**eCRF Audit Trail History**

### Cohort Selection

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

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</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>Sequence</th>
<th>Consent Was</th>
<th>Date Written Consent Obtained</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>OBTAINED</td>
<td>Aug/21/2020</td>
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### Demography

<p>| | |</p>
<table>
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<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>
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**Header Text:** c4591001
**Visit:** V1.DAY1_VAX1.L  **Form:** DATE OF VISIT
**Form Version:** 22-Apr-2020 21:02  **Form Status:** Data Complete, Locked, Frozen, Verified
**Site No:** 1109  **Site Name:** (1109) Accel Research Sites - Clinical Research Unit
**Subject No:** 11091276  **Subject Initials:** ---
**Generated By:** (b) (4)  **Generated Time (GMT):** 29-Mar-2021 10:49

### eCRF Audit Trail History

**Date of Visit**

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<th>Date</th>
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<td>Date of Visit Aug/21/2020</td>
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<td>2.</td>
<td>Erroneous Visit</td>
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### Form Comments

#### Inclusion Criteria Not Met

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<thead>
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<th>Description of Inclusion Criterion Not Met</th>
<th>Not Applicable</th>
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#### Exclusion Criteria Met

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Form Comments: Inclusion Criteria Not Met

1. Description of Inclusion Criterion Not Met

Exclusion Criteria Met

2. Description of Exclusion Criterion Met

Not Applicable
**Header Text:** c4591001  
**Visit:** V1_DAY1_VAX1_L  
**Form:** DISPOSITION - SCREENING  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1109  
**Subject No:** 11091276  
**Generated By:** (b) (4)  

**Site Name:** (1109) Accel Research Sites - Clinical Research Unit  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:49

## eCRF Audit Trail History

### Disposition - Screening

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<tr>
<td><strong>1.</strong></td>
<td>Date of Completion/Discontinuation/Death</td>
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<td><strong>2.</strong></td>
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<td><strong>3.</strong></td>
<td>Status:</td>
<td>COMPLETED</td>
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<td><strong>4.</strong></td>
<td>Specify Status:</td>
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### Medical History Details

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<tbody>
<tr>
<td>Start Date:</td>
<td>Jan/1/2019</td>
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</table>

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<tbody>
<tr>
<td>Start Date:</td>
<td>Jan/1/2015</td>
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<td>Start Date:</td>
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<td>End Date:</td>
<td>Dec/1/2012</td>
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<td>Start Date:</td>
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<td>Ongoing:</td>
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<th>Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies</th>
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<th>Ongoing</th>
<th>End Date</th>
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<tr>
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<td>[HYPERCHOLESTEROLEMIA]</td>
<td>Jan/1/2005</td>
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<td>1.f</td>
<td>[HYSTERECTOMY]</td>
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<td>Jan/1/2019</td>
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<td>[MIGRAINE HEADACHES]</td>
<td>Jan/1/1989</td>
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<td>[OSTEOPOROSIS]</td>
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### eCRF Audit Trail History

**Vital Signs**

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<th>Aug/21/2020</th>
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<tbody>
<tr>
<td>2</td>
<td>Weight</td>
<td>[131.8]</td>
</tr>
<tr>
<td>3</td>
<td>Unit</td>
<td>LB</td>
</tr>
<tr>
<td>4</td>
<td>Height</td>
<td>[68.0]</td>
</tr>
<tr>
<td>5</td>
<td>Unit</td>
<td>in</td>
</tr>
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**Vital Signs Details**

<table>
<thead>
<tr>
<th></th>
<th>Record Identifier</th>
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<tbody>
<tr>
<td></td>
<td>Temperature</td>
<td>[97.8]</td>
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<tr>
<td></td>
<td>Unit</td>
<td>F</td>
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<tr>
<td></td>
<td>Temperature Location</td>
<td>ORAL CAVITY</td>
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</table>
## Lab Urinalysis

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

<p>| | |</p>
<table>
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<tbody>
<tr>
<td><strong>6.a</strong> Sponsor ID:</td>
<td>[113]</td>
</tr>
<tr>
<td><strong>Test:</strong></td>
<td>Choriogonadotropin Beta_PX113</td>
</tr>
<tr>
<td><strong>Result:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Not Done:</strong></td>
<td>NOT DONE</td>
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**Header Text:** c4591001  
**Visit:** V1_DAY1_VAX1_L  
**Form:** RANDOMIZATION  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1109  
**Subject No:** 11091276  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:49

**Site Name:** (1109) Accel Research Sites - Clinical Research Unit  
**Subject Initials:** ---

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### eCRF Audit Trail History

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<td>2. <strong>Randomization Number:</strong> [235764]</td>
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<td>3. <strong>Randomization Group:</strong> [ ]</td>
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**eCRF Audit Trail History**

### Electronic Sample Tracking

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<th>If no sample was collected or sample was not collected according to protocol, please provide reason:</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>SITE</td>
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<td>4</td>
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<td></td>
<td></td>
<td>5.a</td>
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<td></td>
<td></td>
<td></td>
<td>5.b</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>5.c</td>
</tr>
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### Aliquot

Please enter barcode for each aliquot.

<table>
<thead>
<tr>
<th></th>
<th>Sample ID</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>5.a</td>
<td>[BPXRMRT]</td>
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</tr>
<tr>
<td>5.b</td>
<td>[BPXRMV]</td>
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</tr>
<tr>
<td>5.c</td>
<td>[BPXRMT]</td>
<td></td>
</tr>
<tr>
<td>5.d</td>
<td>[BRWLWN]</td>
<td></td>
</tr>
<tr>
<td>5.e</td>
<td>[BRWLWP]</td>
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</table>
### eCRF Audit Trail History

**Electronic Sample Tracking**

<p>| | |</p>
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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></td>
<td>Date of Collection: Aug/21/2020</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 | [BPXRS4] |
|     |   |   |
## eCRF Audit Trail History

### Vaccination

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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<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>
### eCRF Audit Trail History

**Reactogenicity Diary**

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

   **NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT**
**Header Text:** c4591001  
**Visit:** V2_VAX2_L  
**Form:** DATE OF VISIT  
**Form Version:** 22-Apr-2020 21:02  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1109  
**Site Name:** (1109) Accel Research Sites - Clinical Research Unit  
**Subject No:** 11091276  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:49

<table>
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<tr>
<th><strong>eCRF Audit Trail History</strong></th>
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<tbody>
<tr>
<td><strong>Date of Visit</strong></td>
</tr>
<tr>
<td>-----------------------------</td>
</tr>
<tr>
<td>1. Date of Visit</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
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</table>
## Vital Signs Trail History

### Vital Signs Details

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<th>2.a</th>
<th>Record Identifier:</th>
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<tbody>
<tr>
<td></td>
<td>Temperature:</td>
<td>[98.5]</td>
</tr>
<tr>
<td></td>
<td>Unit:</td>
<td>F</td>
</tr>
<tr>
<td></td>
<td>Temperature Location:</td>
<td>ORAL CAVITY</td>
</tr>
</tbody>
</table>

### eCRF Audit Trail History

- **Record Identifier:** 1
- **Temperature:** [98.5]
- **Unit:** F
- **Temperature Location:** ORAL CAVITY
### Lab Urinalysis

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>1.</td>
<td>Lab Panel: <strong>URINALYSIS</strong></td>
</tr>
<tr>
<td>2.</td>
<td>Lab Sub-Panel: <strong>PREGNANCY</strong></td>
</tr>
<tr>
<td>3.</td>
<td>Collection Date: <strong>Sep/9/2020</strong></td>
</tr>
<tr>
<td>4.</td>
<td>Laboratory Name and Address (Derived): <strong>[STUDY SITE]</strong></td>
</tr>
<tr>
<td>5.</td>
<td>Specimen Type: <strong>URINE</strong></td>
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### Lab Result

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

**Electronic Sample Tracking**

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<td>2</td>
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<td>3</td>
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**Aliquot**

Please enter barcode for each aliquot.

<table>
<thead>
<tr>
<th></th>
<th>Sample ID</th>
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<tbody>
<tr>
<td>5.a</td>
<td>[BPXTPT]</td>
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### eCRF Audit Trail History

#### Vaccination

<p>| | |</p>
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<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>
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<tr>
<td>5.</td>
<td>Anatomical Location:</td>
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<tr>
<td>6.</td>
<td>Body Side:</td>
</tr>
<tr>
<td>7.</td>
<td>Route:</td>
</tr>
<tr>
<td>8.</td>
<td>Actual Dose:</td>
</tr>
<tr>
<td>9.</td>
<td>Unit:</td>
</tr>
<tr>
<td>10.</td>
<td>Timeframe Subject Was Observed</td>
</tr>
<tr>
<td>11.</td>
<td>Was the subject observed for at least the protocol specified observation period after investigational product administration?</td>
</tr>
<tr>
<td>Date of Visit</td>
<td>Oct/14/2020</td>
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<tr>
<td>--------------</td>
<td>------------</td>
</tr>
<tr>
<td>1. Date of Visit</td>
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</tr>
<tr>
<td>2. Erroneous Visit</td>
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</table>
**eCRF Audit Trail History**

### Electronic Sample Tracking

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<td>Sample Type</td>
</tr>
<tr>
<td>3.</td>
<td>Sample Collected?</td>
</tr>
<tr>
<td></td>
<td>Date of Collection:</td>
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<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.

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<table>
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</thead>
<tbody>
<tr>
<td>5.a</td>
<td>Sample ID</td>
</tr>
<tr>
<td>5.b</td>
<td>Sample ID</td>
</tr>
<tr>
<td>5.c</td>
<td>Sample ID</td>
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</tbody>
</table>
### Date of Visit

<table>
<thead>
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<th></th>
<th>Date of Visit</th>
<th>//</th>
</tr>
</thead>
</table>

|   | Erroneous Visit | |

### COVID-19 Illness Visit

|   | 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:** 1109  
**Site Name:** (1109) Accel Research Sites - Clinical Research Unit  
**Subject No:** 11091276  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:49
### Signs and Symptoms

1. Date of Assessment: //
2. Date of First Symptom Started: //
3. Symptoms Ongoing?

### Symptoms

4. Symptoms:
   - Was symptom present?

### Symptoms - Other

5. Symptoms - Other Text: [ ]
### 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**

   [ ]
### 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

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

<table>
<thead>
<tr>
<th>COVID-19 Illness Visit</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>3. COVID-19 Illness 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>
<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>
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</table>
### eCRF Audit Trail History

**Disposition - Treatment**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Completion/Discontinuation/Death</td>
<td>Oct/14/2020</td>
</tr>
<tr>
<td>2. Phase of Disposition</td>
<td>VACCINATION</td>
</tr>
<tr>
<td>3. Status</td>
<td>COMPLETED</td>
</tr>
<tr>
<td>4. Specify Status</td>
<td>[ ]</td>
</tr>
</tbody>
</table>
Disposition - Follow-Up

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

1. **Date of Visit**
   - //</br>

2. **Erroneous Visit**

### COVID-19 Repeat Swab

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

---

**Header Text:** c4591001  
**Visit:** POT_COVID_REPEAT_SWAB - New Unscheduled Visit  
**Form:** DATE OF VISIT - REPEAT SWAB  
**Form Version:** 10-Oct-2020 15:57  
**Site No:** 1109  
**Site Name:** (1109) Accel Research Sites - Clinical Research Unit  
**Subject No:** 11091276  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:49  

---

**FDA-CBER-2021-5683-0977422**
<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>
<tr>
<td>[ ]</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>
<tr>
<td>[ ]</td>
</tr>
<tr>
<td>#</td>
</tr>
<tr>
<td>----</td>
</tr>
<tr>
<td>1</td>
</tr>
</tbody>
</table>

End Date Time: Oct/2/2020 11:00
### 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) [Acute appendicitis with necrosis]</td>
</tr>
<tr>
<td>4.</td>
<td>Start Date Time: Sep/30/2020 23:00</td>
</tr>
</tbody>
</table>
| 5. | Is the adverse event still ongoing? NO  
End Date Time: Oct/2/2020 11:00 |
| 6. | Toxicity Grade: 4 |
| 7. | Is the adverse event serious? YES  
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).  
Did this serious event associated with congenital anomaly or birth defect? NO  
Did this serious event result in death? NO  
Did this serious event require or prolong hospitalization? YES  
Did this serious event result in persistent or significant disability/incapacity? NO  
Is this serious event life threatening? NO  
Other medically important serious event NO |
<p>| 8. | Is this adverse event the result of a study Medication Error? NO |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
</table>
| 9. Is this event related to study treatment: | NOT RELATED  
If Not Related to study treatment(s), this event is due to: 
OTHER  
If Other, specify:  
[Infection of appendix] |
<p>| 10. Latest Action Taken with Study Treatment: | NOT APPLICABLE |
| 11. Was a Concomitant Medication given? | YES |
| 12. Was a Non-Drug Treatment given? | YES |
| 13. What was the outcome of this adverse event?: | RECOVERED/RESOLVED |
| 14. Did the adverse event cause the subject to be discontinued from the study? | NO |
| 15. Serious Adverse Event Number: For Pfizer Use Only | [2020399436] |</p>
<table>
<thead>
<tr>
<th>#</th>
<th>Category</th>
<th>Medication Error</th>
<th>Start Date</th>
<th>Is the medication error Still Ongoing</th>
<th>Study Medication Errors Action</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>

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**Header Text:** c4591001  
**Visit:** Logs  
**Form Version:** 17-Jul-2020 21:54  
**Site No:** 1109  
**Subject No:** 11091276  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:49  
**Site Name:** (1109) Accel Research Sites - Clinical Research Unit  
**Subject Initials:** ---  

---
**Back to Form**

### Medication Error

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category:</td>
<td></td>
</tr>
<tr>
<td>Medication Error (Type of Medication Error):</td>
<td>[ ]</td>
</tr>
<tr>
<td>Start Date:</td>
<td>//</td>
</tr>
<tr>
<td>Is the medication error still ongoing?</td>
<td></td>
</tr>
<tr>
<td>Latest Action Taken with Study Treatment:</td>
<td></td>
</tr>
<tr>
<td>Was a Concomitant Medication given?</td>
<td></td>
</tr>
<tr>
<td>Was a Non-Drug Treatment given?</td>
<td></td>
</tr>
<tr>
<td>Did the Medication Error cause the subject to be discontinued from the study?</td>
<td></td>
</tr>
<tr>
<td>Was this medication error associated with any adverse events?</td>
<td></td>
</tr>
<tr>
<td>Serious Adverse Event Number: For Pfizer Use Only</td>
<td>[ ]</td>
</tr>
<tr>
<td>#</td>
<td>Sponsor-Defined Identifier</td>
</tr>
<tr>
<td>---</td>
<td>---------------------------</td>
</tr>
<tr>
<td>1.</td>
<td></td>
</tr>
</tbody>
</table>
### Concomitant Medications

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
<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: 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>
<td></td>
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<tr>
<td>Concomitant Medications</td>
<td></td>
</tr>
<tr>
<td>------------------------------------------------------------</td>
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<tr>
<td>1. What is the medication identifier? ([ ] )</td>
<td></td>
</tr>
<tr>
<td>2. Category:</td>
<td></td>
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<tr>
<td>3. Concomitant Medications</td>
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</tr>
<tr>
<td>Pre-specified:</td>
<td></td>
</tr>
<tr>
<td>4. Medication:</td>
<td></td>
</tr>
<tr>
<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>
<td></td>
</tr>
<tr>
<td>5. Dose:</td>
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<tr>
<td>6. Dose Unit:</td>
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<td>7. Dose Frequency:</td>
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<td>8. Route:</td>
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</tr>
<tr>
<td>9. Start Date:</td>
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<tr>
<td>//</td>
<td></td>
</tr>
<tr>
<td>10. Ongoing?</td>
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Back to Form
<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>
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<tbody>
<tr>
<td>1.</td>
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<td></td>
<td>Repeating Pages</td>
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<tr>
<td>Radiation Treatment</td>
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<td>2. What is the treatment Identifier? [ ]</td>
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<td>3. Concomitant Non-drug Treatment Pre-specified:</td>
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<td>4. Treatment:      [ ]</td>
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<tr>
<td>5. Start Date:     //</td>
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<td>#</td>
<td>Transfusion Type</td>
<td>Date of Transfusion</td>
<td>Form Instance</td>
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<tr>
<td>1.</td>
<td>Repeating Pages</td>
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<tr>
<td>Back to Form</td>
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</tr>
<tr>
<td>1. Date of Visit //</td>
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<tr>
<td>2. Erroneous Visit</td>
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</tr>
<tr>
<td>Vital Signs</td>
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<tr>
<td>1. Date: //</td>
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<table>
<thead>
<tr>
<th>Vital Signs Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Record Identifier:</td>
</tr>
<tr>
<td>Temperature: [ ]</td>
</tr>
<tr>
<td>Unit:</td>
</tr>
<tr>
<td>Temperature Location:</td>
</tr>
</tbody>
</table>
### Lab Urinalysis

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

### Lab Result

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>6.</td>
<td>Sponsor ID: []</td>
</tr>
<tr>
<td></td>
<td>Test:</td>
</tr>
<tr>
<td></td>
<td>Result:</td>
</tr>
<tr>
<td></td>
<td>Not Done:</td>
</tr>
<tr>
<td>Question</td>
<td>Answer</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------</td>
<td>--------</td>
</tr>
<tr>
<td>1. Was there a temporary delay of vaccination?</td>
<td></td>
</tr>
<tr>
<td>2. Treatment Name</td>
<td>[ ]</td>
</tr>
<tr>
<td>3. Formulation</td>
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</tr>
<tr>
<td>4. Dose Date Time</td>
<td>//</td>
</tr>
<tr>
<td>5. Anatomical Location</td>
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</tr>
<tr>
<td>6. Body Side</td>
<td></td>
</tr>
<tr>
<td>7. Route</td>
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</tr>
<tr>
<td>8. Actual Dose</td>
<td>[ ]</td>
</tr>
<tr>
<td>9. Unit</td>
<td></td>
</tr>
<tr>
<td>10. Timeframe Subject Was Observed</td>
<td></td>
</tr>
<tr>
<td>11. Was the subject observed for at least the protocol specified</td>
<td></td>
</tr>
<tr>
<td>observation period after investigational product administration?</td>
<td></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>
<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>
### 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>Feb/23/2021</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>
1. Select appropriate response - Is participant willing to return for Vaccination 3?

Participant is willing to return for Vaccination 3
Participant is:
eligible per local/national recommendations and confirmed to have received
only placebo at Vaccination 1/2
**Treatment Unblinded**

1. Date Treatment Unblinded : Feb/23/2021  
2. Primary Reason for Unblinding: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION
### Withdrawal Of Consent

1. **Withdrawal of Consent Date:** //
### Death Details

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Date of Collection / Notification of Death: //</td>
</tr>
</tbody>
</table>

### Cause of Death

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2.</td>
<td>Cause of Death Status:</td>
</tr>
<tr>
<td></td>
<td>Cause of Death: []</td>
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</tbody>
</table>
Date of Visit

1. Date of Visit Feb/27/2021
2. Erroneous Visit
### eCRF Audit Trail History

#### Informed Consent - Further Vaccination

<table>
<thead>
<tr>
<th></th>
<th>Consent Was:</th>
<th>OBTAINED</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Date Written Consent Obtained</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Feb/27/2021</td>
</tr>
</tbody>
</table>
### Form Comments

#### Inclusion Criteria Not Met

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

#### Exclusion Criteria Met

<table>
<thead>
<tr>
<th>2.</th>
<th>Description of Exclusion Criterion Met</th>
<th>Not Applicable</th>
</tr>
</thead>
</table>
### Disposition - Screening for Further Vaccination

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Date of Completion/Discontinuation/Death: Feb/27/2021</td>
</tr>
<tr>
<td>2.</td>
<td>Phase of Disposition: REPEAT SCREENING 1</td>
</tr>
<tr>
<td>3.</td>
<td>Status: COMPLETED</td>
</tr>
<tr>
<td>4.</td>
<td>Specify Status: [ ]</td>
</tr>
</tbody>
</table>
### Lab Urinalysis

<table>
<thead>
<tr>
<th></th>
<th>Lab Panel:</th>
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</tr>
</thead>
<tbody>
<tr>
<td>2</td>
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</tr>
<tr>
<td>3</td>
<td>Collection Date:</td>
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</tr>
<tr>
<td>4</td>
<td>Laboratory Name and Address (Derived)</td>
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</tr>
<tr>
<td></td>
<td>[ ]</td>
<td>Comments</td>
</tr>
<tr>
<td>5</td>
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### Lab Result

<table>
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<tr>
<th>6.a</th>
<th>Sponsor ID:</th>
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<tbody>
<tr>
<td></td>
<td>[ ]</td>
<td>Comments</td>
</tr>
<tr>
<td></td>
<td>Test:</td>
<td>Choriogonadotropin Beta_PX113</td>
</tr>
<tr>
<td></td>
<td>Result:</td>
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<tr>
<td></td>
<td>Not Done:</td>
<td>Not Applicable</td>
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**Form Comments**

**eCRF Audit Trail History**

---

**Generated Time (GMT): 29-Mar-2021 10:49**
### eCRF Audit Trail History

**Electronic Sample Tracking**

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<th>Data Origin</th>
<th>SITE</th>
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<tbody>
<tr>
<td>2</td>
<td>Sample Type</td>
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</tr>
<tr>
<td>3</td>
<td>Sample Collected?</td>
<td>YES Date of Collection: Feb/27/2021</td>
</tr>
<tr>
<td>4</td>
<td>If no sample was collected or sample was not collected according to protocol, please provide reason:</td>
<td>[ ]</td>
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</tbody>
</table>

#### Aliquot

Please enter barcode for each aliquot.

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>5.a</td>
<td>[BRF6C9]</td>
</tr>
<tr>
<td>5.b</td>
<td>[BS9XGW]</td>
</tr>
<tr>
<td>5.c</td>
<td>[BS9XGX]</td>
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### Electronic Sample Tracking

<p>| | |</p>
<table>
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<tr>
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<td>Data Origin</td>
</tr>
<tr>
<td>2.</td>
<td>Sample Type</td>
</tr>
</tbody>
</table>
| 3. | Sample Collected? | YES  
Date of Collection:  
Feb/27/2021 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ] |

### Aliquot

Please enter barcode for each aliquot.

<p>| | |</p>
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<tr>
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# eCRF Audit Trail History

### Vaccination

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

**Header Text:** c4591001  
**Visit:** V102_VAX4  
**Form:** DATE OF VISIT  
**Form Version:** 22-Apr-2020 21:02  
**Form Status:** Not Started  
**Site No:** 1109  
**Site Name:** (1109) Accel Research Sites - Clinical Research Unit  
**Subject No:** 11091276  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:49

---

**FDA-CBER-2021-5683-0977456**
### Lab Urinalysis

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<td>2.</td>
<td>Lab Sub-Panel:</td>
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<td>3.</td>
<td>Collection Date: //</td>
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<td>4.</td>
<td>Laboratory Name and Address (Derived): [ ]</td>
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<td>Specimen Type:</td>
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</table>

### Lab Result

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<tbody>
<tr>
<td>6.a</td>
<td>Sponsor ID: [ ]</td>
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<tr>
<td></td>
<td>Test:</td>
</tr>
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<td>Result:</td>
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<td></td>
<td>Not Done:</td>
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<td>1. Data Origin</td>
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<td>---</td>
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<td>3. Sample Collected?</td>
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<tr>
<td>4. If no sample was collected or sample was not collected according to protocol, please provide reason:</td>
<td>[ ]</td>
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**Aliquot**

Please enter barcode for each aliquot.

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

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

Contact Outcome

1. Contact Type:
2. Was contact made? 
3. Comments: [ ]
# Date of Visit

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>1.</td>
<td>Date of Visit //</td>
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<tr>
<td>2.</td>
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</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>
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Header Text: c4591001
Visit: V104_MONTH6
Form: CONTACT OUTCOME
Form Version: 22-Apr-2020 21:04
Form Status: Not Started
Site No: 1109
Site Name: (1109) Accel Research Sites - Clinical Research Unit
Subject No: 11091276
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 10:49

FDA-CBER-2021-5683-0977463
<table>
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<tbody>
<tr>
<td>1. Date of Visit //</td>
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<tr>
<td>2. Erroneous Visit</td>
</tr>
</tbody>
</table>
**Contact Outcome**

1. Contact Type: 
2. Was contact made? 
3. Comments: []
### Disposition - Treatment

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

**Site No:** 1109  
**Site Name:** (1109) Accel Research Sites - Clinical Research Unit  
**Subject No:** 11091276  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:49
### eCRF Audit Trail History

**Subject Status**

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</table>
Audit Trail

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

<table>
<thead>
<tr>
<th>Name</th>
<th>Signature Meaning</th>
<th>Date</th>
<th>Type</th>
<th>Action</th>
</tr>
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<tbody>
<tr>
<td>Bruce Rankin</td>
<td>Approved</td>
<td>Mar-10-2021 14:39:27 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>BOOK</td>
<td>Signed</td>
</tr>
</tbody>
</table>

**Affidavit:**

By my dated signature below, I, Bruce Rankin, 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.
### Back to Form

<table>
<thead>
<tr>
<th>Item</th>
<th>Date</th>
<th>User</th>
<th>Comment</th>
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<tbody>
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<td>User</td>
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<tr>
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<td>Feb-27-2021 14:23:17 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>(b) (4), (b) (6)</td>
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**Back to Form**

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<th>Comment</th>
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<tbody>
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<td>Form</td>
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<td>(b) (4), (b) (6)</td>
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**Header Text:** c4591001  
**Visit:** V101_VAX3  
**Form Version:** 20-Feb-2021 02:14  
**Site No:** 1109  
**Subject No:** 11091276  
**Generated By:** (b) (4)  
**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments  
**Form Status:** Data Complete, Frozen, Verified  
**Site Name:** (1109) Accel Research Sites - Clinical Research Unit  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:49
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<td>Item</td>
<td>Date</td>
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<td>Comment</td>
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Back to Form

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<tr>
<td>Item</td>
<td>Date</td>
<td>User</td>
<td>Comment</td>
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<tr>
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</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>5</td>
<td>Feb-27-2021 14:24:17 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
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<td>Not Applicable</td>
</tr>
<tr>
<td>Item</td>
<td>Date</td>
<td>User</td>
<td>Comment</td>
</tr>
<tr>
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<td>------</td>
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<td>---------</td>
</tr>
<tr>
<td>6.a</td>
<td>Feb-27-2021 14:24:17 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>(b) (4), (b) (6)</td>
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<table>
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<th>User</th>
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<td>6.a</td>
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<td>(b) (4), (b) (6)</td>
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</table>
This form requires signing by a member of each of the following signature groups:

- CRF_Sign

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<tr>
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<td>Approved</td>
<td>Mar-10-2021 14:39:27 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>BOOK</td>
<td>Signed</td>
</tr>
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</table>

**Affidavit:**

By my dated signature below, I, Bruce Rankin, 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 | Feb-23-2021 16:45:05 (UTC-05:00) Eastern Time (US & Canada) | Edit - All signatures invalidated |

**Affidavit:**

N/A

| Bruce Rankin | Approved | Oct-29-2020 09:07:56 (UTC-05:00) Eastern Time (US & Canada) | BOOK  | Signed       |

**Affidavit:**

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

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

| (b) (6) | N/A | Oct-28-2020 10:18:16 (UTC-05:00) Eastern Time (US & Canada) | Edit - All signatures invalidated |

**Affidavit:**

N/A
**Affidavit:**

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

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

To this I do attest by supplying my user name and password and clicking the button marked Submit below.
1. Select appropriate response - Protocol version

<table>
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<th>Location</th>
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<th>Value</th>
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<tr>
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<td>(UTC-05:00) Eastern</td>
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<td>Time (US &amp; Canada)</td>
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2. Select appropriate response - What cohort does the subject belong to?

<table>
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<th>Reason</th>
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<td>(b) (4),</td>
<td>Data Entry:</td>
<td>Initial Entry</td>
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<td>(UTC-05:00) Eastern</td>
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<td>(b) (6)</td>
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<td>Date</td>
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<td>Reason</td>
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<td>Query 1: Closed</td>
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<td>Query 1: Answered</td>
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<td>Query 1: Opened</td>
<td>SAE RECON:AER#2020399436 Appendicitis from an Infection(onset date:30SEP2020) was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.</td>
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### 2. Birth Date:

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### 3. Sex:

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### 4. Ethnicity:

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**Back to Form**
### 1. Date of Completion/Discontinuation/Death

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

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

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### 1.b Ongoing:

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

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### 1.c Ongoing:

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**Medical History Term:** DEPRESSION

**Start Date:** Jan/1/2015

**Ongoing:** YES
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### 1.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

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

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### 1.f

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

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

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Medical History
Term: OSTEOPOR
Start Date: Jan/1/2020
Ongoing: YES

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### 6. Body Mass Index:

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#### 7.a Record Identifier:

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#### 7.a Temperature Location:

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Aug-21-2020 10:55:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ORAL CAVITY | Initial Entry
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### 2. Lab Sub-Panel:

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### 3. Collection Date:

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

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### 6.a

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### 6.a Not Done:

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### 2. Sample Type

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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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**Note:** This document contains confidential information. The date and time stamps reflect the time zone differences between Eastern Time (US & Canada) and UTC-05:00. The form version and status indicate that the data is complete, locked, frozen, and verified. The subject and site details are also listed, along with the generated time and user information. The audit trail history includes entries for data entry, sample type, and sample collection, with reasons and dates.
### 5.a

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### 5.a Sample ID

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### 1. Data Origin

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<tbody>
<tr>
<td>Aug-21-2020 10:53:28 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
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<td><strong>Data Entry:</strong> SITE</td>
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### 2. Sample Type

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<td>auto calc (autocalc)</td>
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### 3. Sample Collected?

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<tr>
<td>Aug-21-2020 10:53:38 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
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<td>auto query (autoquery)</td>
<td>Query 1: Deleted</td>
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<td>auto query (autoquery)</td>
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### 5.a

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5. a Sample ID

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

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### 2. Treatment Name

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### 3. Formulation:

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### 4. Dose Date Time:

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### 5. Anatomical Location:

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### 6. Body Side:

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### 10. Timeframe Subject Was Observed

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<td>Data Entry: 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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### 1. Select appropriate response - Reactogenicity diary collection

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<td>THIS SUBJECT is 'Yes' however VAX 1 eDiary</td>
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<td>records are not available for the subject.</td>
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<td>Please verify and update. Else, confirm in</td>
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<td>E-DIARY COLLECTED FOR THIS SUBJECT</td>
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3. Collection Date:

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4. Laboratory Name and Address (Derived)

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### 6.a Not Done:

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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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<tbody>
<tr>
<td>Sep-10-2020 08:23:43 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PF6000</td>
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<td>Query 1: Closed</td>
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<tr>
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<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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<td>Sep-09-2020 16:07:14 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PF6000</td>
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<td>Date</td>
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### 5.a Sample ID

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### 4. Dose Date Time:

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***Confidential***

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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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**I. Date of Visit**

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### 2. Sample Type

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<td>Query 1: Deleted</td>
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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

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### 5.a Sample ID

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<tr>
<td><strong>Data Entry:</strong></td>
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<td><strong>BR84NV</strong></td>
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### 5.b

<table>
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<tr>
<td>Oct-15-2020 06:49:14</td>
<td>ACV0PFEINFP6000</td>
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<td>Initial Entry</td>
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<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
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<td>(b) (6)</td>
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<td><strong>Sample ID:</strong></td>
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### 5.b Sample ID

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<td>Initial Entry</td>
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### 5.c

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<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
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<td>(4),</td>
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<td>(b) (6)</td>
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<td><strong>Data Entry:</strong></td>
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<td><strong>Sample ID:</strong></td>
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<td><strong>BSGWJY</strong></td>
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### 5.c Sample ID

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<td>Oct-15-2020 06:49:24</td>
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<td>BSGWJY</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
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<td>(4),</td>
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<td><strong>Sample ID:</strong></td>
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<tr>
<td><strong>BSGWJY</strong></td>
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</tr>
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</table>
### 1. Date of Completion/Discontinuation/Death:

<table>
<thead>
<tr>
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<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-14-2020 14:49:03 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Oct/14/2020</td>
<td>Initial Entry</td>
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</table>

### 2. Phase of Disposition:

<table>
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<tr>
<th>Date</th>
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<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Oct-14-2020 14:49:03 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: VACCINATION</td>
<td>Initial Entry</td>
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</table>

### 3. Status:

<table>
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<tr>
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<th>Reason</th>
</tr>
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<tbody>
<tr>
<td>Oct-14-2020 14:49:03 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: COMPLETED</td>
<td>Initial Entry</td>
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</table>
### Visit: Logs - Unscheduled

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

**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1109  
**Subject No:** 11091276  
**Generated By:** (b) (4)

**Site Name:** (1109) Accel Research Sites - Clinical Research Unit  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:49

#### Back to Form

<table>
<thead>
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<th>Reason</th>
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<tbody>
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<td>ACV0PFEINF6000</td>
<td>(b) (4), (b) (6)</td>
<td>Form Created</td>
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***Confidential***
### 1. Category:

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<th>Reason</th>
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<tbody>
<tr>
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<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong></td>
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</tr>
<tr>
<td></td>
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<td><strong>ADVERSE EVENT</strong></td>
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</table>

### 2. AE ID:

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<tr>
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<th>Reason</th>
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<td>auto calc (autocalc)</td>
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</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>
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<tbody>
<tr>
<td>Oct-29-2020 05:18:22 (UTC-05:00) Eastern 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>Oct-28-2020 10:18:16 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Answered</td>
<td>Changed Information</td>
</tr>
<tr>
<td>Oct-28-2020 10:18:16 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong></td>
<td>Changed Information</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>Acute appendicitis with necrosis</strong></td>
<td></td>
</tr>
<tr>
<td>Oct-28-2020 09:34:21 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Opened</td>
<td>SAE RECON:AER#2020399436, the term in Safety database was updated to 'acute appendicitis with necrosis'. Please confirm if the event term is the same as &quot;Necrotizing appendicitis&quot;. If so, please consider</td>
</tr>
</tbody>
</table>

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FDA-CBER-2021-5683-0977527
### 4. Start Date Time:

<table>
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<tr>
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<th>Reason</th>
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<tr>
<td>Oct-15-2020 07:38:52</td>
<td>ACV0PFEINFP6000</td>
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<td>Data Entry: Sep/30/2020 23:00</td>
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<td>Time (US &amp; Canada)</td>
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### 5. Is the adverse event still ongoing?

<table>
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<th>Reason</th>
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<tr>
<td>Oct-15-2020 07:38:52</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO End Date Time: Oct/2/2020 11:00</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern</td>
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<tr>
<td>Time (US &amp; Canada)</td>
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### 6. Toxicity Grade:

<table>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: 4</td>
<td>Initial Entry</td>
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<tr>
<td>Time (US &amp; Canada)</td>
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</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>
<td>Oct-28-2020 11:01:39</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 3: Closed</td>
<td>Query closed; will follow for SAE</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern</td>
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<tr>
<td>Time (US &amp; Canada)</td>
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<tr>
<td>Time (US &amp; Canada)</td>
<td>(b) (4), (b) (6)</td>
<td>update with requested COVID test info</td>
<td></td>
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<tr>
<td>-------------------</td>
<td>-----------------</td>
<td>----------------------------------</td>
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<tr>
<td>Oct-27-2020 21:09:56 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Query 3: Opened</td>
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<td>Oct-15-2020 08:12:39 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Query 2: Deleted</td>
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<tr>
<td>Oct-15-2020 08:03:25 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Query 1: Closed</td>
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<tr>
<td>Oct-15-2020 08:03:25 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Data Entry: YES</td>
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<td></td>
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</tbody>
</table>

Is this serious event associated with congenital anomaly or birth defect? 

NO

Did this serious event result in death? 

NO

Did this serious event require or prolong hospitalization? 

YES

Did this serious event result in persistent or significant d...
<table>
<thead>
<tr>
<th>Date/Time</th>
<th>User ID</th>
<th>Action</th>
<th>Details</th>
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<tbody>
<tr>
<td>Oct-15-2020 07:38:52 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 2: Candidate, For AE Appendicitis: Response to &quot;Is the adverse event serious?&quot; is 'Yes' but &quot;Serious Adverse Event Number&quot; is blank.</td>
</tr>
<tr>
<td>Oct-15-2020 07:38:52 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Opened, 'Is the adverse event serious?' is marked as YES, but responses to all of the seriousness criteria are NO. At least one seriousness criterion is expected to be YES for serious events. Please review and update as appropriate.</td>
</tr>
<tr>
<td>Oct-15-2020 07:38:52 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: YES, Is this serious event associated with congenital anomaly or birth defect? NO</td>
</tr>
<tr>
<td>Date</td>
<td>Location</td>
<td>User</td>
<td>Value</td>
</tr>
<tr>
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<tr>
<td>Oct-15-2020 07:38:52 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
</tr>
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</table>

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

- Date: Oct-15-2020 07:38:52 (UTC-05:00) Eastern Time (US & Canada)  
  - Location: ACV0PFEINFP6000  
  - User: (b) (4), (b) (6)  
  - Value: Data Entry: NO

9. Is this event related to study treatment:

- Date: Oct-29-2020 17:27:05 (UTC-05:00) Eastern Time  
  - Location: ACV0PFEINFP6000  
  - User: (b) (4), (b) (6)  
  - Value: Query 2: Closed  
  - Reason: Response satisfies query
Oct-29-2020 08:53:09 (UTC-05:00)
Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Please advise what page
Oct-29-2020 08:44:01 (UTC-05:00)
Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFE SDQ PROD | Query 2: Opened
Oct-26-2020 21:42:20 (UTC-05:00)
Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed
Oct-24-2020 15:04:09 (UTC-05:00)
Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered

Please review "If not related to study treatment other" field, the following text was indicated in the comment field [Infection]. Any symptoms, AEs or other key data should be collected on the appropriate page. Please review and update as necessary.

Query closed; will follow for SAE update with requested COVID test info.

Page 145 of 165
<table>
<thead>
<tr>
<th>Date/Time</th>
<th>Event ID</th>
<th>Data Entry</th>
<th>Query</th>
<th>Notes</th>
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<tbody>
<tr>
<td>Oct-22-2020 23:06:05 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Clinical - COVID testing has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form [#2020399436] to provide whether COVID testing was performed (yes/no) and if yes, the results.</td>
<td></td>
</tr>
<tr>
<td>Oct-15-2020 07:38:52 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify</td>
<td></td>
</tr>
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</table>
### 10. Latest Action Taken with Study Treatment:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
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</table>
(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),  
(b) (6) | Data Entry:  
NOT APPLICABLE | Initial Entry |

### 11. Was a Concomitant Medication given?

<table>
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<tr>
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<th>Reason</th>
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</table>
(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),  
(b) (6) | Data Entry:  
YES | Initial Entry |

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

<table>
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<tr>
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<th>Reason</th>
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</table>
(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),  
(b) (6) | Data Entry:  
YES | Initial Entry |
### 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>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: RECOVERED/RESOLVED</td>
<td>Initial Entry</td>
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### 14. Did the adverse event cause the subject to be discontinued from the study?

<table>
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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>Oct-15-2020 07:38:52 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
</tr>
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### 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>
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<tbody>
<tr>
<td>Oct-15-2020 08:12:39 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: 2020399436</td>
<td>Initial Entry</td>
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1. **Date of Visit**

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<td>Feb-23-2021 16:46:00 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
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<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Feb/23/2021</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>
### 1. Select appropriate response - Is participant willing to return for Vaccination 3?

<table>
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<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
</table>
| Feb-23-2021 16:45:40 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | **Data Entry:** Participant is willing to return for Vaccination 3  
Participant is:  
eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2 | Initial Entry |
### 1. Date Treatment Unblinded:

<table>
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<tr>
<th>Date</th>
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<th>Reason</th>
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<tbody>
<tr>
<td>Feb-23-2021 16:45:05 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Feb/23/2021</td>
<td>Initial Entry</td>
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### 2. Primary Reason for Unblinding:

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<th>Reason</th>
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<tbody>
<tr>
<td>Feb-23-2021 16:45:05 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION</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>Initial Entry</td>
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1. Consent Was:

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<td>Initial Entry</td>
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1. Date of Completion/Discontinuation/Death:

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<th>User</th>
<th>Value</th>
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<tr>
<td>Feb-27-2021 14:23:33</td>
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2. Phase of Disposition:

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<td>Feb-27-2021 14:23:33</td>
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3. Status:

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<td>Data Entry: COMPLETED</td>
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1. **Lab Panel:**

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<td>(b) (4), (b) (6)</td>
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<td>Initial Entry</td>
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2. **Lab Sub-Panel:**

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<td>(b) (4), (b) (6)</td>
<td>Data Entry: Not Applicable</td>
<td>Initial Entry</td>
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3. **Collection Date:**

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

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5. **Specimen Type:**

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<td>(b) (4), (b) (6)</td>
<td>Data Entry: Not Applicable</td>
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6.a

| Date                | Location                | User       | Value                  | Reason          |

***Confidential***
### 6.a Sponsor ID:

<table>
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### 6.a Test:

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### 6.a Result:

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<td>(b) (4), (b) (6)</td>
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### 6.a Not Done:

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1. Data Origin

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<td>Feb-27-2021 14:25:06</td>
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<td>Initial Entry</td>
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2. Sample Type

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<th>Reason</th>
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<tr>
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<td>auto calc (autocalc)</td>
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<td>Initial Entry</td>
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3. Sample Collected?

<table>
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<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
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<tbody>
<tr>
<td>Mar-02-2021 06:52:14</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>Mar-01-2021 06:10:45</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>Feb-27-2021 14:25:06</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>Feb-27-2021 14:25:06</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> YES</td>
<td>Date of Collection: Initial Entry</td>
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### 5.a

<table>
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### 5.a Sample ID

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### 5.b

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<td>Data Entry: Sample ID: BS9XGW</td>
<td>Initial Entry</td>
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### 5.b Sample ID

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<td>(b) (4), (b) (6)</td>
<td>Data Entry: BS9XGW</td>
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### 5.c

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### 5.c Sample ID

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<td>(b) (4)</td>
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**Visit:** V101_VAX3  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1109  
**Subject No:** 11091276  
**Generated By:** (b) (4)  
**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY  
**Form Status:** Data Complete, Frozen, Verified  
**Site Name:** (1109) Accel Research Sites - Clinical Research Unit  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:49
### 1. Data Origin

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<td>auto calc (autocalc)</td>
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<td>Initial Entry</td>
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### 2. Sample Type

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### 3. Sample Collected?

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<td>Query 1: Closed</td>
<td>Close Auto Query</td>
</tr>
<tr>
<td>Mar-01-2021 06:10:45 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
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<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>Feb-27-2021 14:25:18 (UTC-05:00) Eastern 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>
</tr>
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<td>Data Entry: YES</td>
<td>Date of Collection:</td>
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5.a

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<td>(b) (4), (b) (6)</td>
<td>Data Entry: Sample ID: BRF6CY</td>
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5.a Sample ID

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

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### 2. Treatment Name

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<td>Data Entry: BNT162b2</td>
<td>Initial Entry</td>
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### 3. Formulation:

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<td>auto calc (autocalc)</td>
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### 4. Dose Date Time:

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<td>Data Entry: Feb/27/2021 13:37</td>
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### 5. Anatomical Location:

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<td>auto calc (autocalc)</td>
<td>Data Entry: DELTOID MUSCLE</td>
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### 6. Body Side:

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<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
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</table>
### 7. Route:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-27-2021 14:26:05</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td>INTRAMUSCULAR</td>
<td>Initial Entry</td>
</tr>
<tr>
<td></td>
<td>(UTC-05:00) Eastern</td>
<td>(autocalc)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Time (US &amp; Canada)</td>
<td></td>
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</table>

### 8. Actual Dose:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-27-2021 14:26:05</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td>30.0</td>
<td>Initial Entry</td>
</tr>
<tr>
<td></td>
<td>(UTC-05:00) Eastern</td>
<td>(autocalc)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 9. Unit:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-27-2021 14:26:05</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td>ug</td>
<td>Initial Entry</td>
</tr>
<tr>
<td></td>
<td>(UTC-05:00) Eastern</td>
<td>(autocalc)</td>
<td></td>
<td></td>
</tr>
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<td></td>
<td>Time (US &amp; Canada)</td>
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</table>

### 10. Timeframe Subject Was Observed

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-27-2021 14:26:05</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td>30 MINUTES</td>
<td>Initial Entry</td>
</tr>
<tr>
<td></td>
<td>(UTC-05:00) Eastern</td>
<td>(autocalc)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></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>Feb-27-2021 14:26:05</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>YES</td>
<td>Initial Entry</td>
</tr>
<tr>
<td></td>
<td>(UTC-05:00) Eastern</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Time (US &amp; Canada)</td>
<td></td>
<td></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>
</table>
| Oct-14-2020 14:49:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000    | auto calc (autocalc) | **Data Entry:** Initial Entry
|                    |                           |                    | **FOLLOW-UP**      |                 |
| Aug-21-2020 11:00:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000    | auto calc (autocalc) | **Data Entry:** Initial Entry
|                    |                           |                    | **ENROLLED/RANDOMIZED** |                 |
| Aug-21-2020 10:23:42 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000    | auto calc (autocalc) | **Data Entry:** Initial Entry
|                    |                           |                    | **SCREENED**        |                 |

### 2. Subject Status Date

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
</table>
| Oct-14-2020 14:49:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000    | auto calc (autocalc) | **Data Entry:** Initial Entry
|                    |                           |                    | **Oct/14/2020**     |                 |
| Aug-21-2020 11:00:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000    | auto calc (autocalc) | **Data Entry:** Initial Entry
|                    |                           |                    | **Aug/21/2020**     |                 |
| Aug-21-2020 10:23:42 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000    | auto calc (autocalc) | **Data Entry:** Initial Entry
|                    |                           |                    | **Aug/21/2020**     |                 |
### 1. Casebook Signature

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-21-2020 15:25:58</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Click Here to Enable</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

**Note:** The data entry is blocked to ensure confidentiality.