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

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Select appropriate response - Protocol version</td>
</tr>
<tr>
<td>2.</td>
<td>Select appropriate response - What cohort does the subject belong to?</td>
</tr>
</tbody>
</table>
Informed Consent

1. Consent Was: OBTAINED
   Date Written Consent Obtained
   Aug/25/2020
**eCRF Audit Trail History**

<table>
<thead>
<tr>
<th>Demography</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Subject ID</td>
<td>[10931058]</td>
</tr>
<tr>
<td>2. Birth Date:</td>
<td>(b) (6)/1995</td>
</tr>
<tr>
<td>3. Sex:</td>
<td>FEMALE</td>
</tr>
<tr>
<td>4. Ethnicity:</td>
<td>NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN</td>
</tr>
<tr>
<td>5. Race: (Check X all that apply):</td>
<td>WHITE</td>
</tr>
<tr>
<td>6. Racial Designation:</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>Aug/25/2020</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>
### Form Comments

#### Inclusion Criteria Not Met

<table>
<thead>
<tr>
<th></th>
<th>Description of Inclusion Criterion Not Met</th>
<th>Not Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Exclusion Criteria Met

<table>
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<tr>
<th></th>
<th>Description of Exclusion Criterion Met</th>
<th>Not Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Disposition - Screening

1. **Date of Completion/Discontinuation/Death**: Aug/25/2020
2. **Phase of Disposition**: SCREENING
3. **Status**: COMPLETED
4. **Specify Status**: [ ]

### eCRF Audit Trail History

<table>
<thead>
<tr>
<th>Action</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>(b) (4)</td>
<td>FDA-CBER-2021-5683-1019716</td>
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</tbody>
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**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:31
### Medical History Details

<table>
<thead>
<tr>
<th></th>
<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>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>
## Vital Signs

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.</strong> Date:</td>
<td>Aug/25/2020</td>
</tr>
<tr>
<td><strong>2.</strong> Weight:</td>
<td>[136.2]</td>
</tr>
<tr>
<td><strong>3.</strong> Unit:</td>
<td>LB</td>
</tr>
<tr>
<td><strong>4.</strong> Height:</td>
<td>[63.5]</td>
</tr>
<tr>
<td><strong>5.</strong> Unit:</td>
<td>in</td>
</tr>
<tr>
<td><strong>6.</strong> Body Mass Index:</td>
<td>[23.7]</td>
</tr>
</tbody>
</table>

## Vital Signs Details

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>7.a</strong> Record Identifier:</td>
<td>1</td>
</tr>
<tr>
<td>Temperature:</td>
<td>[98.7]</td>
</tr>
<tr>
<td>Unit:</td>
<td>F</td>
</tr>
<tr>
<td>Temperature Location:</td>
<td>ORAL CAVITY</td>
</tr>
<tr>
<td>eCRF Audit Trail History</td>
<td></td>
</tr>
<tr>
<td>--------------------------</td>
<td></td>
</tr>
</tbody>
</table>

**Lab Urinalysis**

1. **Lab Panel:** URINALYSIS  
2. **Lab Sub-Panel:** PREGNANCY  
3. **Collection Date:** Aug/25/2020  
4. **Laboratory Name and Address (Derived):** [STUDY SITE]  
5. **Specimen Type:** URINE

**Lab Result**

6.a **Sponsor ID:** [113]  
**Test:** Choriogonadotropin Beta_PX113  
**Result:** NEGATIVE  
**Not Done:**
**eCRF Audit Trail History**

<table>
<thead>
<tr>
<th>Disposition</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Randomization Date : Aug/25/2020</td>
</tr>
<tr>
<td>2. Randomization Number: [67013]</td>
</tr>
<tr>
<td>3. Randomization Group: [ ]</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>Date of Collection:</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.

<table>
<thead>
<tr>
<th></th>
<th>Sample ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.a</td>
<td>[BP5D41]</td>
</tr>
<tr>
<td>5.b</td>
<td>[BP5D42]</td>
</tr>
<tr>
<td>5.c</td>
<td>[BP5D43]</td>
</tr>
<tr>
<td>5.d</td>
<td>[BPR65W]</td>
</tr>
<tr>
<td>5.e</td>
<td>[BPR65X]</td>
</tr>
</tbody>
</table>
### 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>Date of Collection:</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>
### 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></td>
<td>NO</td>
</tr>
<tr>
<td>2.</td>
<td>Treatment Name</td>
</tr>
<tr>
<td></td>
<td>[BLINDED THERAPY]</td>
</tr>
<tr>
<td>3.</td>
<td>Formulation:</td>
</tr>
<tr>
<td></td>
<td>INJECTION</td>
</tr>
<tr>
<td>4.</td>
<td>Dose Date Time:</td>
</tr>
<tr>
<td></td>
<td>Aug/25/2020 17:21</td>
</tr>
<tr>
<td>5.</td>
<td>Anatomical Location:</td>
</tr>
<tr>
<td></td>
<td>DELTOID MUSCLE</td>
</tr>
<tr>
<td>6.</td>
<td>Body Side:</td>
</tr>
<tr>
<td></td>
<td>RIGHT</td>
</tr>
<tr>
<td>7.</td>
<td>Route:</td>
</tr>
<tr>
<td></td>
<td>INTRAMUSCULAR</td>
</tr>
<tr>
<td>8.</td>
<td>Actual Dose:</td>
</tr>
<tr>
<td></td>
<td>[ ]</td>
</tr>
<tr>
<td>9.</td>
<td>Unit:</td>
</tr>
<tr>
<td>10.</td>
<td>Timeframe Subject Was Observed</td>
</tr>
<tr>
<td></td>
<td>THE PROTOCOL SPECIFIED OBSERVATION PERIOD</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></td>
<td>YES</td>
</tr>
<tr>
<td>Reactogenicity Diary</td>
<td></td>
</tr>
<tr>
<td>----------------------</td>
<td></td>
</tr>
<tr>
<td>1. Select appropriate response - Reactogenicity diary collection</td>
<td>NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT</td>
</tr>
<tr>
<td>Date of Visit</td>
<td>Description</td>
</tr>
<tr>
<td>---------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>1.</td>
<td>Date of Visit Sep/18/2020</td>
</tr>
<tr>
<td>2.</td>
<td>Erroneous Visit</td>
</tr>
</tbody>
</table>
### Vital Signs Details

2.a  | Record Identifier: | 1  
    | Temperature: | [98.3]  
    | Unit: | F  
    | Temperature Location: | ORAL CAVITY
### eCRF Audit Trail History

#### Lab Urinalysis

1. Lab Panel: URINALYSIS
2. Lab Sub-Panel: PREGNANCY
3. Collection Date: Sep/18/2020
4. Laboratory Name and Address (Derived): [STUDY SITE]
5. Specimen Type: URINE

#### Lab Result

6.a Sponsor ID: [113]
Test: Choriogonadotropin Beta PX113
Result: POSITIVE
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></td>
<td>Date of Collection:</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.

<table>
<thead>
<tr>
<th>5.a</th>
<th>Sample ID</th>
<th>[BPR6R8]</th>
</tr>
</thead>
</table>
### Vaccination

<table>
<thead>
<tr>
<th></th>
<th>Question</th>
<th>Status</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Was there a temporary delay of vaccination?</td>
<td>Not Done</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Treatment Name</td>
<td>Not Done</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Formulation:</td>
<td>Not Done</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Dose Date Time:</td>
<td>Not Done</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Anatomical Location:</td>
<td>Not Done</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Body Side:</td>
<td>Not Done</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Route:</td>
<td>Not Done</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Actual Dose:</td>
<td>Not Done</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Unit:</td>
<td>Not Done</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Timeframe Subject Was Observed</td>
<td>Not Done</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Was the subject observed for at least the protocol specified observation period after investigational product administration?</td>
<td>Not Done</td>
<td></td>
</tr>
</tbody>
</table>
### Date of Visit

<table>
<thead>
<tr>
<th></th>
<th>Date of Visit</th>
<th>Erroneous Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td>//</td>
</tr>
<tr>
<td>2.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## 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:** [

<table>
<thead>
<tr>
<th>Aliquot</th>
</tr>
</thead>
</table>

**Please enter barcode for each aliquot.**

5. **Sample ID** [

---

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

**Generated Time (GMT):** 29-Mar-2021 10:31

---

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931058

**Subject Initials:** ---

---

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

**Form Status:** Not Started

---

**Header Text:** c4591001

**Visit:** V3_MONTH1_POSTVAX2_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
## Date of Visit

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Date of Visit //</td>
</tr>
<tr>
<td>2.</td>
<td>Erroneous Visit</td>
</tr>
</tbody>
</table>
### 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** [ ]
<table>
<thead>
<tr>
<th>Date of Visit</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Visit</td>
<td>//</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>

**Header Text:** c4591001  
**Visit:** V5_MONTH12_L  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1093  
**Subject No:** 10931058  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:31  
**Site Name:** (1093) Meridian Clinical Research  
**Subject Initials:** ---  
**Form:** DATE OF VISIT  
**Form Status:** Not Started
# 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
   - [ ]
<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>

**Date of Visit**

1. Date of Visit //
2. Erroneous Visit
### Electronic Sample Tracking

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</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.</td>
<td>Sample ID [ ]</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>
<tr>
<td>COVID-19 Illness Visit</td>
<td></td>
</tr>
<tr>
<td>3. COVID-19 Illness Visit:</td>
<td></td>
</tr>
<tr>
<td>Signs and Symptoms</td>
<td></td>
</tr>
<tr>
<td>----------------------------</td>
<td></td>
</tr>
<tr>
<td>1. Date of Assessment:</td>
<td>//</td>
</tr>
<tr>
<td>2. Date of First Symptom Started:</td>
<td>//</td>
</tr>
<tr>
<td>3. Symptoms Ongoing?</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Symptoms - Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>5. Symptoms - Other Text:</td>
</tr>
<tr>
<td>1.</td>
</tr>
<tr>
<td>----</td>
</tr>
<tr>
<td>2.</td>
</tr>
<tr>
<td>3.</td>
</tr>
<tr>
<td>4.</td>
</tr>
</tbody>
</table>

**Aliquot**

Please enter barcode for each aliquot.

| 5. | Sample ID | [] |
| 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: |
| 5. | Sample ID |

Please enter barcode for each aliquot.
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?**
### Illness Details

<table>
<thead>
<tr>
<th></th>
<th>Category of Clinical Event:</th>
</tr>
</thead>
<tbody>
<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>

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**Header Text:** c4591001  
**Visit:** POT_COVID_ILL - New Unscheduled Visit  
**Form Version:** 06-Jul-2020 21:52  
**Site No:** 1093  
**Subject No:** 10931058  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:31
<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>

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

   [ ]
### Date of Visit

1. Date of Visit //
2. Erroneous Visit
# Unplanned Assessments

1. Assessments

---

**Visit:** Unplanned - New Unscheduled Visit  
**Form Version:** 22-Apr-2020 21:04  
**Site No:** 1093  
**Subject No:** 10931058  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:31  
**Site Name:** (1093) Meridian Clinical Research  
**Subject Initials:** ---  
**Form:** UNPLANNED VISIT  
**Form Status:** Not Started  

---

**Final On:** 01-Apr-2021 03:39 (GMT)
### eCRF Audit Trail History

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

**eCRF Audit Trail History**

**Disposition - Follow-Up**

1. Date of Completion/Discontinuation/Death: Nov/9/2020
2. Phase of Disposition: FOLLOW-UP
3. Status: LOST TO FOLLOW-UP
4. Specify Status: [Subject was lost to follow up.]
<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>

<table>
<thead>
<tr>
<th>COVID-19 Repeat Swab</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. COVID-19 Repeat Swab:</td>
</tr>
</tbody>
</table>
### 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**

   [ ]
<table>
<thead>
<tr>
<th>#</th>
<th>Category</th>
<th>AE Identifier</th>
<th>Adverse Event</th>
<th>Start Date</th>
<th>Is the Adverse Event Still Ongoing</th>
<th>Form Instance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>ADVERSE EVENT</td>
<td>1</td>
<td>EXPOSURE DURING PREGNANCY</td>
<td>Aug/25/2020 00:00</td>
<td>YES</td>
<td>Repeating Pages</td>
</tr>
</tbody>
</table>

**Header Text:** c4591001

**Visit:** Logs

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

**Site No:** 1093

**Site Name:** (1093) Meridian Clinical Research

**Subject No:** 10931058

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:31
### Adverse Event Report

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Category: ADVERSE EVENT</td>
</tr>
<tr>
<td>2.</td>
<td>AE ID: [1]</td>
</tr>
<tr>
<td>3.</td>
<td>Adverse Event: (If possible specify diagnosis, not individual symptoms) [EXPOSURE DURING PREGNANCY]</td>
</tr>
<tr>
<td>4.</td>
<td>Start Date Time: Aug/25/2020 00:00</td>
</tr>
<tr>
<td>5.</td>
<td>Is the adverse event still ongoing? YES</td>
</tr>
<tr>
<td>6.</td>
<td>Toxicity Grade: Not Applicable</td>
</tr>
<tr>
<td>7.</td>
<td>Is the adverse event serious? NO</td>
</tr>
<tr>
<td>8.</td>
<td>Is this adverse event the result of a study Medication Error? NO</td>
</tr>
<tr>
<td>9.</td>
<td>Is this event related to study treatment: NOT RELATED</td>
</tr>
<tr>
<td></td>
<td>If Not Related to study treatment(s), this event is due to: OTHER</td>
</tr>
<tr>
<td></td>
<td>If Other, specify: [PREGNANCY]</td>
</tr>
<tr>
<td>10.</td>
<td>Latest Action Taken with Study Treatment: DRUG WITHDRAWN</td>
</tr>
<tr>
<td>11.</td>
<td>Was a Concomitant Medication given? NO</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td><strong>12.</strong> Was a Non-Drug Treatment given?</td>
<td>NO</td>
</tr>
<tr>
<td><strong>13.</strong> What was the outcome of this adverse event?:</td>
<td>UNKNOWN</td>
</tr>
<tr>
<td><strong>14.</strong> Did the adverse event cause the subject to be discontinued from the study?</td>
<td>NO</td>
</tr>
<tr>
<td><strong>15.</strong> 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>

---

**FDA-CBER-2021-5683-1019755**
## 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

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:  
   //
<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

<table>
<thead>
<tr>
<th>No.</th>
<th>Description</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>What is the medication identifier?</td>
<td>[ ]</td>
</tr>
<tr>
<td>2</td>
<td>Category</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Concomitant Medications Pre-specified</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>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).</td>
<td>[ ]</td>
</tr>
<tr>
<td>5</td>
<td>Dose</td>
<td>[ ]</td>
</tr>
<tr>
<td>6</td>
<td>Dose Unit</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Dose Frequency</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Route</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Start Date: //</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Ongoing?</td>
<td></td>
</tr>
<tr>
<td>#</td>
<td>Category</td>
<td>Treatment Identifier</td>
</tr>
<tr>
<td>----</td>
<td>----------</td>
<td>----------------------</td>
</tr>
<tr>
<td>1.</td>
<td></td>
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</tr>
</tbody>
</table>
### Radiation Treatment

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

<table>
<thead>
<tr>
<th>#</th>
<th>Transfusion Type</th>
<th>Date of Transfusion</th>
<th>Form Instance</th>
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</thead>
<tbody>
<tr>
<td>1.</td>
<td>Repeating Pages</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td>Transfusion Type:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Date of Transfusion: //</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

Site No: 1093  
Subject No: 10931058  
Generated By: (b) (4)  
Site Name: (1093) Meridian Clinical Research  
Subject Initials: ---  
Generated Time (GMT): 29-Mar-2021 10:31
### Date of Visit

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Date of Visit //</td>
</tr>
<tr>
<td>2.</td>
<td>Erroneous Visit</td>
</tr>
</tbody>
</table>
**Vital Signs**

1. Date: //

**Vital Signs Details**

2. Record Identifier:  
   Temperature: [ ]  
   Unit:  
   Temperature Location: 
### Lab Urinalysis

1. **Lab Panel:**

2. **Lab Sub-Panel:**

3. **Collection Date:** //

4. **Laboratory Name and Address (Derived):** [ ]

5. **Specimen Type:**

### Lab Result

6. **Sponsor ID:** [ ]

   - **Test:**
   - **Result:**
   - **Not Done:**

---

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form Version:** 20-Feb-2021 02:14

**Site No:** 1093

**Subject No:** 10931058

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

**Generated Time (GMT):** 29-Mar-2021 10:31
### 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>Contact Outcome</td>
<td></td>
</tr>
<tr>
<td>-----------------</td>
<td></td>
</tr>
<tr>
<td>1. Contact Type:</td>
<td></td>
</tr>
<tr>
<td>2. Was contact made?</td>
<td></td>
</tr>
<tr>
<td>3. Comments: [ ]</td>
<td></td>
</tr>
</tbody>
</table>

**Form**: CONTACT OUTCOME - MONTH 1

**Visit**: Unplanned Vaccination - Unscheduled

**Form Version**: 10-Oct-2020 15:57

**Site No**: 1093

**Site Name**: (1093) Meridian Clinical Research

**Subject No**: 10931058

**Subject Initials**: ---

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

**Generated Time (GMT)**: 29-Mar-2021 10:31
<table>
<thead>
<tr>
<th>Contact Outcome</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Contact Type:</td>
<td></td>
</tr>
<tr>
<td>2. Was contact made?</td>
<td></td>
</tr>
<tr>
<td>3. Comments:</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form Version:** 10-Oct-2020 16:01

**Site No:** 1093

**Subject No:** 10931058

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

**Generated Time (GMT):** 29-Mar-2021 10:31

**Form:** CONTACT OUTCOME - MONTH 6

**Form Status:** Not Started

**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---
<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:** V201_SURVEIL_CONSENT - Unscheduled  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1093  
**Subject No:** 10931058  
**Generated By:** (b) (4)  
**Form:** DATE OF VISIT  
**Form Status:** Not Started  
**Site Name:** (1093) Meridian Clinical Research  
**Generated Time (GMT):** 29-Mar-2021 10:31
Informed Consent - Asymptomatic Surveillance

1. Consent Was:
### 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** [ ]
### 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 [ ]
<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>
### Further Vaccination Confirmation

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Select appropriate response - Is participant willing to return for Vaccination 3?</td>
</tr>
</tbody>
</table>
## Treatment Unblinded

1. Date Treatment Unblinded: //
2. Primary Reason for Unblinding:
<table>
<thead>
<tr>
<th>Withdrawal Of Consent</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Withdrawal of Consent Date : //</td>
</tr>
</tbody>
</table>
### Death Details

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

### Cause of Death

2. Cause of Death Status: 
   Cause of Death: [ ]
eCRF Audit Trail History

Subject Status

<table>
<thead>
<tr>
<th></th>
<th>Subject Status</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>DISCONTINUED</td>
<td>Nov/9/2020</td>
</tr>
<tr>
<td>2</td>
<td>Subject Status Date</td>
<td>Nov/9/2020</td>
</tr>
</tbody>
</table>
**eCRF Audit Trail History**

**Casebook Signature Form**

| 1. | Casebook Signature | Click Here to Enable |
**Audit Trail**

This form requires signing by a member of each of the following signature groups:
- CRF_Sign
- CRF_Sign_1

<table>
<thead>
<tr>
<th>Name</th>
<th>Signature Meaning</th>
<th>Date</th>
<th>Type</th>
<th>Action</th>
</tr>
</thead>
</table>

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**Header Text:** c4591001
**Visit:** Investigator Signature - Unscheduled
**Form:** CASEBOOK SIGNATURE FORM
**Form Version:** 22-Apr-2020 21:04
**Form Status:** Data Complete, Verified
**Site No:** 1093
**Site Name:** (1093) Meridian Clinical Research
**Subject No:** 10931058
**Subject Initials:** ---
**Generated By:** (b) (4)
**Generated Time (GMT):** 29-Mar-2021 10:31
<table>
<thead>
<tr>
<th>Item</th>
<th>Date</th>
<th>User</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form</td>
<td>Aug-26-2020 11:32:01 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>(b) (4), (b) (6)</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>
### GENERAL MEDICAL HISTORY - Comments

**Visit:** V1_DAY1_VAX1_L  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1093  
**Subject No:** 10931058  
**Generated By:** (b) (4)  
**Site Name:** (1093) Meridian Clinical Research  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:31  

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

<table>
<thead>
<tr>
<th>Item</th>
<th>Date</th>
<th>User</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form</td>
<td>Aug-26-2020 11:32:39 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>(b) (4), (b) (6)</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>
**Header Text:** c4591001  
**Visit:** V2_VAX2_L  
**Form Version:** 22-Apr-2020 21:04  
**Site No:** 1093  
**Subject No:** 10931058  
**Generated By:** (b) (4)  

**Form:** VACCINATION - Comments  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site Name:** (1093) Meridian Clinical Research  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:31

<table>
<thead>
<tr>
<th>Item</th>
<th>Date</th>
<th>User</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form</td>
<td>Nov-02-2020 08:31:16 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>(b) (4), (b) (6)</td>
<td>Not Done</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>1</td>
<td>Nov-02-2020 08:31:16 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>(b) (4), (b) (6)</td>
<td>Not Done</td>
</tr>
<tr>
<td>1</td>
<td>Sep-25-2020 12:54:56 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>(b) (4), (b) (6)</td>
<td>VACCINATION WAS NOT DONE; SUBJECT HAS CONFIRMED PREGNANCY</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>2</td>
<td>Nov-02-2020 08:31:16 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>(b) (4), (b) (6)</td>
<td>Not Done</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>3</td>
<td>Nov-02-2020 08:31:16 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>(b) (4), (b) (6)</td>
<td>Not Done</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>4</td>
<td>Nov-02-2020 08:31:16 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>(b) (4), (b) (6)</td>
<td>Not Done</td>
</tr>
<tr>
<td>4</td>
<td>Sep-25-2020 12:55:05 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>(b) (4), (b) (6)</td>
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<tr>
<td>Item</td>
<td>Date</td>
<td>User</td>
<td>Comment</td>
</tr>
<tr>
<td>------</td>
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**Form:** VACCINATION - Comments  
**Form Version:** 22-Apr-2020 21:04  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1093  
**Site Name:** (1093) Meridian Clinical Research  
**Subject No:** 10931058  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:31
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- CRF_Sign
- CRF_Sign_1

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<tr>
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<td>Nov-17-2020 17:29:26 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>BOOK</td>
<td>Signed</td>
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**Affidavit:**
By my dated signature below, I, DavidEnsz, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

| (b) (6)               | N/A               | Nov-16-2020 10:46:43 (UTC-06:00) Central Time (US & Canada) |        | Edit - All signatures invalidated           |
| David Ensz            | Approved          | Nov-06-2020 22:47:44 (UTC-06:00) Central Time (US & Canada) | BOOK   | Signed                                      |

**Affidavit:**
By my dated signature below, I, DavidEnsz, 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: N/A

David Ensz  Approved  Nov-03-2020 17:04:25 (UTC-06:00) Central Time (US & Canada)  BOOK  Signed

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

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

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

(b) (6)  N/A  Nov-03-2020 13:50:09 (UTC-06:00) Central Time (US & Canada)  Edit - All signatures invalidated

Affidavit: N/A

David Ensz  Approved  Nov-03-2020 10:41:24 (UTC-06:00) Central Time (US & Canada)  BOOK  Signed

Affidavit:
By my dated signature below, I, DavidEnsz, 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  Oct-26-2020 14:40:25 (UTC-06:00) Central Time (US & Canada)  Edit - All signatures invalidated

Affidavit: N/A

David Ensz  Approved  Oct-26-2020 14:40:25 (UTC-06:00) Central Time (US & Canada)  BOOK  Signed
Affidavit:
By my dated signature below, I, David Ensz, 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:
N/A

Affidavit:
David Ensz
Approved

Affidavit:
By my dated signature below, I, David Ensz, 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

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<th>Value</th>
<th>Reason</th>
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2. Select appropriate response - What cohort does the subject belong to?

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**Consent Was:**

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<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
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<td>Date Written Consent Obtained Aug/25/2020</td>
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1. **Subject ID**

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<td>(autocalc)</td>
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2. **Birth Date:**

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3. **Sex:**

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<td>Initial Entry</td>
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5. **Race: (Check X all that apply):**

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### 3. Status:

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### 4. Height:

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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aug-26-2020 11:33:04</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Data Entry: 1</td>
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</table>

### 7.a Temperature:

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### 7.a Unit:

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<tbody>
<tr>
<td>Aug-26-2020 11:33:04 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4)</td>
<td>98.7</td>
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### 7.a Temperature Location:

<table>
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<tr>
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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Aug-26-2020 11:33:04 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4)</td>
<td>Temperature 38.7 F is outside of Normal Range 97 - 99.5 F.</td>
<td>Data Entry: 38.7</td>
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Initial Entry
### 1. Lab Panel:

<table>
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<tr>
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<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Aug-26-2020 11:33:10</td>
<td>(UTC-06:00) Central Time</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry:</td>
</tr>
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<td></td>
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<td>URINALYSIS</td>
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### 2. Lab Sub-Panel:

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<td>auto calc (autocalc)</td>
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### 3. Collection Date:

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<th>Reason</th>
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<tbody>
<tr>
<td>Aug-26-2020 11:33:10</td>
<td>(UTC-06:00) Central Time</td>
<td>(b)</td>
<td>Data Entry:</td>
<td>Aug/25/2020</td>
</tr>
<tr>
<td></td>
<td>(US &amp; Canada)</td>
<td>(4)</td>
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</tr>
<tr>
<td></td>
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<td>(6)</td>
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### 4. Laboratory Name and Address (Derived)

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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Aug-26-2020 11:33:10</td>
<td>(UTC-06:00) Central Time</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry:</td>
</tr>
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<td>(US &amp; Canada)</td>
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<td>STUDY SITE</td>
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### 5. Specimen Type:

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<th>Reason</th>
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<td>Aug-26-2020 11:33:10</td>
<td>(UTC-06:00) Central Time</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry:</td>
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### 6.a

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<th>Reason</th>
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<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry:</td>
</tr>
<tr>
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<td>(US &amp; Canada)</td>
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<td>Sponsor-Define 113</td>
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**6.a Sponsor ID:**

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<tr>
<td>Aug-26-2020 11:33:10 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b), (4), (6)</td>
<td><strong>Data Entry:</strong> Choriogonadotropin Beta PX113</td>
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**6.a Result:**

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<tbody>
<tr>
<td>Aug-26-2020 11:33:10 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b), (4), (6)</td>
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### Randomization Date:

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<tbody>
<tr>
<td>Aug-26-2020 11:33:29 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
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<td><strong>Data Entry:</strong> Aug/25/2020</td>
<td>Initial Entry</td>
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### Randomization Number:

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### 1. Data Origin

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<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
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<td>Initial Entry</td>
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<td>(US &amp; Canada)</td>
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### 2. Sample Type

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### 3. Sample Collected?

<table>
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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Aug-27-2020 08:40:43</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Closed</td>
<td>Close Auto Query</td>
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<tr>
<td>(UTC-06:00) Central Time</td>
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<td>(US &amp; Canada)</td>
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<tr>
<td>Aug-26-2020 23:47:48</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Opened</td>
<td>'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time</td>
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<tr>
<td>(US &amp; Canada)</td>
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</tr>
<tr>
<td>Aug-26-2020 11:33:35</td>
<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>
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<tr>
<td>(UTC-06:00) Central Time</td>
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<tr>
<td>(US &amp; Canada)</td>
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<tr>
<td>Aug-26-2020 11:33:35</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: YES</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time</td>
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<td>(US &amp; Canada)</td>
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### 5. Sample ID

<table>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Sample ID: BP5D41</td>
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**5.a Sample ID**

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<th>Reason</th>
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**5.b Sample ID**

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<tr>
<td>Aug-27-2020 08:40:55 (UTC-06:00) Central Time (US &amp; Canada)</td>
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<td>Data Entry: Sample ID: BP5D42</td>
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**5.c Sample ID**

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<tr>
<td>Aug-27-2020 08:41:02 (UTC-06:00) Central Time (US &amp; Canada)</td>
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**5.d**

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<tr>
<td>Date/Time</td>
<td>Site No</td>
<td>Subject No</td>
<td>Data Entry</td>
<td>Transcription Error</td>
</tr>
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<td>------------</td>
<td>------------</td>
<td>---------------------</td>
</tr>
<tr>
<td>Sep-08-2020 09:33:33 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>1093</td>
<td>10931058</td>
<td>Sample ID: BPR65W</td>
<td>Transcription Error</td>
</tr>
<tr>
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<td>ACV0PFEINFP6000</td>
<td>(b)(4), (b)(6)</td>
<td>Sample ID: BPR66F</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>Date</td>
<td>Location</td>
<td>User</td>
<td>Value</td>
<td>Reason</td>
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<td>---------------------------------------------------------</td>
</tr>
<tr>
<td>Sep-08-2020</td>
<td>ACV0PFEINFP6000.InFormAdapter.Discrepancy</td>
<td>DMW QUERY (b) (4)</td>
<td>Query 1: Closed</td>
<td>Auto closed by Validation Check: VC_BEETRK001_06</td>
</tr>
<tr>
<td>15:00:56</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
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</tr>
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<td>Sep-08-2020</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Answered</td>
<td>Transcription Error</td>
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<tr>
<td>09:33:33</td>
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<tr>
<td>Sep-08-2020</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: BPR65 W</td>
<td>Transcription Error</td>
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<tr>
<td>Sep-07-2020</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Reissued: Opened</td>
<td>DM1: Page is now unfrozen, kindly make appropriate update.</td>
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<td>00:19:59</td>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Answered</td>
<td>PLEASE UNLOCK SO THAT I MAY CHANGED THE BARCODE</td>
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<td>DMW QUERY (b) (4)</td>
<td>Query 1: Opened</td>
<td>DMW4607963:The barcode BPR66F is recorded for two subjects 10931057 and 10931058. Please review and update as appropriate.</td>
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<td>Value</td>
<td>Reason</td>
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<td>(b)</td>
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<td>(4), (6)</td>
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## 5.e Sample ID

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<tbody>
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<td><strong>Sep-08-2020</strong></td>
<td>ACV0PFEINFP6000.InFormAdapter.Discrepancy</td>
<td>DMW QUERY</td>
<td>(b) (4)</td>
<td>Auto closed by Validation Check: VC_BEETRK001_06</td>
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<td>(b) (4), (b)</td>
<td>Query 1: Answe red</td>
<td>PLEASE UNLOCK SO I MAY CHANGE THE BARCODE</td>
</tr>
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<td>17:42:23</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
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<tr>
<td><strong>Sep-04-2020</strong></td>
<td>ACV0PFEINFP6000.InFormAdapter.Discrepancy</td>
<td>DMW QUERY</td>
<td>(b) (4)</td>
<td>DMW4607964: The barcode BPR66G is recorded for two subjects 10931057 and 10931058. Please review and update as appropriate.</td>
</tr>
<tr>
<td>02:18:19</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
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<tr>
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<td>Data Entry:</td>
<td>Initial Entry</td>
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<td>08:51:25</td>
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**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History  
**Form Version:** 22-Apr-2020 21:03  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Visit:** V1_DAY1_VAX1_L  
**Site No:** 1093  
**Site Name:** (1093) Meridian Clinical Research  
**Subject No:** 10931058  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:31  
**Generated Time (GMT):** 29-Mar-2021 10:31  

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**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  
**Visit:** V1_DAY1_VAX1_L  
**Site No:** 1093  
**Site Name:** (1093) Meridian Clinical Research  
**Subject No:** 10931058  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:31
### 1. Data Origin

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### 2. Sample Type

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### 3. Sample Collected?

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<tbody>
<tr>
<td>Aug-27-2020 08:58:28</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>auto query (autoquery)</td>
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<td>Close Auto Query</td>
</tr>
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<td>Aug-26-2020 23:47:48</td>
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<td>Query 1: Opened</td>
<td>'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.</td>
</tr>
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<td>'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.</td>
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**5.a**
5.a Sample ID

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<td>Time (US &amp; Canada)</td>
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5.a Sample ID
### 1. Was there a temporary delay of vaccination?

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<td>Aug-26-2020 11:34:16 (UTC-06:00) Central Time (US &amp; Canada)</td>
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### 2. Treatment Name

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<td>auto calc (autocalc)</td>
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### 3. Formulation:

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### 4. Dose Date Time:

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<th>Value</th>
<th>Reason</th>
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<tbody>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Aug/25/2020 17:21</td>
<td>Initial Entry</td>
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### 5. Anatomical Location:

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<td>Data Entry: DELTOID MUSCLE</td>
<td>Initial Entry</td>
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### 6. Body Side:

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<tbody>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: RIGHT</td>
<td>Initial Entry</td>
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7. **Route:**

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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Aug-26-2020 11:34:16</td>
<td>ACV0PFEINF6000</td>
<td>auto calc</td>
<td><strong>Data Entry:</strong></td>
<td>Initial Entry</td>
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<tr>
<td></td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>(autocalc)</td>
<td>INTRAMUSCULAR</td>
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10. **Timeframe Subject Was Observed**

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<th>Reason</th>
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<td>ACV0PFEINF6000</td>
<td>auto calc</td>
<td><strong>Data Entry:</strong></td>
<td>Initial Entry</td>
</tr>
<tr>
<td></td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>(autocalc)</td>
<td>THE PROTOCOL SPECIFIED OBSERVATION PERIOD</td>
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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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<th>Value</th>
<th>Reason</th>
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<tbody>
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<td>Aug-26-2020 11:34:16</td>
<td>ACV0PFEINF6000</td>
<td>(b)</td>
<td><strong>Data Entry:</strong>&lt;sup&gt;(4), (6)&lt;/sup&gt;</td>
<td>Initial Entry</td>
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<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
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<td>YES</td>
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</table>
### 1. Select appropriate response - Reactogenicity diary collection

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<th>Location</th>
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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Sep-04-2020 00:32:07 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Sep-03-2020 13:10:25 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Answered</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Sep-03-2020 13:10:25 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Sep-03-2020 10:26:41 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Opened</td>
<td>eDiary: REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT is 'Yes' however VAX 1 eDiary records are not available for the subject. Please verify and update. Else, confirm in query response appropriately.</td>
</tr>
<tr>
<td>Aug-26-2020 11:35:12 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT</td>
<td>Initial Entry</td>
</tr>
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</table>
### Date of Visit

<table>
<thead>
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</tr>
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<tbody>
<tr>
<td>Oct-26-2020 15:04:22</td>
<td>ACV0PFEINFP6000</td>
<td>Hayley Wyper</td>
<td>Query 3: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
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<td>(b) (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Oct-26-2020 09:58:15</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
<td>Query 3: Answered</td>
<td>SUBJECT HAS BEEN SCHEDULED NUMEROUS TIMES FOR A V3 AND HAS NOT SHOWN UP.</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td></td>
<td>(b) (6)</td>
<td></td>
<td>GETTING CLARIFICATION ON IF SUBJECT IS GOING TO BE BROUGHT IN FOR FURTHER SAFETY FOLLOW UPS OR NOT.</td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
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<tr>
<td>Oct-23-2020 17:12:08</td>
<td>ACV0PFEINFP6000</td>
<td>Hayley Wyper</td>
<td>Query 3: Opened</td>
<td>CLINQUERY: Please clarify if subject has continued in study for safety follow up? (treatment discontinued). V3 not completed</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
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<td>(b) (4)</td>
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<td>Time (US &amp; Canada)</td>
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<td>Sep-28-2020 23:48:49</td>
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<td>(b) (4), (b)</td>
<td>Query 2: Closed</td>
<td>As per site confirmation - updated PD tracker</td>
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<td>(b) (6)</td>
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<td>Time (US &amp; Canada)</td>
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<tr>
<td>Sep-28-2020 08:47:24</td>
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<td>(b) (4), (b)</td>
<td>Query 2: Answered</td>
<td>Original value is correct</td>
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<tr>
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<tr>
<td>Time (US &amp; Canada)</td>
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<tr>
<td>Sep-28-2020 06:34:48</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
<td>Query 2: Opened</td>
<td>PDQ: DOV at this visit is out of window (1 day) from DOV (25/Aug/2020) at V1D1VX1L. Please reconcile and update accordingly, else confirm date is correct as is.</td>
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**Header Text:** c4591001

**Visit:** V2_VAX2_L

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

**Site No:** 1093

**Subject No:** 10931058

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

**Generated Time (GMT):** 29-Mar-2021 10:31

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<td>DM: Kindly review and complete 'Date of Visit, Nasal Swab, Vaccination, Vital Signs' forms at this visit. Thank you.</td>
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**Site Name:** (1093) Meridian Clinical Research

**Subject Initials:** ---

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

---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 10:31

---

***Confidential***

---

FDA-CBER-2021-5683-1019825
**Back to Form**

### 1. Date:

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### 2.a

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</tbody>
</table>

#### 2.a Temperature Location:

<table>
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<tr>
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<th>Value</th>
<th>Reason</th>
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<tbody>
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<td></td>
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<tr>
<td>Date</td>
<td>Time</td>
<td>Time Zone</td>
<td>User</td>
<td>Data Entry</td>
</tr>
<tr>
<td>-----------------</td>
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<td>---------------------</td>
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<tr>
<td>Sep-25-2020</td>
<td>12:29:39</td>
<td>(UTC-06:00) Central</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Time (US &amp; Canada)</td>
<td></td>
<td>Data Entry:</td>
</tr>
<tr>
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<td>ORAL CAVITY</td>
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**Header Text:**
c4591001
Visit: V2_VAX2_L
Form: VITAL SIGNS - TEMP - eCRF Audit Trail History
Form Version: 15-Sep-2020 21:54
Site No: 1093
Site Name: (1093) Meridian Clinical Research
Subject No: 10931058
Subject Initials: ---
Generated By: (b) (4)
### 1. Lab Panel:

<table>
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<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Sep-25-2020 12:29:46 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> URINALYSIS</td>
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### 2. Lab Sub-Panel:

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<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> PREGNANCY</td>
<td>Initial Entry</td>
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### 3. Collection Date:

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<th>Value</th>
<th>Reason</th>
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<td>Sep-25-2020 12:29:46 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b), (4), (6)</td>
<td><strong>Data Entry:</strong> Sep/18/2020</td>
<td>Initial Entry</td>
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### 4. Laboratory Name and Address (Derived)

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<th>Reason</th>
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<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> STUDY SITE</td>
<td>Initial Entry</td>
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### 5. Specimen Type:

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<tbody>
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<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
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<td>Initial Entry</td>
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### 6.a

<table>
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<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> Sponsor-Define 113</td>
<td>Initial Entry</td>
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### 6.6 Sponsor ID:

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<tbody>
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<td>auto calc (autocalc)</td>
<td>Data Entry: 113</td>
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### 6.6 Test:

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<tbody>
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<td>Sep-25-2020 12:29:46 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Choriogonadotropin Beta_PX113</td>
<td>Initial Entry</td>
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</table>

### 6.6 Result:

<table>
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<th>Value</th>
<th>Reason</th>
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<tr>
<td>Nov-08-2020 08:58:09 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 3: Reissu e d:Cand i date</td>
<td>Issue added in DM Meeting and Q &amp; A sheet.</td>
</tr>
<tr>
<td>Nov-04-2020 05:00:14 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 3: Resolved on EOT form</td>
<td>Resolved on EOT form</td>
</tr>
<tr>
<td>Nov-02-2020 16:21:40 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 3: Answered</td>
<td>DISPOSITION eCRF WAS STATU E AS AS PREGNANCY, WAS QUERIED TO CHANGE DISPOSITION TO</td>
</tr>
<tr>
<td>Date</td>
<td>Event Description</td>
<td>Resolution</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------------------</td>
<td>---------------------------------------------------------------------</td>
<td>-------------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nov-01-2020 23:04:03</td>
<td>ACV0PFEINFP6000.InFormAdapter.Discrepancy DMW QUERY</td>
<td>DMW5235566;There is a pregnancy test with a positive result, but there is no disposition eCRF with a 'Status' of PREGNANCY with a disposition date on or after the pregnancy test date. Please review and update as appropriate.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sep-29-2020 06:09:34</td>
<td>ACV0PFEINFP6000</td>
<td>Query 2: Closed per SITE response, added to PD tracker</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sep-28-2020 08:48:09</td>
<td>ACV0PFEINFP6000</td>
<td>Query 2: Answered</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sep-28-2020 02:25:14</td>
<td>ACV0PFEINFP6000</td>
<td>Query 2: Opened</td>
<td></td>
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</tr>
<tr>
<td>Sep-27-2020 02:02:37</td>
<td>ACV0PFEINFP6000</td>
<td>Query 1: Closed</td>
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<tr>
<td>Sep-25-2020 12:30:40</td>
<td>ACV0PFEINFP6000</td>
<td>Query 1: Answered</td>
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'ADVERSE EVENT'.
<table>
<thead>
<tr>
<th>Central Time</th>
<th>ACV0PFEINFP6000</th>
<th>auto query (autoquery)</th>
<th>Query 1: Opened</th>
<th>Lab result is “Positive”, but subject has been vaccinated. Please review and update as appropriate. Else explain.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-25-2020</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: POSITIVE</td>
<td>Initial Entry</td>
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<tr>
<td>12:29:46</td>
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<tr>
<td>(UTC-06:00)</td>
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<tr>
<td>Central Time</td>
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<tr>
<td>(US &amp; Canada)</td>
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<tr>
<td>Sep-25-2020</td>
<td>ACV0PFEINFP6000</td>
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<tr>
<td>12:29:46</td>
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<td></td>
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</tr>
<tr>
<td>(UTC-06:00)</td>
<td></td>
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</tr>
<tr>
<td>Central Time</td>
<td></td>
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<tr>
<td>(US &amp; Canada)</td>
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1. Data Origin

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Sep-21-2020 08:28:30 (UTC-06:00) Central 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>
<th>Location</th>
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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Sep-21-2020 08:28:30 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> NASAL_SWAB</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>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-21-2020 08:28:48 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Deleted</td>
<td>Close Auto Query</td>
</tr>
<tr>
<td>Sep-21-2020 08:28:30 (UTC-06:00) Central Time (US &amp; Canada)</td>
<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>
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<tr>
<td>Sep-21-2020 08:28:30 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b), (4), (6)</td>
<td><strong>Data Entry:</strong> YES Date of Collection: Sep/18/2020</td>
<td>Initial Entry</td>
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5.a

<table>
<thead>
<tr>
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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Sep-21-2020 08:28:48 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b), (4), (6)</td>
<td><strong>Data Entry:</strong> Sample ID: BPR6R8</td>
<td>Initial Entry</td>
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</table>

5.a Sample ID
<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>Sep-21-2020 08:28:48 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: BPR6R8</td>
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### 1. Was there a temporary delay of vaccination?

<table>
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<tbody>
<tr>
<td>Nov-03-2020 06:48:20</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Closed</td>
<td>Response satisfies query</td>
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<td>(UTC-06:00) Central</td>
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<tr>
<td>Time (US &amp; Canada)</td>
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<tr>
<td>Nov-02-2020 08:31:16</td>
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<td><strong>Data Entry:</strong> Not Done</td>
<td>Initial Entry</td>
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<td>(UTC-06:00) Central</td>
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<tr>
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<td>Time (US &amp; Canada)</td>
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<tr>
<td>Nov-02-2020 05:03:09</td>
<td>ACV0PFEINFP6000</td>
<td>Balaji Prabu R</td>
<td>Query 1: Opened</td>
<td>In case subject did not receive</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td></td>
<td>(b) (4)</td>
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<td>vaccination, please remove the</td>
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<tr>
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<td>response entered as NO and</td>
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<td>apply form level comment as</td>
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<td>NOT DONE. Else clarify.</td>
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### 2. Treatment Name

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<td>Initial Entry</td>
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<td>(UTC-06:00) Central</td>
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### 3. Formulation:

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<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Not Done</td>
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### 4. Dose Date Time:

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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Sep-25-2020 12:55:05 (UTC-06:00) Central Time (US &amp; Canada)</td>
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### 5. Anatomical Location:

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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Nov-02-2020 08:31:16 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
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<td>Initial Entry</td>
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### 6. Body Side:

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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Sep-25-2020 12:55:12 (UTC-06:00) Central Time (US &amp; Canada)</td>
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<td>(b), (4), (6)</td>
<td>Data Entry: Not Done</td>
<td>Initial Entry</td>
</tr>
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### 7. Route:

<table>
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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Nov-02-2020 08:31:16 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b), (4), (6)</td>
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<td>Initial Entry</td>
</tr>
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### 8. Actual Dose:

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<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Nov-02-2020 08:31:16 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b), (4), (6)</td>
<td>Data Entry: Not Done</td>
<td>Initial Entry</td>
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### 9. Unit:

<table>
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<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Nov-02-2020 08:31:16 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b), (4), (6)</td>
<td>Data Entry: Not Done</td>
<td>Initial Entry</td>
</tr>
</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>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-02-2020 08:31:16</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4)</td>
<td>Data Entry: Not Done</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td>Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sep-25-2020 12:55:20</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4)</td>
<td>Data Entry: Not Done</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td>Time (US &amp; Canada)</td>
<td>(b) (6)</td>
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<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>Sep-28-2020 08:46:57 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b), (4), (6)</td>
<td>Data Entry: Sep/18/2020</td>
<td>Initial Entry</td>
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</table>

### 2. Phase of Disposition:

<table>
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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-28-2020 08:46:57 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: VACCINATION</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

### 3. Status:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-30-2020 14:09:13 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Hayley Wyper (b) (4)</td>
<td>Query 3: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Nov-30-2020 13:55:34 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 3: Answered</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Nov-30-2020 13:55:34 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: PREGNANCY</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Nov-30-2020 10:39:47 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Hayley Wyper (b) (4)</td>
<td>Query 3: Opened</td>
<td>CLINQUERY: Since the AE involved was a Pregnancy, please capture PREGNANCY as the status selection. Apologies for prior instruction to change as appears in audit trail.</td>
</tr>
<tr>
<td>Oct-29-2020 07:40:18 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Katherine Puig (b) (4)</td>
<td>Query 2: Closed</td>
<td>query logic incorrect</td>
</tr>
<tr>
<td>Oct-29-2020 01:33:14</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Reissued:Opened</td>
<td>DM 1: Status is</td>
</tr>
<tr>
<td>Date/Time</td>
<td>User/Action</td>
<td>Description</td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------------------------------</td>
<td>--------------------------------------------------</td>
<td>------------------------------------------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oct-27-2020 08:17:46</td>
<td>ACV0PFEINFP6000</td>
<td>Query 2: Answered SUBJEC IS NOT DISCONTINUED FROM STUDY. SUBJECT IS STILL INCLUDED IN STUDY FOR FOLLOW UP PROCEDURES. WILL NOT BE VACCINATED AGAIN.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oct-27-2020 03:28:18</td>
<td>ACV0PFEINFP6000</td>
<td>Query 2: Reissued:Opened DM: Per CRF CR 8.55.2, If Adverse Event is primary reason the Participant was discontinued from study then corresponding AE should have 'Did the adverse event cause the Participant to be discontinued from the study?' as Yes. Please review and update CRF.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oct-27-2020 03:19:01</td>
<td>ACV0PFEINFP6000</td>
<td>Query 1: Closed Closed as data updated.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oct-26-2020 09:11:01</td>
<td>ACV0PFEINFP6000</td>
<td>Query 2: Answered SUBJECT IS NOT DISCONTINUED FROM STUDY. SUBJECT IS STILL INCLUDED IN STUDY FOR FOLLOW UP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date and Time (UTC)</td>
<td>Event</td>
<td>Description</td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------------------</td>
<td>--------</td>
<td>-------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oct-26-2020 09:08:29</td>
<td>auto query</td>
<td>Query 2: Opened</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Status is reported as Adverse Event, but there is no Adverse Event with 'Did the adverse event cause the subject to be discontinued from the study' reported as YES. Please check and correct the data.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oct-26-2020 09:08:29</td>
<td>auto query</td>
<td>Query 1: Answered</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Transcription Error</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oct-26-2020 09:08:29</td>
<td>auto query</td>
<td>Data Entry: ADVERSE EVENT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Transcription Error</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oct-26-2020 09:08:29</td>
<td>auto query</td>
<td>Query 1: Reissued:Opened</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>DM: Per previous response, 'HE AE IS THE PRIMARY REASON FOR THE WITHDRAWAL' kindly consider to update status as 'ADVERSE EVENT'.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oct-16-2020 07:24:09</td>
<td></td>
<td>Query 1: Reissued:Candidate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Status needs to be updated as AE.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>THE AE IS THE PRIMARY REASON FOR THE WITHDRAWAL; SUBJECT IS PREGNANT.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oct-14-2020 11:28:15</td>
<td></td>
<td>Query 1: Reissued:Opened</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>DM1: As per CRF CR Section 8.55.2, If there are two or more reasons for withdrawal and an adverse event is one of them, the</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date/Time</td>
<td>ACV0PFEINFP6000</td>
<td>Event Type</td>
<td>Comment</td>
<td></td>
</tr>
<tr>
<td>-------------------</td>
<td>----------------</td>
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<td>----------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Oct-12-2020 15:53:14 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Answered</td>
<td>REASON FOR DISCONTINUATION IS PREGNANCY. AE WAS MADE.</td>
<td></td>
</tr>
<tr>
<td>Oct-08-2020 08:56:42 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Opened</td>
<td>DM: The Adverse Event Action Taken is DRUG WITHDRAWN but reason for treatment discontinuation is not reported as ADVERSE EVENT or DEATH. Please review and clarify.</td>
<td></td>
</tr>
<tr>
<td>Sep-28-2020 08:46:57 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: PREGNANCY</td>
<td>Initial Entry</td>
<td></td>
</tr>
</tbody>
</table>

adverse event is considered the primary reason. Kindly update data accordingly, else clarify. Thank you.
### 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>Jan-05-2021 16:50:51 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Nov/9/2020</td>
<td>Initial Entry</td>
</tr>
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</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>Jan-05-2021 16:50:51 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: FOLLOW-UP</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

### 3. Status:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-31-2021 23:46:28 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Closed</td>
<td></td>
</tr>
<tr>
<td>Jan-29-2021 10:24:25 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 3: Closed</td>
<td></td>
</tr>
<tr>
<td>Jan-29-2021 10:23:58 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 3: Opened</td>
<td></td>
</tr>
<tr>
<td>Jan-29-2021 10:23:58 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 2: Answered Transcription Error</td>
<td></td>
</tr>
<tr>
<td>Jan-29-2021 10:23:58 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Response to &quot;Status&quot; is LOST TO FOLLOW-UP but &quot;Specify Status&quot; is missing.</td>
<td></td>
</tr>
<tr>
<td>Date/Time</td>
<td>ID</td>
<td>Data Entry</td>
<td>Query 2: Reissued: Opened</td>
<td>Query 2: Answered</td>
</tr>
<tr>
<td>-------------------------</td>
<td>-------------</td>
<td>------------</td>
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<td>-------------------</td>
</tr>
<tr>
<td>Jan-29-2021 10:23:58</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
<td>Lost To Follow-Up</td>
<td>As per your response 'SUBJECT DID NOT DISCONTINUE DUE TO PREGNANCY. SUBJECT WAS LOST TO FOLLOW UP,' please update the status of this subject accordingly on DISPOSITION forms at both EOT and FUP visits.</td>
</tr>
<tr>
<td>Jan-29-2021 01:04:54</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
<td>Lost To Follow-Up</td>
<td>SUBJECT DID NOT DISCONTINUE DUE TO PREGNANCY. SUBJECT WAS LOST TO FOLLOW UP.</td>
</tr>
<tr>
<td>Jan-28-2021 16:15:25</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
<td>Lost To Follow-Up</td>
<td>Response does not satisfy query. If subject discontinued due to the pregnancy, the date on this CRF should be updated to be same as EOT date.</td>
</tr>
<tr>
<td>Jan-28-2021 12:55:46</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
<td>Lost To Follow-Up</td>
<td>SUBJECT WAS LOST TO FOLLOW UP AFTER MULTIPLE TIMES OF TRYING TO CONTACT THEM.</td>
</tr>
<tr>
<td>Jan-27-2021 08:14:14</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
<td>Lost To Follow-Up</td>
<td>Status is Pregnancy but site replied that subject is Lost to Follow-Up. What is the reason of the subject discontinuation?</td>
</tr>
</tbody>
</table>
If it's the pregnancy, the date should be updated to be same as EOT. If it's Lost to Follow-Up, status should be updated accordingly.

<table>
<thead>
<tr>
<th>Date</th>
<th>Time (UTC-06:00)</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-25-2021</td>
<td>13:02:16</td>
<td>ACV0PFEINFP6000</td>
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<tr>
<td>Jan-25-2021</td>
<td>01:03:51</td>
<td>ACV0PFEINFP6000.InFormAdapter.Discrepancy</td>
</tr>
<tr>
<td>Jan-11-2021</td>
<td>19:22:47</td>
<td>ACV0PFEINFP6000</td>
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<tr>
<td>Jan-08-2021</td>
<td>13:04:31</td>
<td>ACV0PFEINFP6000</td>
</tr>
<tr>
<td>Jan-08-2021</td>
<td>12:07:27</td>
<td>ACV0PFEINFP6000</td>
</tr>
</tbody>
</table>

DMW6937447: Response to 'Status' is PREGNANCY, but there is no pregnancy tests with a positive result with a 'Collection Date' on or before the disposition date. Please review and update as appropriate.

Response satisfies query

Transcription Error

Transcription Error

Clinical Subject followup disposition is Completed; however,
subj did not finish the 2 yr study. Per CRF completion guidelines Sect 8.56, instructions for PG subjects (pg 204), Pregnancy should be entered

4. Specify Status:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-29-2021 10:24:25</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
<td>Data Entry: Subject was lost to follow up.</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td></td>
<td>(6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td>Location</td>
<td>User</td>
<td>Value</td>
<td>Reason</td>
</tr>
<tr>
<td>----------------------</td>
<td>---------------------</td>
<td>------------</td>
<td>-------------------</td>
<td>---------------</td>
</tr>
<tr>
<td>Sep-25-2020 13:03:18</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
<td>Form Created</td>
</tr>
</tbody>
</table>

**Back to Form**
### 1. Category:

<table>
<thead>
<tr>
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<th>User</th>
<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Sep-25-2020 13:03:18 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong></td>
<td>Initial Entry</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>ADVERSE EVENT</td>
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### 2. AE ID:

<table>
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<tr>
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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Sep-25-2020 13:03:18 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong></td>
<td>Initial Entry</td>
</tr>
<tr>
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<td></td>
<td></td>
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</tr>
</tbody>
</table>

### 3. Adverse Event:
*(If possible specify diagnosis, not individual symptoms)*

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-11-2021 19:23:07 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 4: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Jan-05-2021 16:51:31 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 4: Answered</td>
<td>entry updated</td>
</tr>
<tr>
<td>Jan-04-2021 15:18:37 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 4: Opened</td>
<td>Clinical As per query response, subject is lost to followup. Please complete the F/U disposition CRF with final date of followup.</td>
</tr>
<tr>
<td>Jan-04-2021 15:09:30 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 3: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Jan-04-2021 14:14:09 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 3: Answered</td>
<td>SUBJECT WAS LOST TO FOLLOW UP. UNSURE ON HOW TO PROCEED.</td>
</tr>
<tr>
<td>Dec-22-2020 12:14:35 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 3: Opened</td>
<td>Clinical - Please submit SAE update with prior pregnancy Hx with outcome if ever PG, maternal smoke/alcohol/illicit drug use, and father information</td>
</tr>
<tr>
<td>Date/Time</td>
<td>Subject ID</td>
<td>Event Type</td>
<td>Message Description</td>
<td></td>
</tr>
<tr>
<td>----------------------------------</td>
<td>--------------</td>
<td>---------------------</td>
<td>--------------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Dec-22-2020 10:15:38</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 3: Candidate</td>
<td></td>
</tr>
<tr>
<td>Nov-17-2020 03:55:12</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Closed</td>
<td></td>
</tr>
<tr>
<td>Nov-16-2020 15:26:02</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Reissued:Candidate</td>
<td></td>
</tr>
<tr>
<td>Nov-16-2020 11:19:37</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: EXPOSURE DURING PREGNANCY</td>
<td></td>
</tr>
<tr>
<td>Nov-16-2020 10:51:10</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: MATERNAL EXPOSURE DURING PREGNANCY</td>
<td></td>
</tr>
<tr>
<td>Nov-16-2020 10:46:43</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: MATERNAL EXPOSURE DURING PREGNANCY</td>
<td></td>
</tr>
</tbody>
</table>

Clinical - Please submit SAE update with prior pregnancy Hx with outcome if ever PG, maternal smoke/alcohol/illicit drug use, and father information including age and same use profile.

SAE term updated from pregnancy to exposure during pregnancy in SDB.

Awaiting safety update.

Transcription Error.

SAE RECON 4: The term in Safety database is still reported as PREGNANCY, a follow up AEM form is needed to update term in Safety database. Please submit to match term in both database.

Transcription Error.
### ADVERSE EVENT REPORT - eCRF Audit Trail History

<table>
<thead>
<tr>
<th>Date/Time</th>
<th>User</th>
<th>Event</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-16-2020 09:58:00</td>
<td>ACV0PFEINFP6000</td>
<td>Query 2: Reissued:Opened</td>
<td>SAE RECON 3: Per confirmation from PSSR, last follow up form received on 09NOV2020 does not indicate update in term. Please submit a follow up AEM form to update term to exposure during pregnancy in Safety database.</td>
</tr>
<tr>
<td>Nov-14-2020 09:33:52</td>
<td>ACV0PFEINFP6000</td>
<td>Query 2: Reissued:Pending SDB update</td>
<td></td>
</tr>
<tr>
<td>Nov-13-2020 17:35:08</td>
<td>ACV0PFEINFP6000</td>
<td>Query 2: Answered</td>
<td>FOLLOW UP REPORT TO UPDATE EVENT TERM WAS SUBMITTED</td>
</tr>
<tr>
<td>Nov-13-2020 05:49:52</td>
<td>ACV0PFEINFP6000</td>
<td>Query 2: Reissued:Opened</td>
<td>SAE RECON 2: DSU Confirmed; We have not received a follow-up report updating event term. Please submit a follow up AEM form to update term to exposure during pregnancy in Safety database.</td>
</tr>
<tr>
<td>Nov-12-2020 05:37:11</td>
<td>ACV0PFEINFP6000</td>
<td>Query 2: Reissued:Candidate</td>
<td>For PSSR confirmation</td>
</tr>
<tr>
<td>Nov-11-2020 08:49:47</td>
<td>ACV0PFEINFP6000</td>
<td>Query 2: Answered</td>
<td>FORM HAS ALREADY BEEN SUBMITTED.</td>
</tr>
<tr>
<td>Nov-11-2020 07:47:07</td>
<td>ACV0PFEINFP6000</td>
<td>Query 2: Reissued:Opened</td>
<td>SAE RECON 1: Per PSSR confirmation AEM form received however, the term still reported as pregnancy. Please submit a follow up AEM form to update term in Safety database.</td>
</tr>
<tr>
<td>Nov-07-2020 09:45:47</td>
<td>ACV0PFEINFP6000</td>
<td>Query 2: Reissued:Candidate</td>
<td>SAE RECON: To check next SAE listing</td>
</tr>
<tr>
<td>Central Time (US &amp; Canada)</td>
<td>Form ID: ACV0PFEINFP6000</td>
<td>Data Entry: EXPOSURE DURING PREGNANCY</td>
<td>Query 2: Answered</td>
</tr>
<tr>
<td>---------------------------</td>
<td>--------------------------</td>
<td>----------------------------------------</td>
<td>------------------</td>
</tr>
<tr>
<td>Nov-06-2020 17:13:01 (UTC-06:00)</td>
<td>(b) (4), (b) (6)</td>
<td></td>
<td>UPDATED SAE FORM SUBMITTED WITH UPDATED TERM OF 'EXPOSURE DURING PREGNANCY'</td>
</tr>
<tr>
<td>Nov-04-2020 04:47:44 (UTC-06:00)</td>
<td>(b) (4), (b) (6)</td>
<td></td>
<td>Please confirm if a follow up AEM form was submitted to update term in SDB.</td>
</tr>
<tr>
<td>Nov-03-2020 13:50:49 (UTC-06:00)</td>
<td>auto query (autoquery)</td>
<td></td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Nov-03-2020 07:45:42 (UTC-06:00)</td>
<td>(b) (4), (b) (6)</td>
<td></td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Oct-12-2020 18:15:33 (UTC-06:00)</td>
<td>(b) (4), (b) (6)</td>
<td></td>
<td>SAE RECON:AER#2020363457, the term in both database was recorded as pregnancy. Based on the latest EDP guidance, the term should be reported as 'EXPOSURE DURING PREGNANCY'. Please confirm and update. A follow up AEM form is required to update SDB.</td>
</tr>
<tr>
<td>Oct-12-2020 15:52:14 (UTC-06:00)</td>
<td>(b) (4), (b) (6)</td>
<td></td>
<td>query closed; will follow for SAE safety update with BCP start month</td>
</tr>
<tr>
<td>Sep-28-2020 14:42:42 (UTC-06:00)</td>
<td>(b) (4), (b) (6)</td>
<td></td>
<td>SAFETY REPORT WILL BE SENT</td>
</tr>
</tbody>
</table>

**Header Text:** c4591001  
**Visit:** Logs - Unscheduled  
**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1093  
**Subject No:** 10931058  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:31
subject was in when contraception failed; submit a safety report with the updated start date

### 4. Start 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>Nov-23-2020 03:38:13</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>(b)</td>
<td>(4), (b)</td>
<td>Query 2: Closed</td>
</tr>
<tr>
<td>Nov-20-2020 11:35:25</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>(b)</td>
<td>(4), (b)</td>
<td></td>
</tr>
<tr>
<td>Nov-20-2020 11:04:57</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>(b)</td>
<td>(4), (b)</td>
<td>Data Entry:</td>
</tr>
<tr>
<td>Nov-20-2020 05:16:44</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b)</td>
<td>(4), (b)</td>
</tr>
<tr>
<td>Oct-17-2020 07:54:12</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b)</td>
<td>(4), (b)</td>
</tr>
<tr>
<td>Oct-16-2020 14:08:09</td>
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<td>ACV0PFEINFP6000</td>
<td>(b)</td>
<td>(4), (b)</td>
</tr>
</tbody>
</table>
5. Is the adverse event still ongoing?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-06-2021 22:59:37</td>
<td>ACV0PFEINFP6000</td>
<td>(b) 4, (b) 6</td>
<td>Query 1: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Jan-06-2021 14:21:11</td>
<td>ACV0PFEINFP6000</td>
<td>(b) 4, (b) 6</td>
<td>Query 1: Answered</td>
<td>FUP PAGE HAS ALREADY BEEN DONE.</td>
</tr>
<tr>
<td>Jan-05-2021 23:22:40</td>
<td>ACV0PFEINFP6000</td>
<td>(b) 4, (b) 6</td>
<td>Query 1: Reissued:Opened</td>
<td>DM: If subject is lost to follow up then consider updating FUP page as appropriate. Thank you.</td>
</tr>
<tr>
<td>Jan-05-2021 17:03:24</td>
<td>ACV0PFEINFP6000</td>
<td>(b) 4, (b) 6</td>
<td>Query 1: Answered</td>
<td>subject was lost to follow up.</td>
</tr>
<tr>
<td>Jan-05-2021 16:50:51</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Opened</td>
<td>'Disposition Follow-up form is</td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Data Entry: YES</td>
<td>Initial Entry</td>
<td></td>
</tr>
<tr>
<td>-------------------</td>
<td>-----------------</td>
<td>----------------</td>
<td>---------------</td>
<td></td>
</tr>
<tr>
<td>Nov-03-2020 13:51:36 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>(b) (4), (b) (6)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

completed and this Adverse Event is still ongoing. Please review and update as appropriate.
### 5. Is the adverse event still ongoing?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-03-2020 13:51:24</td>
<td>ACV0PFEINFP6000</td>
<td>(b), (4), (6)</td>
<td>Data Entry:</td>
<td>Transcription Error</td>
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<tr>
<td>(UTC-06:00) Central</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sep-25-2020 13:03:18</td>
<td>ACV0PFEINFP6000</td>
<td>(b), (4), (6)</td>
<td>Data Entry:</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 6. Toxicity Grade:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-06-2020 09:16:15</td>
<td>ACV0PFEINFP6000</td>
<td>Hayley Wyper</td>
<td>Query 2: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td></td>
<td>(b), (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nov-06-2020 08:28:35</td>
<td>ACV0PFEINFP6000</td>
<td>(b), (4), (6)</td>
<td>Data Entry:</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nov-06-2020 08:28:26</td>
<td>ACV0PFEINFP6000</td>
<td>auto query</td>
<td>Query 2: Answered</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td></td>
<td>(autoquery)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nov-06-2020 08:28:26</td>
<td>ACV0PFEINFP6000</td>
<td>(b), (4), (6)</td>
<td>Data Entry:</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nov-06-2020 08:02:11</td>
<td>ACV0PFEINFP6000</td>
<td>Hayley Wyper</td>
<td>Query 2: Opened</td>
<td>CLINQUERY: Toxicity grade for EDP can be entered as Not Applicable (via comment option). Please update</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td></td>
<td>(b), (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sep-29-2020 02:00:50</td>
<td>ACV0PFEINFP6000</td>
<td>(b), (4), (6)</td>
<td>Query 1: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sep-28-2020 08:46:08</td>
<td>ACV0PFEINFP6000</td>
<td>auto query</td>
<td>Query 1: Answered</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td></td>
<td>(autoquery)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</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>Oct-02-2020 09:39:42 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 3: Deleted</td>
<td>Close Auto Query</td>
</tr>
<tr>
<td>Sep-29-2020 13:35:36 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Sep-29-2020 08:45:51 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 3: Candidate</td>
<td>For AE PREGNANCY: Response to &quot;Is the adverse event serious?&quot; is 'No' but &quot;Serious Adverse Event Number&quot; is present.</td>
</tr>
<tr>
<td>Sep-29-2020 08:45:51 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 2: Answered</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Sep-29-2020 08:45:51 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Sep-28-2020 14:39:12 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Opened</td>
<td>CLINQUERY According to CRF completion guidelines (Sect 8.49.2.5), pregnancy</td>
</tr>
<tr>
<td>Date/Time</td>
<td>User ID</td>
<td>Note</td>
<td></td>
<td></td>
</tr>
<tr>
<td>------------------------</td>
<td>---------</td>
<td>-------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sep-28-2020 05:38:17</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery) Query 1: Closed Close Auto Query</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sep-28-2020 00:24:43</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6) Query 1: Opened For AE PREGNANCY: Response to &quot;Is the adverse event serious?&quot; is 'Yes' but &quot;Serious Adverse Event Number&quot; is blank.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sep-25-2020 13:03:18</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery) Query 1: Candidate For AE PREGNANCY: Response to &quot;Is the adverse event serious?&quot; is 'Yes' but &quot;Serious Adverse Event Number&quot; is blank.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sep-25-2020 13:03:18</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6) Data Entry: 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? NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

is reported as an Adverse event (non-serious) although an exposure during pregnancy form is sent to the SAE vendor; please update severity.
**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>Sep-25-2020 13:03:18 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
<td>NO</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

**Data Entry:**

**Reason:**

**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>
</thead>
<tbody>
<tr>
<td>Sep-25-2020 13:03:18 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
<td>NOT RELATED</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

**Data Entry:**

**Reason:**

*If Not Related to study treatment(s), this event is due to:

OTHER

*If Other, specify:

PREGNANCY

**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>
</thead>
<tbody>
<tr>
<td>Sep-29-2020 05:41:53 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Hayley Wyper</td>
<td>Query 1: Closed</td>
<td>Response satisfies query</td>
</tr>
</tbody>
</table>

Did this serious event result in persistent or significant disability/incapacity?

NO

Is this serious event life threatening?

NO

Other medically important serious event

YES
<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-28-2020 08:46:21</td>
<td>ACV0PFEINFP6000</td>
<td>(b)</td>
<td>(4), (6)</td>
<td>Query 1: Answered</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td>Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td>TAB WILL BE COMPLETED</td>
</tr>
<tr>
<td>Sep-28-2020 05:08:55</td>
<td>ACV0PFEINFP6000</td>
<td>Hayley</td>
<td>Wyper</td>
<td>Query 1: Opened</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td>Time (US &amp; Canada)</td>
<td>(b)</td>
<td>(4)</td>
<td>CLINQUERY: Please complete EOT tab to capture end of treatment data</td>
</tr>
<tr>
<td>Sep-25-2020 13:03:18</td>
<td>ACV0PFEINFP6000</td>
<td>(b)</td>
<td>(4), (6)</td>
<td>Data Entry: DRUG WITHDRAWN</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td>Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

### 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>
</thead>
<tbody>
<tr>
<td>Sep-25-2020 13:03:18</td>
<td>ACV0PFEINFP6000</td>
<td>(b)</td>
<td>(4), (6)</td>
<td>Data Entry: NO</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td>Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-25-2020 13:03:18</td>
<td>ACV0PFEINFP6000</td>
<td>(b)</td>
<td>(4), (6)</td>
<td>Data Entry: NO</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td>Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td>Initial Entry</td>
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</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-16-2020 13:50:26</td>
<td>ACV0PFEINFP6000</td>
<td>(b)</td>
<td>(4), (6)</td>
<td>Query 4: Closed</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td>Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Nov-16-2020 13:50:07</td>
<td>ACV0PFEINFP6000</td>
<td>(b)</td>
<td>(4), (6)</td>
<td>Query 5: Closed</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td>Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Nov-16-2020 11:30:59</td>
<td>ACV0PFEINFP6000</td>
<td>(b)</td>
<td>(4), (b)</td>
<td>Query 5: Answered</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td>Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td>AE is ongoing</td>
</tr>
<tr>
<td>Nov-16-2020 11:19:37</td>
<td>ACV0PFEINFP6000</td>
<td>auto query</td>
<td>(autoquery)</td>
<td>Query 5: Opened</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td></td>
<td></td>
<td></td>
<td>For AE EXPOSURE DURING</td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
<td>User</td>
<td>Query</td>
<td>AE IS STILL ONGOING.</td>
<td></td>
</tr>
<tr>
<td>-------------------</td>
<td>------</td>
<td>-------</td>
<td>---------------------</td>
<td></td>
</tr>
<tr>
<td>Nov-16-2020 10:48:42 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 4: Answered</td>
<td></td>
</tr>
<tr>
<td>Nov-16-2020 10:46:43 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 4: Opened</td>
<td></td>
</tr>
<tr>
<td>Nov-05-2020 02:17:06 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 3: Closed</td>
<td></td>
</tr>
<tr>
<td>Nov-04-2020 07:57:37 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 3: Answered</td>
<td></td>
</tr>
<tr>
<td>Nov-04-2020 04:46:21 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Closed</td>
<td></td>
</tr>
<tr>
<td>Nov-04-2020 02:22:15 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 3: Reissued:Opened</td>
<td></td>
</tr>
<tr>
<td>Date/Time</td>
<td>Query ID</td>
<td>Query Status</td>
<td>Response Details</td>
<td></td>
</tr>
<tr>
<td>-------------------------------</td>
<td>-------------------</td>
<td>--------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Nov-03-2020 13:52:06</td>
<td>ACV0PFEINFP6000</td>
<td>Query 3: Answered</td>
<td>THERE IS NO END DATE PROVIDED</td>
<td></td>
</tr>
<tr>
<td>Nov-03-2020 13:51:36</td>
<td>ACV0PFEINFP6000</td>
<td>Query 3: Opened</td>
<td>For AE EXPOSURE DURING PREGNANCY: Response to &quot;What was the outcome of this adverse event?&quot; is 'Unknown' but End Date/Time is provided or &quot;Is the adverse event still ongoing?&quot; is marked &quot;Yes&quot;.</td>
<td></td>
</tr>
<tr>
<td>Nov-03-2020 13:51:24</td>
<td>ACV0PFEINFP6000</td>
<td>Query 2: Closed</td>
<td>Close Auto Query</td>
<td></td>
</tr>
<tr>
<td>Nov-03-2020 13:50:49</td>
<td>ACV0PFEINFP6000</td>
<td>Query 2: Opened</td>
<td>For AE EXPOSURE DURING PREGNANCY: Response to &quot;What was the outcome of this adverse event?&quot; is 'Unknown' but End Date/Time is provided or &quot;Is the adverse event still ongoing?&quot; is marked &quot;Yes&quot;.</td>
<td></td>
</tr>
<tr>
<td>Nov-03-2020 13:50:09</td>
<td>ACV0PFEINFP6000</td>
<td>Query 2: Opened</td>
<td>For AE PREGNANCY: Response to &quot;What was the outcome of this adverse event?&quot; is 'Unknown' but End Date/Time is provided or &quot;Is the adverse event still ongoing?&quot; is marked &quot;Yes&quot;.</td>
<td></td>
</tr>
<tr>
<td>Nov-03-2020 13:50:09</td>
<td>ACV0PFEINFP6000</td>
<td>Query 1: Answered</td>
<td>Transcription Error</td>
<td></td>
</tr>
</tbody>
</table>

adverse event still ongoing?" is marked "Yes". Please update or clarify.
### 14. Did the adverse event cause the subject to be discontinued from the study?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-25-2020 13:03:18</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
</tr>
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</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-02-2020 09:39:42</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Event is a nonserious event. AER remains valid in Safety database per case processing convention.</td>
<td></td>
</tr>
</tbody>
</table>
### 15. Serious Adverse Event Number: For Pfizer Use Only

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-28-2020 05:38:17 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000 (b) (4), (b) (6)</td>
<td>Data Entry: 2020363457</td>
<td>Initial Entry</td>
<td></td>
</tr>
</tbody>
</table>
1. Subject Status

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-29-2021 10:23:58 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: DISCONTINUED</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Jan-08-2021 13:04:31 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: DISCONTINUED</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Jan-05-2021 16:50:51 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: COMPLETED</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>Nov-30-2020 13:55:34 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: DISCONTINUED</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Oct-26-2020 09:08:29 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: DISCONTINUED</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Sep-28-2020 08:46:57 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: DISCONTINUED</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Aug-26-2020 11:33:29 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: ENROLLED/RANDOMIZED</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>Aug-26-2020 11:32:10 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: SCREENED</td>
<td>Initial Entry</td>
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</tbody>
</table>

2. Subject Status Date

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-29-2021 10:23:58 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: Nov/9/2020</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Jan-08-2021 13:04:31 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: Nov/9/2020</td>
<td>Transcription Error</td>
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</table>
### SUBJECT STATUS - eCRF Audit Trail History

**Header Text:** c4591001  
**Visit:** Subject Status - Unscheduled  
**Form:** SUBJECT STATUS - eCRF Audit Trail History  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1093  
**Subject No:** 10931058  
**Generated By:** (b) (4)  

### Form Status: Data Complete, Verified  
**Site Name:** (1093) Meridian Clinical Research  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:31

<table>
<thead>
<tr>
<th>Date/Time</th>
<th>Site Time Zone</th>
<th>ACV0PFEINFP6000</th>
<th>Data Entry</th>
<th>Entry Type</th>
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<tbody>
<tr>
<td>Jan-05-2021 16:50:51</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: Nov/9/2020</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>Nov-30-2020 13:55:34</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: Sep/18/2020</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Oct-26-2020 09:08:29</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: Sep/18/2020</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Sep-28-2020 08:46:57</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: Sep/18/2020</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>Aug-26-2020 11:32:10</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: Aug/25/2020</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>
### 1. Casebook Signature

<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>Oct-15-2020 15:22:19</td>
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<td>(b) (4)</td>
<td>Data Entry:  Click Here to Enable</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>