. Sample Collected?

<table>
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<tbody>
<tr>
<td>Dec-21-2020 15:41:07</td>
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<td>auto query (autoquery)</td>
<td>Query 1: Deleted</td>
<td>Close Auto Query</td>
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<td>Date of Collection: Dec/21/2020</td>
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### 5.a

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<td>Data Entry: Sample ID: BRJC7M</td>
<td>Initial Entry</td>
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<tr>
<td>Date</td>
<td>Location</td>
<td>User</td>
<td>Value</td>
<td>Reason</td>
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<td>Data Entry: BRJC7M</td>
<td>Initial Entry</td>
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<td>Initial Entry</td>
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<td>(b) (4), (b) (6)</td>
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### 5.d Sample ID

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### 5.e

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### 5.e Sample ID

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### 1. Data Origin

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<td>Dec-21-2020 15:42:05 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
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<td>Data Entry: SITE</td>
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### 2. Sample Type

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### 3. Sample Collected?

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<tbody>
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<td>Query 1: Deleted</td>
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<td>auto query (autoquery)</td>
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<td>Data Entry: YES</td>
<td>Date of Collection: Dec/21/2020</td>
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### 5.a

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<td>(b) (4), (b) (6)</td>
<td>Data Entry: Sample ID: BRJC75</td>
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### 5.1 Sample ID

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

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### 2. Treatment Name

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### 4. Dose Date Time:

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### 5. Anatomical Location:

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<td>Time (US &amp; Canada)</td>
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### 6. Body Side:

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***Confidential***
### 7. Route:

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<td>Initial Entry</td>
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### 8. Actual Dose:

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### 10. Timeframe Subject Was Observed

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

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### 1. Date Treatment Unblinded:

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### 2. Primary Reason for Unblinding:

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### 1. Date of Visit

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### 3. Collection Date:

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### 4. Laboratory Name and Address (Derived)

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### 6.a

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### 2. Sample Type

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### 3. Sample Collected?

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### 5.a

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Audit Trail History:
- **Form Version:** 22-Apr-2020 21:03
- **Form Status:** Data Complete, Frozen, Verified
- **Site No:** 1111
- **Site Name:** (1111) Fleming Island Center for Clinical Research
- **Subject No:** 11111139
- **Subject Initials:** ---
- **Generated Time (GMT):** 29-Mar-2021 10:58
### 1. Was there a temporary delay of vaccination?

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### 3. Formulation:

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### 5. Anatomical Location:

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### 6. Body Side:

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### 1. Date of Visit

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<td>Query I: Opened</td>
<td>DM: Patient completed Vaccination 3 visit through the 1-month post vaccination visit after the Vaccination 4. Please complete treatment disposition CRF and update date of EOT2 to match date of visit at visit 103.</td>
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<td>Feb-09-2021 13:55:32 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
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<td>Data Entry: Feb/8/2021</td>
<td>Initial Entry</td>
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1. **Contact Type:**

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<th>User</th>
<th>Value</th>
<th>Reason</th>
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<td>Feb-09-2021 13:55:47</td>
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<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> TELEPHONE VISIT</td>
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2. **Was contact made?**

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

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<td>Feb-11-2021 08:13:31</td>
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<td>Query 1: Closed</td>
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<td>Feb-10-2021 17:00:02</td>
<td>ACV0PFEINFP6000,InForm.Adapter.Discrepancy</td>
<td>DMW QUERY</td>
<td>(b) (4)</td>
<td>Query 1: Opened</td>
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**2. Phase of Disposition:**

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**3. Status:**

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## 1. Subject Status

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<tbody>
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<td>ACV0PFEINFP6000</td>
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<td><strong>Data Entry:</strong> FOLLOW-UP</td>
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<td>Time (US &amp; Canada)</td>
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<tr>
<td>Aug-21-2020 13:02:14</td>
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<td>Aug-21-2020 12:58:25</td>
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<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> SCREENED</td>
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## 2. Subject Status Date

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<td><strong>Data Entry:</strong> Oct/6/2020</td>
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<td>Time (US &amp; Canada)</td>
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## 1. Casebook Signature

<table>
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<th>Date</th>
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**Form**: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

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

**Site Name**: (1111) Fleming Island Center for Clinical Research

**Generated Time (GMT)**: 29-Mar-2021 10:58