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

<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**

<table>
<thead>
<tr>
<th>1. Consent Was:</th>
<th>OBTAINED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Written Consent Obtained</td>
<td>Aug/27/2020</td>
</tr>
</tbody>
</table>
### Header Text:
- **Visit:** COHORT_SELECTION
- **Form:** DEMOGRAPHY

### Form Version:
- **Form Version:** 06-Jul-2020 21:55
- **Form Status:** Data Complete, Locked, Frozen, Verified

### Site Information:
- **Site No:** 1123
- **Site Name:** (1123) Meridian Clinical Research

### Subject Information:
- **Subject No:** 11231204
- **Subject Initials:** ---

### Generated By:
- **Generated By:** (b) (4)
- **Generated Time (GMT):** 29-Mar-2021 11:09

### eCRF Audit Trail History

### Demography

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Subject ID</td>
</tr>
<tr>
<td>2.</td>
<td>Birth Date:</td>
</tr>
<tr>
<td>3.</td>
<td>Sex:</td>
</tr>
<tr>
<td>4.</td>
<td>Ethnicity:</td>
</tr>
<tr>
<td>5.</td>
<td>Race: (Check X all that apply):</td>
</tr>
<tr>
<td>6.</td>
<td>Racial Designation:</td>
</tr>
</tbody>
</table>
**Date of Visit**

1. Date of Visit | Aug/27/2020
2. Erroneous Visit |
### Form Comments

**Inclusion Criteria Not Met**

1. **Description of Inclusion Criterion Not Met**: Not Applicable

**Exclusion Criteria Met**

2. **Description of Exclusion Criterion Met**: Not Applicable
### eCRF Audit Trail History

## Disposition - Screening

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

<table>
<thead>
<tr>
<th>Line/MH Number</th>
<th>Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies</th>
<th>Start Date</th>
<th>Ongoing</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>[Attention deficit hyperactive disorder]</td>
<td>Dec/UNK/2018</td>
<td>YES</td>
</tr>
<tr>
<td>2</td>
<td>[Anxiety]</td>
<td>Dec/UNK/2018</td>
<td>YES</td>
</tr>
<tr>
<td>3</td>
<td>[Depression]</td>
<td>Dec/UNK/2018</td>
<td>YES</td>
</tr>
</tbody>
</table>
**Vital Signs**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Date: Aug/27/2020</td>
</tr>
<tr>
<td>2.</td>
<td>Weight: [83.9]</td>
</tr>
<tr>
<td>3.</td>
<td>Unit: kg</td>
</tr>
<tr>
<td>4.</td>
<td>Height: [156.4]</td>
</tr>
<tr>
<td>5.</td>
<td>Unit: cm</td>
</tr>
<tr>
<td>6.</td>
<td>Body Mass Index: [34.3]</td>
</tr>
</tbody>
</table>

**Vital Signs Details**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>7.a</td>
<td>Record Identifier: 1</td>
</tr>
<tr>
<td></td>
<td>Temperature: [36.7]</td>
</tr>
<tr>
<td></td>
<td>Unit: C</td>
</tr>
<tr>
<td></td>
<td>Temperature Location: ORAL CAVITY</td>
</tr>
<tr>
<td>Lab Urinalysis</td>
<td></td>
</tr>
<tr>
<td>---------------</td>
<td></td>
</tr>
<tr>
<td>1. Lab Panel:</td>
<td>URINALYSIS</td>
</tr>
<tr>
<td>2. Lab Sub-Panel:</td>
<td>PREGNANCY</td>
</tr>
<tr>
<td>3. Collection Date:</td>
<td>Aug/27/2020</td>
</tr>
<tr>
<td>4. Laboratory Name and Address (Derived):</td>
<td>[STUDY SITE]</td>
</tr>
<tr>
<td>5. Specimen Type:</td>
<td>URINE</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lab Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.a</td>
</tr>
<tr>
<td>Test:</td>
</tr>
<tr>
<td>Result:</td>
</tr>
<tr>
<td>Not Done:</td>
</tr>
</tbody>
</table>
**eCRF Audit Trail History**

<table>
<thead>
<tr>
<th>Disposition</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Randomization Date :</td>
<td>Aug/27/2020</td>
</tr>
<tr>
<td>2. Randomization Number:</td>
<td>[71165]</td>
</tr>
<tr>
<td>3. Randomization Group:</td>
<td>[ ]</td>
</tr>
</tbody>
</table>
### eCRF Audit Trail History

#### Electronic Sample Tracking

1. **Data Origin** | SITE
2. **Sample Type** | SERUM
3. **Sample Collected?** | YES  
   Date of Collection: Aug/27/2020
4. **If no sample was collected or sample was not collected according to protocol, please provide reason:** [ ]

#### Aliquot

Please enter barcode for each aliquot.

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5.a</td>
<td>Sample ID</td>
<td>[BM567X]</td>
</tr>
<tr>
<td>5.b</td>
<td>Sample ID</td>
<td>[BM567Y]</td>
</tr>
<tr>
<td>5.c</td>
<td>Sample ID</td>
<td>[BM567Z]</td>
</tr>
<tr>
<td>5.d</td>
<td>Sample ID</td>
<td>[BLZF4Y]</td>
</tr>
<tr>
<td>5.e</td>
<td>Sample ID</td>
<td>[BLZF4Z]</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.

| 5.a | Sample ID | [BM5680] |
## 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>eCRF Audit Trail History</td>
<td></td>
</tr>
<tr>
<td>--------------------------</td>
<td></td>
</tr>
<tr>
<td>Reactogenicity Diary</td>
<td></td>
</tr>
<tr>
<td>1. Select appropriate response</td>
<td>NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT</td>
</tr>
<tr>
<td>- Reactogenicity diary collection</td>
<td></td>
</tr>
</tbody>
</table>
### eCRF Audit Trail History

**Date of Visit**

<table>
<thead>
<tr>
<th></th>
<th>Date of Visit</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Date of Visit</td>
<td>Sep/15/2020</td>
</tr>
<tr>
<td>2.</td>
<td>Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>
### eCRF Audit Trail History

#### Vital Signs

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Date:</td>
</tr>
</tbody>
</table>

#### Vital Signs Details

<table>
<thead>
<tr>
<th>2.a</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Record Identifier:</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Temperature:</td>
<td>[36.8]</td>
</tr>
<tr>
<td></td>
<td>Unit:</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td>Temperature Location:</td>
<td>ORAL CAVITY</td>
</tr>
</tbody>
</table>
## Lab Urinalysis

1. **Lab Panel:** URINALYSIS
2. **Lab Sub-Panel:** PREGNANCY
3. **Collection Date:** Sep/15/2020
4. **Laboratory Name and Address (Derived):** [STUDY SITE]
5. **Specimen Type:** URINE

## Lab Result

<table>
<thead>
<tr>
<th>6.a</th>
<th><strong>Sponsor ID:</strong></th>
<th>[113]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Test:</strong></td>
<td>Choriogonadotropin Beta_PX113</td>
</tr>
<tr>
<td></td>
<td><strong>Result:</strong></td>
<td>NEGATIVE</td>
</tr>
<tr>
<td></td>
<td><strong>Not Done:</strong></td>
<td></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>
</tbody>
</table>
| 3. | Sample Collected? | YES  
   Date of Collection: Sep/15/2020 |
| 4. | If no sample was collected  
or sample was not collected  
according to protocol,  
please provide reason: | [ ] |

**Aliquot**

Please enter barcode for each aliquot.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5.a</td>
<td>Sample ID</td>
</tr>
</tbody>
</table>
### eCRF Audit Trail History

#### Vaccination

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Was there a temporary delay of vaccination?</td>
</tr>
<tr>
<td>2.</td>
<td>Treatment Name</td>
</tr>
<tr>
<td>3.</td>
<td>Formulation:</td>
</tr>
<tr>
<td>4.</td>
<td>Dose Date Time:</td>
</tr>
<tr>
<td>5.</td>
<td>Anatomical Location:</td>
</tr>
<tr>
<td>6.</td>
<td>Body Side:</td>
</tr>
<tr>
<td>7.</td>
<td>Route:</td>
</tr>
<tr>
<td>8.</td>
<td>Actual Dose:</td>
</tr>
<tr>
<td>9.</td>
<td>Unit:</td>
</tr>
<tr>
<td>10.</td>
<td>Timeframe Subject Was Observed</td>
</tr>
<tr>
<td>11.</td>
<td>Was the subject observed for at least the protocol specified observation period after investigational product administration?</td>
</tr>
</tbody>
</table>
### Header Text:
- **c4591001**
- **Visit:** V3_MONTH1_POSTVAX2_L
- **Form:** DATE OF VISIT
- **Form Version:** 22-Apr-2020 21:02
- **Site No:** 1123
- **Site Name:** (1123) Meridian Clinical Research
- **Subject No:** 11231204
- **Subject Initials:** ---
- **Generated By:** (b) (4)
- **Generated Time (GMT):** 29-Mar-2021 11:09

### eCRF Audit Trail History

<table>
<thead>
<tr>
<th>Date of Visit</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Visit</td>
<td>Oct/13/2020</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>

---

**FDA-CBER-2021-5683-0930829**

---

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***Confidential***

FDA-CBER-2021-5683-0930829
**Electronic Sample Tracking**

1. **Data Origin** | SITE  
2. **Sample Type** | SERUM  
3. **Sample Collected?** | YES  
   **Date of Collection:** Oct/13/2020  
4. **If no sample was collected or sample was not collected according to protocol, please provide reason:** [ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a **Sample ID** | [BM5P4V]  
5.b **Sample ID** | [BM5P4W]  
5.c **Sample ID** | [BM5P4X]  
5.d **Sample ID** | [BMN2V9]  
5.e **Sample ID** | [BMN2VB]
<table>
<thead>
<tr>
<th>Date of Visit</th>
<th>Mar/9/2021</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>
### Electronic Sample Tracking

1. **Data Origin:** SITE
2. **Sample Type:** SERUM
3. **Sample Collected?**
   - **YES**
   - **Date of Collection:** Mar/9/2021
4. **If no sample was collected or sample was not collected according to protocol, please provide reason:** [ ]

### Aliquot

Please enter barcode for each aliquot.

<table>
<thead>
<tr>
<th></th>
<th>Sample ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.a</td>
<td>[BRKHGP]</td>
</tr>
<tr>
<td>5.b</td>
<td>[BRKHGR]</td>
</tr>
<tr>
<td>5.c</td>
<td>[BRKHGS]</td>
</tr>
<tr>
<td>5.d</td>
<td>[BSM0PZ]</td>
</tr>
<tr>
<td>5.e</td>
<td>[BSM0R0]</td>
</tr>
<tr>
<td>Date of Visit</td>
<td></td>
</tr>
<tr>
<td>--------------</td>
<td></td>
</tr>
<tr>
<td>1. Date of Visit //</td>
<td></td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>
# 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>

**Header Text:** c4591001

**Visit:** V6_MONTH24_L  
**Form:** DATE OF VISIT

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

**Site No:** 1123  
**Site Name:** (1123) Meridian Clinical Research

**Subject No:** 11231204  
**Subject Initials:** ---

**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 11:09
### 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>

**COVID-19 Illness Visit**

| 3. COVID-19 Illness Visit: |          |

---

**Header Text:** c4591001  
**Visit:** POT_COVID_ILL - New Unscheduled Visit  
**Form:** DATE OF VISIT - ILLNESS ONSET  
**Form Version:** 22-Apr-2020 21:03  
**Form Status:** Not Started  
**Site No:** 1123  
**Site Name:** (1123) Meridian Clinical Research  
**Subject No:** 11231204  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 11:09

---

(b) (4)  

FDA-CBER-2021-5683-0930837
<table>
<thead>
<tr>
<th>Signs and Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Assessment: //</td>
</tr>
<tr>
<td>2. Date of First Symptom Started: //</td>
</tr>
<tr>
<td>3. Symptoms Ongoing?</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>
</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>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>Electronic Sample Tracking</td>
<td></td>
</tr>
<tr>
<td>---------------------------</td>
<td>--</td>
</tr>
<tr>
<td>1. Data Origin</td>
<td></td>
</tr>
<tr>
<td>2. Sample Type</td>
<td></td>
</tr>
<tr>
<td>3. Sample Collected?</td>
<td></td>
</tr>
<tr>
<td>4. If no sample was collected or sample was not collected according to protocol, please provide reason:</td>
<td>[]</td>
</tr>
</tbody>
</table>

### Aliquot

Please enter barcode for each aliquot.

| 5. Sample ID | [] |
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?**
<table>
<thead>
<tr>
<th></th>
<th>Illness Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Category of Clinical Event:</td>
</tr>
<tr>
<td>2</td>
<td>Was a diagnosis obtained for Potential COVID-19 Illness?</td>
</tr>
<tr>
<td>3</td>
<td>Toxicity Grade:</td>
</tr>
</tbody>
</table>

Form: ILLNESS DETAILS
Form Version: 06-Jul-2020 21:52
Form Status: Not Started
Site No: 1123
Site Name: (1123) Meridian Clinical Research
Subject No: 11231204
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 11:09
## Date of Visit

1. Date of Visit: //
2. Erroneous Visit:

## COVID-19 Illness Visit

3. COVID-19 Illness Visit:
### Electronic Sample Tracking

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

### Aliquot

Please enter barcode for each aliquot.

5. Sample ID  [ ]
<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>
<tr>
<td>Unplanned Assessments</td>
<td></td>
</tr>
<tr>
<td>-----------------------</td>
<td></td>
</tr>
<tr>
<td>1. Assessments</td>
<td></td>
</tr>
</tbody>
</table>
**eCRF Audit Trail History**

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

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

1. Date of Visit //
2. Erroneous Visit

**COVID-19 Repeat Swab**

3. COVID-19 Repeat Swab:
### 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>Oct/22/2020</td>
<td>UNK:UNK</td>
<td>Repeating Pages</td>
</tr>
</tbody>
</table>
# Adverse Event Report

1. **Category:** ADVERSE EVENT

2. **AE ID:** [1]

3. **Adverse Event:**
   (If possible specify diagnosis, not individual symptoms) [exposure during pregnancy]

4. **Start Date Time:** Oct/22/2020 UNK:UNK

5. **Is the adverse event still ongoing?** YES

6. **Toxicity Grade:** Not Applicable

## Comments
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>7.</strong></td>
<td>Is the adverse event serious?</td>
</tr>
<tr>
<td><strong>If Yes, NOTIFY PFIZER IMMEDIATELY.</strong></td>
<td></td>
</tr>
<tr>
<td>Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).</td>
<td>NO</td>
</tr>
<tr>
<td><strong>8.</strong></td>
<td>Is this adverse event the result of a study Medication Error?</td>
</tr>
<tr>
<td><strong>If Yes, record the type of medication error on the Medication Error Log.</strong></td>
<td>NO</td>
</tr>
<tr>
<td><strong>9.</strong></td>
<td>Is this event related to study treatment:</td>
</tr>
<tr>
<td><strong>NOT RELATED</strong></td>
<td></td>
</tr>
<tr>
<td>If Not Related to study treatment(s), this event is due to:</td>
<td></td>
</tr>
<tr>
<td>OTHER</td>
<td></td>
</tr>
<tr>
<td>If Other, specify:</td>
<td></td>
</tr>
<tr>
<td>[unknown]</td>
<td></td>
</tr>
<tr>
<td><strong>10.</strong></td>
<td>Latest Action Taken with Study Treatment:</td>
</tr>
<tr>
<td><strong>NOT APPLICABLE</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Question</td>
</tr>
<tr>
<td>---</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>11</td>
<td>Was a Concomitant Medication given?</td>
</tr>
<tr>
<td>12</td>
<td>Was a Non-Drug Treatment given?</td>
</tr>
<tr>
<td>13</td>
<td>What was the outcome of this adverse event?</td>
</tr>
<tr>
<td>14</td>
<td>Did the adverse event cause the subject to be discontinued from the study?</td>
</tr>
<tr>
<td>15</td>
<td>Serious Adverse Event Number: For Pfizer Use Only</td>
</tr>
<tr>
<td>#</td>
<td>Category</td>
</tr>
<tr>
<td>---</td>
<td>----------</td>
</tr>
<tr>
<td>1.</td>
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</tr>
</tbody>
</table>

**Header Text:** c4591001  
**Visit:** Logs  
**Form Version:** 17-Jul-2020 21:54  
**Site No:** 1123  
**Subject No:** 11231204  
**Generated By:** (b) (4)  
**Site Name:** (1123) Meridian Clinical Research  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 11:09
**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**

---

**Back to Form**
<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>
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<td>Repeating Pages</td>
</tr>
</tbody>
</table>

**Header Text:** c4591001  
**Visit:** Logs  
**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1123  
**Site Name:** (1123) Meridian Clinical Research  
**Subject No:** 11231204  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 11:09  

---
## Concomitant Medications

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<tr>
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<tbody>
<tr>
<td>1.</td>
<td>What is the medication identifier?</td>
</tr>
<tr>
<td>2.</td>
<td>Category:</td>
</tr>
<tr>
<td>3.</td>
<td>Concomitant Medications Pre-specified:</td>
</tr>
<tr>
<td>4.</td>
<td>Medication:</td>
</tr>
<tr>
<td></td>
<td>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>
</tr>
<tr>
<td>5.</td>
<td>Date:</td>
</tr>
<tr>
<td>#</td>
<td>Sponsor-Defined Identifier</td>
</tr>
<tr>
<td>---</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>1.</td>
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</tr>
</tbody>
</table>

Site No: 1123
Subject No: 11231204
Generated By: (b) (4)
Concomitant Medications

1. What is the medication identifier?  
   [ ]

2. Category:

3. Concomitant Medications Pre-specified:

4. Medication:

   Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

   [ ]

5. Dose:  
   [ ]

6. Dose Unit:

7. Dose Frequency:

8. Route:

9. Start Date:  
   //

10. Ongoing?
<table>
<thead>
<tr>
<th>#</th>
<th>Category</th>
<th>Treatment Identifier</th>
<th>Con Non-Drug Treatments Pre-specified</th>
<th>Treatment</th>
<th>Start Date</th>
<th>Form Instance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
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<td></td>
<td></td>
<td></td>
<td>Repeating Pages</td>
</tr>
</tbody>
</table>
Radiation Treatment

1. Category:

2. What is the treatment Identifier? [ ]

3. Concomitant Non-drug Treatment Pre-specified:

4. Treatment: [ ]

5. Start Date: //

6. Ongoing?
<table>
<thead>
<tr>
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<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>
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<td></td>
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<tr>
<td>Back to Form</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>--------------</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Transfusion Type:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Date of Transfusion: //</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date of Visit</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>--------------</td>
<td>---</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Date of Visit</td>
<td>//</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vital Signs Details</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------------------</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Record Identifier:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temperature: [ ]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unit:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temperature Location:</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

**Vital Signs**

1. Date: //

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VITAL SIGNS - TEMP

**Form Version:** 20-Feb-2021 02:16

**Form Status:** Not Started

**Site No:** 1123

**Site Name:** (1123) Meridian Clinical Research

**Subject No:** 11231204

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09
<table>
<thead>
<tr>
<th><strong>Lab Urinalysis</strong></th>
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<tbody>
<tr>
<td>1. Lab Panel:</td>
</tr>
<tr>
<td>2. Lab Sub-Panel:</td>
</tr>
<tr>
<td>3. Collection Date:</td>
</tr>
<tr>
<td>4. Laboratory Name and Address (Derived)</td>
</tr>
<tr>
<td>5. Specimen Type:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Lab Result</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>6. Sponsor ID:</td>
</tr>
<tr>
<td>Test:</td>
</tr>
<tr>
<td>Result:</td>
</tr>
<tr>
<td>Not Done:</td>
</tr>
<tr>
<td>Vaccination</td>
</tr>
<tr>
<td>----------------</td>
</tr>
<tr>
<td>1. Was there a temporary delay of vaccination?</td>
</tr>
<tr>
<td>2. Treatment Name</td>
</tr>
<tr>
<td>3. Formulation:</td>
</tr>
<tr>
<td>4. Dose Date Time:</td>
</tr>
<tr>
<td>5. Anatomical Location:</td>
</tr>
<tr>
<td>6. Body Side:</td>
</tr>
<tr>
<td>7. Route:</td>
</tr>
<tr>
<td>8. Actual Dose:</td>
</tr>
<tr>
<td>9. Unit:</td>
</tr>
<tr>
<td>10. Timeframe Subject Was Observed</td>
</tr>
<tr>
<td>11. Was the subject observed for at least the protocol specified observation period after investigational product administration?</td>
</tr>
<tr>
<td><strong>Contact Outcome</strong></td>
</tr>
<tr>
<td>---------------------</td>
</tr>
<tr>
<td>1. Contact Type:</td>
</tr>
<tr>
<td>2. Was contact made?</td>
</tr>
<tr>
<td>3. Comments: [ ]</td>
</tr>
</tbody>
</table>
### Contact Outcome

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>1.</td>
<td>Contact Type:</td>
</tr>
<tr>
<td>2.</td>
<td>Was contact made?</td>
</tr>
<tr>
<td>3.</td>
<td>Comments: [ ]</td>
</tr>
</tbody>
</table>

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**Header Text:** c4591001  
**Visit:** Unplanned Vaccination - Unscheduled  
**Form:** CONTACT OUTCOME - MONTH 6  
**Form Version:** 10-Oct-2020 16:01  
**Form Status:** Not Started  
**Site No:** 1123  
**Site Name:** (1123) Meridian Clinical Research  
**Subject No:** 11231204  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 11:09
**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>

**Header Text:** c4591001  
**Visit:** V201_SURVEIL_CONSENT - Unscheduled  
**Form:** DATE OF VISIT  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1123  
**Site Name:** (1123) Meridian Clinical Research  
**Subject No:** 11231204  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 11:09
Informed Consent - Asymptomatic Surveillance

1. Consent Was:
<table>
<thead>
<tr>
<th><strong>Electronic Sample Tracking</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Data Origin</td>
</tr>
<tr>
<td>2. Sample Type</td>
</tr>
<tr>
<td>3. Sample Collected?</td>
</tr>
<tr>
<td>4. If no sample was collected or sample was not collected according to protocol, please provide reason: [ ]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Aliquot</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Please enter barcode for each aliquot.</td>
</tr>
<tr>
<td>5. Sample ID [ ]</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**

   | [] |
**eCRF Audit Trail History**

**Date of Visit**

<table>
<thead>
<tr>
<th></th>
<th>Date of Visit</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Date of Visit</td>
<td>Feb/15/2021</td>
</tr>
<tr>
<td>2</td>
<td>Erroneous Visit</td>
<td></td>
</tr>
<tr>
<td>1. Select appropriate response</td>
<td>Participant is willing to return for Vaccination 3</td>
<td></td>
</tr>
<tr>
<td>-------------------------------</td>
<td>--------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>- Is participant willing to return for Vaccination 3?</td>
<td>Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2</td>
<td></td>
</tr>
</tbody>
</table>
### eCRF Audit Trail History

**Treatment Unblinded**

<table>
<thead>
<tr>
<th></th>
<th>Date Treatment Unblinded</th>
<th>Primary Reason for Unblinding</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Feb/15/2021</td>
<td>ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
</tr>
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**Header Text:** c4591001  
**Visit:** Disposition - Unscheduled  
**Form:** TREATMENT UNBLINDED  
**Form Version:** 22-Apr-2020 21:03  
**Form Status:** Data Complete, Frozen, Verified  
**Site No:** 1123  
**Site Name:** (1123) Meridian Clinical Research  
**Subject No:** 11231204  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 11:09

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## Withdrawal Of Consent

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

---

**Header Text:** c4591001  
**Visit:** Disposition - Unscheduled  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1123  
**Subject No:** 11231204  
**Generated By:** (b) (4)  

**Form:** WITHDRAWAL OF CONSENT  
**Form Status:** Not Started  
**Site Name:** (1123) Meridian Clinical Research  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 11:09
**Death Details**

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

**Cause of Death**

2. Cause of Death Status: 
   Cause of Death: [ ]
**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled  
**Form:** SUBJECT STATUS

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

**Site No:** 1123  
**Site Name:** (1123) Meridian Clinical Research

**Subject No:** 11231204  
**Subject Initials:** ---

**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 11:09

---

**eCRF Audit Trail History**

**Subject Status**

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<tr>
<td>1.</td>
<td>Subject Status</td>
</tr>
<tr>
<td>2.</td>
<td>Subject Status Date</td>
</tr>
<tr>
<td><strong>Header Text:</strong> c4591001</td>
<td><strong>Form:</strong> CASEBOOK SIGNATURE FORM</td>
</tr>
<tr>
<td>--------------------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td><strong>Visit:</strong> Investigator Signature - Unscheduled</td>
<td><strong>Form Status:</strong> Data Complete, Verified</td>
</tr>
<tr>
<td><strong>Form Version:</strong> 22-Apr-2020 21:04</td>
<td><strong>Site Name:</strong> (1123) Meridian Clinical Research</td>
</tr>
<tr>
<td><strong>Site No:</strong> 1123</td>
<td><strong>Subject Initials:</strong> ---</td>
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<tr>
<td><strong>Subject No:</strong> 11231204</td>
<td><strong>Generated Time (GMT):</strong> 29-Mar-2021 11:09</td>
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<tr>
<td><strong>Generated By:</strong> (b) (4)</td>
<td><strong>Generated Time (GMT):</strong> 29-Mar-2021 11:09</td>
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**eCRF Audit Trail History**

**Casebook Signature Form**

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<th>1. Casebook Signature</th>
<th>Click Here to Enable</th>
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**FDA-CBER-2021-5683-0930881**
<table>
<thead>
<tr>
<th>Name</th>
<th>Signature Meaning</th>
<th>Date</th>
<th>Type</th>
<th>Action</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>(b)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

This form requires signing by a member of each of the following signature groups:
- CRF_Sign
- CRF_Sign_1
**Inclusion/Exclusion Criteria**

<table>
<thead>
<tr>
<th>Item</th>
<th>Date</th>
<th>User</th>
<th>Comment</th>
</tr>
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**Additional Information**

- **Visit:** V1_DAY1_VAX1_L
- **Form Version:** 30-Jul-2020 21:29
- **Site No:** 1123
- **Site Name:** (1123) Meridian Clinical Research
- **Subject No:** 11231204
- **Generated By:** (b) (4)
- **Generated Time (GMT):** 29-Mar-2021 11:09
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Back to Form

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

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<th>Signature Meaning</th>
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Affidavit:
N/A

Brandon Essink
Approved
Oct-21-2020 22:20:19 (UTC-06:00) Central Time (US & Canada)
BOOK
Signed

Affidavit:
By my dated signature below, I, BrandonEssink, 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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### 2. Select appropriate response - What cohort does the subject belong to?

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### 2. Birth Date:

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**Visit:** COHORT_SELECTION
**Form:** DEMOGRAPHY - eCRF Audit Trail History
**Form Version:** 06-Jul-2020 21:55
**Site No:** 1123
**Site Name:** (1123) Meridian Clinical Research
**Subject No:** 11231204
**Subject Initials:** ---
**Generated By:** (b) (4)
**Generated Time (GMT):** 29-Mar-2021 11:09

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***Confidential***
### Demographic Information

**Data Entry:**

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

- **(b) (4)** NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
- **(b) (6)**

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**Header Text:** c4591001

**Visit:** COHORT_SELECTION

**Form:** DEMOGRAPHY - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1123

**Site Name:** (1123) Meridian Clinical Research

**Subject No:** 11231204

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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

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**Site No:** 1123

**Site Name:** (1123) Meridian Clinical Research

**Subject No:** 11231204

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09
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**1.a Line/MH Number:**

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

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### 1.a Ongoing:

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### 1.b

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<td><strong>Visit:</strong> V1_DAY1_VAX1_L</td>
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### 1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

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**Data Entry:**
- Line/MH N: 3
- Medical History Term: on
- Start Date: Dec/UNK/2018
- Ongoing: YES
### 1.c Line/MH Number:

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

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### 1.c Start Date:

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Temperature: 36.7 (Initial Entry)
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**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

**Site No:** 1123

**Subject No:** 11231204

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

**Generated Time (GMT):** 29-Mar-2021 11:09
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6.a

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6.a Sponsor ID:

**CONFIDENTIAL**
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***Confidential***

FDA-CBER-2021-5683-0930907
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**Value:** BM567Z  
**Reason:** Initial Entry
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### 5.e

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Aug-28-2020 11:21:39 (UTC-06:00) Central Time (US & Canada)

Aug-28-2020 11:21:39 (UTC-06:00) Central Time (US & Canada)

'Sample Collected?' is Yes, however
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**5.a Sample ID**

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**Data Entry:** Aug/27/2020 16:09

**6. Body Side:**

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**Data Entry:** RIGHT

**7. Route:**

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**Data Entry:** INTRAMUSCULAR
10. Timeframe Subject Was Observed

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

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**Data Entry:**

NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
## 1. Date of Visit

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2.a Record Identifier:

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### 6.a

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

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

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### 3. Sample Collected?

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<td>Sep-16-2020 07:35:05 (UTC-06:00)</td>
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### 5.a

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### 5.a Sample ID

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### 3. Formulation:

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### 4. Dose Date Time:

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### 6. **Body Side:**

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### 7. **Route:**

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### 10. Timeframe Subject Was Observed

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

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2. Sample Type

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3. Sample Collected?

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<td>auto query (autoquery)</td>
<td>Query 1: Candidate</td>
<td>'Sample Collected?' is Yes, however</td>
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Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Site No: 1123
Site Name: (1123) Meridian Clinical Research
Subject No: 11231204
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 11:09

Data Entry:
BM5P4V
Initial Entry
Oct/13/2020

Sample ID

Date: Oct-14-2020 09:02:26
Location: ACV0PFEINFP6000
User: (b) (4), (b) (6)
Value: BM5P4V
Data Entry: Initial Entry

5.b
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**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1123  
**Subject No:** 11231204  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 11:09

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**(UTC-06:00) Central Time (US & Canada) | D: VB**

**5.e Sample ID**

- **Data Entry:** BMN2VB

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***Confidential***
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**User:** ACV0PFEINFP6000

**Site:** (1123) Meridian Clinical Research

**Subject:** 11231204

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09
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**1. Data Origin**

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**2. Sample Type**

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3. Sample Collected?

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<td>Query 1: Candidate</td>
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***Confidential***
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**5.a Sample ID**

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<td>Initial Entry</td>
</tr>
<tr>
<td>09:10:06 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td>BRKH</td>
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<td>Mar-10-2021</td>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: Sample I</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>09:10:17 (UTC-06:00) Central Time (US &amp; Canada)</td>
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### 5.d

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<tbody>
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### 5.e

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Header Text: c4591001
Visit: V4_MONTH6_L
Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Site No: 1123
Site Name: (1123) Meridian Clinical Research
Subject No: 11231204
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 11:09

D: 0

(U TC-06:00) Central Time (US & Canada)
### 1. Date of Completion/Discontinuation/Death:

<table>
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<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Oct-13-2020 16:30:39</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Oct/13/2020</td>
<td>Initial Entry</td>
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<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
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### 2. Phase of Disposition:

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<td>auto calc (autocalc)</td>
<td>Data Entry: VACCINATION</td>
<td>Initial Entry</td>
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<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
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### 3. Status:

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<td>Oct-13-2020 16:30:39</td>
<td>ACV0PFEINFP6000</td>
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<td>Data Entry: COMPLETED</td>
<td>Initial Entry</td>
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**Visit:** Logs - Unscheduled  
**Form:** ADVERSE EVENT REPORT - Audit Trail  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1123  
**Site Name:** (1123) Meridian Clinical Research  
**Subject No:** 11231204  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 11:09

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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
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<tbody>
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<td>Feb-23-2021</td>
<td>ACV0PF6INFP6000</td>
<td>(b) (4),</td>
<td>Form Created</td>
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<tr>
<td>11:17:42</td>
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<td>(b) (6)</td>
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<td>(UTC-06:00)</td>
<td>Central Time (US &amp; Canada)</td>
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<td>Date</td>
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<td>Reason</td>
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<tr>
<td>--------------------</td>
<td>-----------------------------------</td>
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<tr>
<td>Feb-23-2021 11:17:42 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> ADVERSE EVENT</td>
<td>Initial Entry</td>
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<table>
<thead>
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<th>Location</th>
<th>User</th>
<th>Value</th>
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<tbody>
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<td>Feb-23-2021 11:17:42 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> 1</td>
<td>Initial Entry</td>
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3. Adverse Event: *(If possible specify diagnosis, not individual symptoms)*

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<tr>
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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mar-08-2021 01:19:29 (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>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Mar-04-2021 12:43:43 (UTC-06:00)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Reissue d:Candidate</td>
<td>Pending SDB update</td>
</tr>
<tr>
<td>Central Time</td>
<td>Form Number</td>
<td>Query</td>
<td>Details</td>
<td></td>
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<tr>
<td>---------------</td>
<td>-------------</td>
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<td>------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Mar-04-2021</td>
<td>ACV0PFEINFP6000</td>
<td>1: Answered</td>
<td>F/U report sent 04 Mar 2021 via fax.</td>
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</tr>
<tr>
<td>08:58:09</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UTC-06:00</td>
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</tr>
<tr>
<td>Central Time</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mar-03-2021</td>
<td>ACV0PFEINFP6000</td>
<td>1: Reissue d:Opened</td>
<td>SAE RECON: Term in Safety database still recorded as pregnancy. Please confirm if a follow up SAE form was submitted to update term in Safety database</td>
<td></td>
</tr>
<tr>
<td>07:54:31</td>
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<tr>
<td>Mar-01-2021</td>
<td>ACV0PFEINFP6000</td>
<td>1: Reissue d:Candidate</td>
<td>Pending SDB update</td>
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</tr>
<tr>
<td>04:04:29</td>
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<tr>
<td>Central Time</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feb-26-2021</td>
<td>ACV0PFEINFP6000</td>
<td>1: Answered</td>
<td>Will submit f/u SAE form with updated term.</td>
<td></td>
</tr>
<tr>
<td>16:30:07</td>
<td></td>
<td></td>
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<tr>
<td>UTC-06:00</td>
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<td>Central Time</td>
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</tr>
<tr>
<td>Feb-23-2021</td>
<td>ACV0PFEINFP6000</td>
<td>1: Opened</td>
<td>SAE RECON: AER#2021036854, term in Safety Database was</td>
<td></td>
</tr>
<tr>
<td>23:43:42</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>UTC-06:00</td>
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<tr>
<td>Central Time</td>
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</table>
**(b) (4)**

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**4. Start Date Time:**

<table>
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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
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<tbody>
<tr>
<td>Feb-24-2021 13:58:28</td>
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<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 Time (US &amp; Canada)</td>
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<td>Feb-24-2021 08:14:44</td>
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<td>auto query (autoquery)</td>
<td>Query 1: Answered</td>
<td>Transcription Error</td>
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### 5. Is the adverse event still ongoing?

<table>
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<th>User</th>
<th>Value</th>
<th>Reason</th>
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<td>Feb-23-2021</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong></td>
<td>Initial Entry</td>
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<tr>
<td>11:17:42</td>
<td></td>
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<td>Yes</td>
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</table>

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Query 1: Opened

SAE RECON: AER#2021036854, onsets were recorded as 22Oct2020 in the Safety database however, recorded as UNKOct2020 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.
6. Toxicity Grade:

<table>
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<td>Query 1: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Feb-24-2021 08:15:29 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Answered</td>
<td>NA per crf guidelines</td>
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<td><strong>Data Entry:</strong></td>
<td>Not Applicable</td>
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<td>Query 1: Opened</td>
<td>DM: The response for &quot;Toxicity Grade&quot; is missing. Kindly review and update.</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>
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<tr>
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<td>Response satisfies query</td>
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<td>Query 3: Answered</td>
<td>please clarify. changed to non-serious</td>
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<td>(US &amp; Canada)</td>
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<tr>
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<td>ACV0PFEINFP6000</td>
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<td>Query 3: Reissued: Opened</td>
<td>DM: Change is not noted. Seriousness criteria is met there is an abnormal pregnancy outcome/protocol section 8.3.5.1. Please update seriousness criteria accordingly.</td>
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<tr>
<td>Mar-04-2021</td>
<td>ACV0PFEINFP6000</td>
<td>auto query</td>
<td>Query 3: Answered</td>
<td>changed per DM</td>
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<tr>
<td>Date/Time</td>
<td>Subject No</td>
<td>Subject Initials</td>
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<td>Mar-04-2021 08:58:38 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>(b) (4), (b) (6)</td>
<td>changed per DM</td>
</tr>
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<td>Mar-01-2021 04:05:34 (UTC-06:00) Central Time (US &amp; Canada)</td>
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<td>(b) (4), (b) (6)</td>
<td>(b) (4), (b) (6)</td>
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<tr>
<td>Feb-26-2021 08:58:07 (UTC-06:00) Central Time (US &amp; Canada)</td>
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<td>(b) (4), (b) (6)</td>
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<td>(b) (4), (b) (6)</td>
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<tr>
<td>Date/Time</td>
<td>Action</td>
<td>Event Note</td>
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<td>Query 3: Opened</td>
<td>SAE RECON: AER#2021036854,'EXPOSURE DURING PREGNANCY' event was appropriately reported to safety; however, seriousness criteria is met there is an abnormal pregnancy outcome/protocol section 8.3.5.1. Please update seriousness criteria accordingly.</td>
<td></td>
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</tr>
<tr>
<td>Feb-23-2021 23:40:30 Central Time (US &amp; Canada)</td>
<td>Query 1: Deleted</td>
<td>Query can be addressed internally</td>
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<td>Feb-23-2021 11:18:38 Central Time (US &amp; Canada)</td>
<td>Query 2: Closed</td>
<td>Close Auto Query</td>
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</tr>
<tr>
<td>Feb-23-2021 11:18:38 Central Time (US &amp; Canada)</td>
<td>Data Entry: YES Is this serious data entry?</td>
<td>Transcription Error</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
vent associated with congenital anomaly or birth defect?  

NO

Did this serious event result in death?  

NO

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

NO

Is this serious event life threatening?

NO
<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Entry By</th>
<th>Entry Type</th>
<th>Query</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-23-2021 11:17:42 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 2: Opened</td>
<td>Is this adverse event serious?&quot; is reported 'Yes', but at least one seriousness criteria is missing. Please review and update as appropriate.</td>
<td></td>
</tr>
<tr>
<td>Feb-23-2021 11:17:42 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Candidate</td>
<td>For AE exposure during pregnancy: Response to &quot;Is the adverse event serious?&quot; is 'Yes' but &quot;Serious Adverse Event Number&quot; is blank.</td>
<td></td>
</tr>
<tr>
<td>Feb-23-2021 11:17:42 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry</td>
<td>YES, Other</td>
<td></td>
</tr>
</tbody>
</table>
8. Is this adverse event the result of a study Medication Error?  
If Yes, record the type of medication error on the Medication Error Log.

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-23-2021 11:17:42 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

9. Is this event related to study treatment:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-23-2021 11:17:42 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NOT RELATED</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

OTHER
<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-23-2021</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> NOT APPLICABLE</td>
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</table>

11. **Was a Concomitant Medication given?**

<table>
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<tr>
<th>Date</th>
<th>Location</th>
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<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-23-2021</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> NO</td>
</tr>
<tr>
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</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>
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<tbody>
<tr>
<td>Feb-23-2021</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> NO</td>
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<tr>
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</tbody>
</table>

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

If Other, specify:
unknown
## ADVERSE EVENT REPORT - eCRF Audit Trail

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail

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

**Form Status:** Data Complete

**Site No:** 1123

**Site Name:** (1123) Meridian Clinical Research

**Subject No:** 11231204

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

<table>
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<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-24-2021 03:46:21</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
<td>Query 1: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>(Central Time (US &amp; Canada))</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feb-23-2021 11:18:19</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
<td>Query 1: Answered</td>
<td>per crf guidelines this is correct</td>
</tr>
<tr>
<td>(UTC-06:00)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feb-23-2021 11:17:42</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: 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>
</tr>
<tr>
<td>(UTC-06:00)</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

**Data Entry:** UNKNOWN

**Initial Entry**
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>Feb-23-2021</td>
<td>ACV0PFENFP6000 (UTC-06:00)</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> NO</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>11:17:42</td>
<td>Central Time (US &amp; Canada)</td>
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</table>
### 1. Date of Visit

<table>
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<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-16-2021 13:12:05 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Feb/15/2021</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>
### 1. Select appropriate response - Is participant willing to return for Vaccination 3?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-16-2021</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Participant is willing to return for Vaccination 3</td>
</tr>
<tr>
<td>13:12:15</td>
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<tr>
<td>(UTC-06:00)</td>
<td></td>
<td></td>
<td>Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2</td>
</tr>
<tr>
<td>Central Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

**Data Entry**: Participant is willing to return for Vaccination 3

**Participant is**: eligible and NOT confirmed to have received only placebo at Vaccination 1/2
### 1. Date Treatment Unblinded:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Feb-16-2021</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Feb/15/2021</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>13:11:55 (UTC-06:00) Central Time (US &amp; Canada)</td>
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</table>

### 2. Primary Reason for Unblinding:

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<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Feb-16-2021</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>13:11:55 (UTC-06:00) Central Time (US &amp; Canada)</td>
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### 1. Subject Status

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Oct-13-2020</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> FOLLOW-UP</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>16:30:39 (UTC-06:00) Central Time (US &amp; Canada)</td>
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<tr>
<td>Aug-28-2020</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> ENROLLED/RANDOMIZED</td>
<td>Initial Entry</td>
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<tr>
<td>Aug-28-2020</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> SCREENED</td>
<td>Initial Entry</td>
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### 2. Subject Status Date

<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>Feb-23-2021</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>23:54:48 (UTC-06:00) Central Time (US &amp; Canada)</td>
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<tr>
<td>Feb-23-2021</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: A</td>
<td>AE added</td>
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<tr>
<td>Date/Time</td>
<td>Event</td>
<td>Data Entry</td>
<td>Response</td>
<td>Description</td>
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<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Feb-17-2021 19:06:17</td>
<td>SAE RECON:AER#2021146306 opened</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Non serious AE of PREGNANCY was reported in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.</td>
</tr>
<tr>
<td>Oct-13-2020 16:30:39</td>
<td>auto calc (autocalc)</td>
<td>ACV0PFEINFP6000</td>
<td></td>
<td>Data Entry: Oct/13/2020 Initial Entry</td>
</tr>
<tr>
<td>Aug-28-2020 08:51:48</td>
<td>auto calc (autocalc)</td>
<td>ACV0PFEINFP6000</td>
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<td>Data Entry: Aug/27/2020 Initial Entry</td>
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<tr>
<td>Aug-28-2020 08:49:25</td>
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<td>ACV0PFEINFP6000</td>
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<td>Data Entry: Aug/27/2020 Initial Entry</td>
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<td>Visit: Subject Status - Unscheduled</td>
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<td>Form Version: 22-Apr-2020 21:03</td>
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<td>Form: SUBJECT STATUS - eCRF Audit Trail History</td>
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<td>Subject Initials: ---</td>
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<td>Generated By: (b) (4)</td>
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<td>Generated Time (GMT): 29-Mar-2021 11:09</td>
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<tr>
<td>Canada)</td>
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### 1. Casebook Signature

<table>
<thead>
<tr>
<th>Date</th>
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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Oct-21-2020 22:20:11</td>
<td>ACV0PFEINFP6000</td>
<td>Brandon Essink</td>
<td><strong>Data Entry:</strong> Click Here to Enable</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

**(b) (4)**