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

1. Select appropriate response - Protocol version
   24 JUL 2020

2. Select appropriate response - What cohort does the subject belong to?
   STAGE 3 COHORTS
### Informed Consent

<table>
<thead>
<tr>
<th></th>
<th>Consent Was:</th>
<th>Date Written Consent Obtained</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>OBTAINED</td>
<td>Aug/29/2020</td>
</tr>
</tbody>
</table>
### Demography

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</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>
<tr>
<td>Date of Visit</td>
<td>Aug/29/2020</td>
</tr>
<tr>
<td>--------------</td>
<td>-------------</td>
</tr>
<tr>
<td>1. Date of Visit</td>
<td>Aug/29/2020</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>
**Form Comments**

### Inclusion Criteria Not Met

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

### Exclusion Criteria Met

2. **Description of Exclusion Criterion Met**
   - Not Applicable
## Disposition - Screening

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

**eCRF Audit Trail History**

- (b) (4) FDA-CBER-2021-5683-1022353

- (b) (4) FDA-CBER-2021-5683-1022353
Medical History Details

1.a  
<table>
<thead>
<tr>
<th>Line/MH Number:</th>
<th>[1]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:</td>
<td>[seasonal allergies]</td>
</tr>
<tr>
<td>Start Date:</td>
<td>UNK/UNK/2006</td>
</tr>
<tr>
<td>Ongoing:</td>
<td>YES</td>
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</table>

1.b  
<table>
<thead>
<tr>
<th>Line/MH Number:</th>
<th>[2]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:</td>
<td>[vasectomy]</td>
</tr>
<tr>
<td>Start Date:</td>
<td>UNK/UNK/2014</td>
</tr>
<tr>
<td>Ongoing:</td>
<td>NO</td>
</tr>
<tr>
<td>End Date:</td>
<td>UNK/UNK/2014</td>
</tr>
</tbody>
</table>
### Vital Signs

1. **Date:** Aug/29/2020
2. **Weight:** [87.5]
3. **Unit:** kg
4. **Height:** [167.0]
5. **Unit:** cm
6. **Body Mass Index:** [31.4]

### Vital Signs Details

7.a **Record Identifier:** 1
   - **Temperature:** [98.0]
   - **Unit:** F
   - **Temperature Location:** ORAL CAVITY
**Header Text:** c4591001  
**Visit:** V1_DAY1_VAX1_L  
**Form:** RANDOMIZATION  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1095  
**Site Name:** (1095) Tekton Research  
**Subject No:** 10951173  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:39

### eCRF Audit Trail History

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<td>Aug/29/2020</td>
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<td>2. Randomization Number:</td>
<td>[74020]</td>
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<td>3. Randomization Group:</td>
<td>[ ]</td>
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### eCRF Audit Trail History

**Electronic Sample Tracking**

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<tr>
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<tr>
<td>2.</td>
<td>Sample Type</td>
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<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>
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### Aliquot

Please enter barcode for each aliquot.

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<table>
<thead>
<tr>
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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>
</tr>
<tr>
<td>5.d</td>
<td>Sample ID</td>
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<tr>
<td>5.e</td>
<td>Sample ID</td>
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### eCRF Audit Trail History

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<tr>
<th>Electronic Sample Tracking</th>
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<tbody>
<tr>
<td>1. Data Origin</td>
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<td>2. Sample Type</td>
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<td>3. Sample Collected?</td>
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<td>Date of Collection:</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>
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</tbody>
</table>

#### Aliquot

Please enter barcode for each aliquot.

<p>| 5.a Sample ID | [BP3BHM] |</p>
<table>
<thead>
<tr>
<th><strong>Vaccination</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. <strong>Was there a temporary delay of vaccination?</strong></td>
<td><strong>NO</strong></td>
</tr>
<tr>
<td>2. <strong>Treatment Name</strong></td>
<td><strong>[BLINDED THERAPY]</strong></td>
</tr>
<tr>
<td>3. <strong>Formulation:</strong></td>
<td><strong>INJECTION</strong></td>
</tr>
<tr>
<td>4. <strong>Dose Date Time:</strong></td>
<td><strong>Aug/29/2020 15:16</strong></td>
</tr>
<tr>
<td>5. <strong>Anatomical Location:</strong></td>
<td><strong>DELTOID MUSCLE</strong></td>
</tr>
<tr>
<td>6. <strong>Body Side:</strong></td>
<td><strong>LEFT</strong></td>
</tr>
<tr>
<td>7. <strong>Route:</strong></td>
<td><strong>INTRAMUSCULAR</strong></td>
</tr>
<tr>
<td>8. <strong>Actual Dose:</strong></td>
<td><strong>[]</strong></td>
</tr>
<tr>
<td>9. <strong>Unit:</strong></td>
<td></td>
</tr>
<tr>
<td>10. <strong>Timeframe Subject Was Observed</strong></td>
<td><strong>THE PROTOCOL SPECIFIED OBSERVATION PERIOD</strong></td>
</tr>
<tr>
<td>11. <strong>Was the subject observed for at least the protocol specified observation period after investigational product administration?</strong></td>
<td><strong>YES</strong></td>
</tr>
</tbody>
</table>
**Reactogenicity Diary**

1. Select appropriate response - Reactogenicity diary collection

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>NO</td>
<td>REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT</td>
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</table>
**eCRF Audit Trail History**

**Date of Visit**

<table>
<thead>
<tr>
<th></th>
<th>Date of Visit</th>
<th>Oct/12/2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Erroneous Visit</td>
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</table>
**Vital Signs Details**

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<thead>
<tr>
<th>2.a</th>
<th>Record Identifier:</th>
<th>1</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Temperature:</td>
<td>[97.6]</td>
</tr>
<tr>
<td></td>
<td>Unit:</td>
<td>F</td>
</tr>
<tr>
<td></td>
<td>Temperature Location:</td>
<td>ORAL CAVITY</td>
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</table>
### eCRF Audit Trail History

**Electronic Sample Tracking**

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<td>Data Origin</td>
</tr>
<tr>
<td><strong>2.</strong></td>
<td>Sample Type</td>
</tr>
<tr>
<td><strong>3.</strong></td>
<td>Sample Collected?</td>
</tr>
<tr>
<td></td>
<td>Date of Collection:</td>
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<tr>
<td><strong>4.</strong></td>
<td>If no sample was collected or sample was not collected according to protocol, please provide reason:</td>
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</tbody>
</table>

**Aliquot**

Please enter barcode for each aliquot.

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</tr>
</thead>
<tbody>
<tr>
<td><strong>5.a</strong></td>
<td>Sample ID</td>
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</table>
### Vaccination

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

<table>
<thead>
<tr>
<th>Date of Visit</th>
<th>Nov/11/2020</th>
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<tbody>
<tr>
<td>1. Date of Visit</td>
<td>Nov/11/2020</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
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</table>
### Electronic Sample Tracking

<table>
<thead>
<tr>
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<th>Data Origin</th>
<th>Sample Type</th>
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<tbody>
<tr>
<td>1.</td>
<td>SITE</td>
<td>SERUM</td>
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<table>
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<th></th>
<th>Sample Collected?</th>
<th>Date of Collection:</th>
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<tbody>
<tr>
<td>3.</td>
<td>YES</td>
<td>Nov/11/2020</td>
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<table>
<thead>
<tr>
<th></th>
<th>If no sample was collected or sample was not collected according to protocol, please provide reason:</th>
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<tbody>
<tr>
<td>4.</td>
<td>[ ]</td>
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### Aliquot

Please enter barcode for each aliquot.

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<thead>
<tr>
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<th>Sample ID</th>
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<tbody>
<tr>
<td>5.a</td>
<td>[BPLJWV]</td>
</tr>
<tr>
<td>5.b</td>
<td>[BRDG1M]</td>
</tr>
<tr>
<td>5.c</td>
<td>[BRDG1N]</td>
</tr>
<tr>
<td>5.d</td>
<td>[BRDG1P]</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:** V5_MONTH12_L  
**Form:** DATE OF VISIT  
**Form Version:** 22-Apr-2020 21:02  
**Form Status:** Not Started  
**Site No:** 1095  
**Site Name:** (1095) Tekton Research  
**Subject No:** 10951173  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:39
### 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>
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>
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</tbody>
</table>

**COVID-19 Illness Visit**

<table>
<thead>
<tr>
<th>3. COVID-19 Illness Visit:</th>
<th></th>
</tr>
</thead>
</table>
### Header Text
- **c4591001**
- **Visit:** POT_COVID_ILL - New Unscheduled Visit
- **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
- **Form Version:** 20-Feb-2021 02:17
- **Site No:** 1095
- **Site Name:** (1095) Tekton Research
- **Subject No:** 10951173
- **Subject Initials:** ---
- **Generated By:** (b) (4)
- **Generated Time (GMT):** 29-Mar-2021 10:39

### 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

<p>| | |</p>
<table>
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<tr>
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<tbody>
<tr>
<td>1.</td>
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<td>4.</td>
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#### Aliquot

Please enter barcode for each aliquot.

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### Health Care Utilization

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>1.</td>
<td>Physician or Healthcare Professional:</td>
</tr>
<tr>
<td></td>
<td>Occurrence of Visits or Contacts:</td>
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### Health Care Utilization Other

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>2.</td>
<td>Other Type of Practitioner Specify: [ ]</td>
</tr>
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</table>

### Health Care Utilization

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>3.</td>
<td>Has the subject been hospitalized due to potential COVID-19 illness?</td>
</tr>
</tbody>
</table>
Illness Details

1. Category of Clinical Event:

2. Was a diagnosis obtained for Potential COVID-19 Illness?

3. Toxicity Grade:
<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>
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</table>

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

<p>| | |</p>
<table>
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<tbody>
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<td>1.</td>
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<td>2.</td>
<td>Sample Type</td>
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<tr>
<td>3.</td>
<td>Sample Collected?</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>
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### Aliquot

Please enter barcode for each aliquot.

<p>| | |</p>
<table>
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</thead>
<tbody>
<tr>
<td>5.</td>
<td>Sample ID [ ]</td>
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<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>
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</table>
Unplanned Assessments

<table>
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FDA-CBER-2021-5683-1022382
**Disposition - Treatment**

<table>
<thead>
<tr>
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<th><strong>Date of Completion/Discontinuation/Death:</strong> Sep/5/2020</th>
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</thead>
<tbody>
<tr>
<td>2</td>
<td><strong>Phase of Disposition:</strong> VACCINATION</td>
</tr>
<tr>
<td>3</td>
<td><strong>Status:</strong> ADVERSE EVENT</td>
</tr>
<tr>
<td>4</td>
<td><strong>Specify Status:</strong> [ ]</td>
</tr>
<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

<table>
<thead>
<tr>
<th></th>
<th>Date of Visit</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>//</td>
</tr>
<tr>
<td>2</td>
<td>Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>

### COVID-19 Repeat Swab

<table>
<thead>
<tr>
<th></th>
<th>COVID-19 Repeat Swab:</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</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>
<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>#</td>
<td>Category</td>
</tr>
<tr>
<td>----</td>
<td>----------------</td>
</tr>
<tr>
<td>1.</td>
<td>ADVERSE EVENT</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>DELETED</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>ADVERSE EVENT</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)
   [STEMI: ST elevation Myocardial Infarction]

4. **Start Date Time:** Sep/5/2020 UNK:UNK

5. **Is the adverse event still ongoing?** NO
   - **End Date Time:** Sep/9/2020 UNK:UNK

6. **Toxicity Grade:** 4

7. **Is the adverse event serious?**
   - **YES**
     - Is this serious event associated with congenital anomaly or birth defect?
       - **NO**
     - Did this serious event result in death?
       - **NO**
     - Did this serious event require or prolong hospitalization?
       - **YES**
     - Did this serious event result in persistent or significant disability/incapacity?
       - **NO**
     - Is this serious event life threatening?
       - **YES**
     - Other medically important serious event
       - **NO**

8. **Is this adverse event the result of a study Medication Error?**
   - **NO**

9. **Is this event related to study treatment:**
   - **NOT RELATED**
     - If Not Related to study treatment(s), this event is due to:
       - **OTHER**
     - If Other, specify:
       - [undiagnosed Obstructive CAD]
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>10.</td>
<td>Latest Action Taken with Study Treatment: NOT APPLICABLE</td>
</tr>
<tr>
<td>11.</td>
<td>Was a Concomitant Medication given? YES</td>
</tr>
<tr>
<td>12.</td>
<td>Was a Non-Drug Treatment given? YES</td>
</tr>
<tr>
<td>13.</td>
<td>What was the outcome of this adverse event?: RECOVERED/RESOLVED</td>
</tr>
<tr>
<td>14.</td>
<td>Did the adverse event cause the subject to be discontinued from the study? NO</td>
</tr>
<tr>
<td>15.</td>
<td>Serious Adverse Event Number: For Pfizer Use Only [2020365372]</td>
</tr>
</tbody>
</table>
**Adverse Event Report**

1. **Category:** ADVERSE EVENT

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

3. **Adverse Event:**
   (If possible specify diagnosis, not individual symptoms)
   [Right sided coronary artery blockage]

4. **Start Date Time:** Sep/5/2020 UNK:UNK

5. **Is the adverse event still ongoing?**
   NO
   **End Date Time:**
   Sep/9/2020 UNK:UNK

6. **Toxicity Grade:** 2

7. **Is the adverse event serious?**
   YES
   - Is this serious event associated with congenital anomaly or birth defect?
   - Did this serious event require or prolong hospitalization?
     YES
   - Did this serious event result in death?
   - Did this serious event result in persistent or significant disability/incapacity?
   - Is this serious event life threatening?
   - Other medically important serious event

8. **Is this adverse event the result of a study Medication Error?**
   NO
   If Yes, record the type of medication error on the Medication Error Log.

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:
      [CAD]

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 | []
### 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: [3]</td>
</tr>
<tr>
<td>3.</td>
<td>Adverse Event: [Coronary Artery Disease]</td>
</tr>
<tr>
<td>4.</td>
<td>Start Date Time: Sep/5/2020 UNK:UNK</td>
</tr>
<tr>
<td>5.</td>
<td>Is the adverse event still ongoing? YES</td>
</tr>
<tr>
<td>6.</td>
<td>Toxicity Grade: 2</td>
</tr>
<tr>
<td>7.</td>
<td>Is the adverse event serious? NO</td>
</tr>
<tr>
<td></td>
<td>If Yes, NOTIFY PFIZER IMMEDIATELY.</td>
</tr>
<tr>
<td></td>
<td>Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).</td>
</tr>
<tr>
<td>8.</td>
<td>Is this adverse event the result of a study Medication Error? NO</td>
</tr>
<tr>
<td></td>
<td>If Yes, record the type of medication error on the Medication Error Log.</td>
</tr>
<tr>
<td>9.</td>
<td>Is this event related to study treatment: NOT RELATED</td>
</tr>
<tr>
<td></td>
<td>If Not Related to study treatment(s), this event is due to: OTHER</td>
</tr>
<tr>
<td></td>
<td>If Other, specify: [CAD]</td>
</tr>
<tr>
<td>10.</td>
<td>Latest Action Taken with Study Treatment: NOT APPLICABLE</td>
</tr>
<tr>
<td>11.</td>
<td>Was a Concomitant Medication given? YES</td>
</tr>
<tr>
<td>12.</td>
<td>Was a Non-Drug Treatment given? NO</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>13.</td>
<td>What was the outcome of this adverse event?:</td>
</tr>
<tr>
<td></td>
<td>NOT RECOVERED/NOT RESOLVED</td>
</tr>
<tr>
<td>14.</td>
<td>Did the adverse event cause the subject to be discontinued from the study?</td>
</tr>
<tr>
<td></td>
<td>NO</td>
</tr>
<tr>
<td>15.</td>
<td>Serious Adverse Event Number: For Pfizer Use Only</td>
</tr>
<tr>
<td></td>
<td>[ ]</td>
</tr>
<tr>
<td>#</td>
<td>Category</td>
</tr>
<tr>
<td>---</td>
<td>----------</td>
</tr>
<tr>
<td>1.</td>
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</tbody>
</table>

**Final On:** 01-Apr-2021 03:49 (GMT)
### Medication Error

1. **Category:**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Medication Error (Type of Medication Error):</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

3. **Start Date:**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>4. Is the medication error still ongoing?</td>
<td>//</td>
</tr>
</tbody>
</table>

5. **Latest Action Taken with Study Treatment:**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>6. Was a Concomitant Medication given?</td>
<td></td>
</tr>
</tbody>
</table>

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

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>8. Did the Medication Error cause the subject to be discontinued from the study?</td>
<td></td>
</tr>
</tbody>
</table>

9. **Was this medication error associated with any adverse events?**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>10. 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>1</td>
</tr>
</tbody>
</table>
### Concomitant Medications

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>What is the medication identifier?</td>
<td>[1]</td>
</tr>
<tr>
<td>2.</td>
<td>Category:</td>
<td>VACCINATIONS</td>
</tr>
<tr>
<td>3.</td>
<td>Concomitant Medications Pre-specified:</td>
<td>NO</td>
</tr>
<tr>
<td>4.</td>
<td>Medication:</td>
<td>[Influenza vaccine 1 dose IM once for influenza prevention]</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>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>Date:</td>
<td>Oct/28/2020</td>
</tr>
<tr>
<td>#</td>
<td>Sponsor-Defined Identifier</td>
<td>Category for Medication</td>
</tr>
<tr>
<td>---</td>
<td>---------------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>1.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

**Note:** This form is used to report concomitant medications prohibited. Each row represents a different medication.
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>
<td></td>
<td></td>
<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?**

---

**Back to Form**
<table>
<thead>
<tr>
<th>#</th>
<th>Transfusion Type</th>
<th>Date of Transfusion</th>
<th>Form Instance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Repeating Pages</td>
<td></td>
<td></td>
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</tbody>
</table>

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**FDA-CBER-2021-5683-1022402**

---

***Confidential***
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>1.</td>
<td>Transfusion Type:</td>
</tr>
<tr>
<td>2.</td>
<td>Date of Transfusion: //</td>
</tr>
</tbody>
</table>
### eCRF Audit Trail History

<table>
<thead>
<tr>
<th>Date of Visit</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Visit</td>
<td>Feb/4/2021</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>
# Vital Signs Details

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Feb/4/2021</td>
</tr>
</tbody>
</table>

## Vital Signs Details

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2.a</td>
<td></td>
</tr>
<tr>
<td>Record Identifier:</td>
<td>1</td>
</tr>
<tr>
<td>Temperature:</td>
<td>[98.0]</td>
</tr>
<tr>
<td>Unit:</td>
<td>F</td>
</tr>
<tr>
<td>Temperature Location:</td>
<td>ORAL CAVITY</td>
</tr>
</tbody>
</table>
## Vaccination

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Was there a temporary delay of vaccination?</td>
<td>YES</td>
</tr>
<tr>
<td>Date of First Delay:</td>
<td>Oct/12/2020</td>
</tr>
<tr>
<td>Reason(s) for Temporary Delay of Vaccination:</td>
<td>FEVER OR ACUTE ILLNESS</td>
</tr>
<tr>
<td>2. Treatment Name</td>
<td>[BLINDED THERAPY]</td>
</tr>
<tr>
<td>3. Formulation:</td>
<td>INJECTION</td>
</tr>
<tr>
<td>4. Dose Date Time:</td>
<td>Feb/4/2021 11:01</td>
</tr>
<tr>
<td>5. Anatomical Location:</td>
<td>DELTOID MUSCLE</td>
</tr>
<tr>
<td>6. Body Side:</td>
<td>LEFT</td>
</tr>
<tr>
<td>7. Route:</td>
<td>INTRAMUSCULAR</td>
</tr>
<tr>
<td>8. Actual Dose:</td>
<td>[ ]</td>
</tr>
<tr>
<td>9. Unit:</td>
<td></td>
</tr>
<tr>
<td>10. Timeframe Subject Was Observed</td>
<td>THE PROTOCOL SPECIFIED OBSERVATION PERIOD</td>
</tr>
<tr>
<td>11. Was the subject observed for at least the protocol specified observation period after investigational product administration?</td>
<td>YES</td>
</tr>
</tbody>
</table>
### Contact Outcome

1. **Contact Type:**

2. **Was contact made?**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 6

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

**Form Status:** Not Started

**Site No:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951173

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

---

**FDA-CBER-2021-5683-1022408**
## Date of Visit

1. **Date of Visit**

2. **Erroneous Visit**
Informed Consent - Asymptomatic Surveillance

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

### Aliquot

Please enter barcode for each aliquot.
| Date of Visit | | |
|---------------|---------------|
| 1. Date of Visit | Feb/2/2021 |
| 2. Erroneous Visit | |

**eCRF Audit Trail History**

**Date of Visit**

1. Date of Visit
2. Erroneous Visit

**Form: DATE OF VISIT**

- **Form Version:** 22-Apr-2020 21:02
- **Form Status:** Data Complete, Frozen, Verified
- **Site No:** 1095
- **Site Name:** (1095) Tekton Research
- **Subject No:** 10951173
- **Subject Initials:** ---
- **Generated By:** (b) (4)
- **Generated Time (GMT):** 29-Mar-2021 10:39
<table>
<thead>
<tr>
<th><strong>Further Vaccination Confirmation</strong></th>
<th></th>
</tr>
</thead>
</table>
| 1. Select appropriate response - Is participant willing to return for Vaccination 3? | Participant is willing to return for Vaccination 3
Participant is:
eligible and NOT confirmed to have received only placebo at Vaccination 1/2 |
<table>
<thead>
<tr>
<th>eCRF Audit Trail History</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment Unblinded</td>
</tr>
<tr>
<td>1. Date Treatment Unblinded : Feb/2/2021</td>
</tr>
<tr>
<td>2. Primary Reason for Unblinding: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION</td>
</tr>
</tbody>
</table>
## Withdrawal Of Consent

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

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

**Cause of Death**

<p>| 2. Cause of Death Status: | |
| Cause of Death: | [ ] |</p>
<table>
<thead>
<tr>
<th>Date of Visit</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Visit</td>
<td>Feb/4/2021</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td>ERRONEOUS VISIT</td>
</tr>
<tr>
<td>No.</td>
<td>Consent Was:</td>
</tr>
<tr>
<td>-----</td>
<td>--------------</td>
</tr>
<tr>
<td>1</td>
<td>Not Done</td>
</tr>
</tbody>
</table>

**Informed Consent - Further Vaccination**

**Consent Was:** Not Done

---

**Generated Time (GMT):** 29-Mar-2021 10:39
### Form Comments

#### Inclusion Criteria Not Met

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

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Date of Completion/Discontinuation/Death:</td>
<td>Not Done</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>//</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Phase of Disposition:</td>
<td>Not Done</td>
</tr>
<tr>
<td>3</td>
<td>Status:</td>
<td>Not Done</td>
</tr>
<tr>
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**Generated Time (GMT):** 29-Mar-2021 10:39
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- CRF_Sign
- CRF_Sign_1

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Subject No: 10951173
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 10:39

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**Generated By:** (b) (4)  
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**Form Version:** 10-Dec-2020 02:26  
**Site No:** 1095  
**Subject No:** 10951173  
**Generated By:** (b) (4)  
**Form:** VACCINATION - Comments  
**Form Status:** Data Complete, Frozen, Verified  
**Site Name:** (1095) Tekton Research  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:39

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- CRF_Sign
- CRF_Sign_1

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**Affidavit:**
N/A

Paul Pickrell
Approved
Nov-17-2020 19:54:27 (UTC-06:00) Central Time (US & Canada)
BOOK
Signed

**Affidavit:**
By my dated signature below, I, Paul Pickrell, 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.

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**Affidavit:**
N/A

Paul Pickrell
Approved
Nov-14-2020 07:24:46 (UTC-06:00) Central Time (US & Canada)
BOOK
Signed

**Affidavit:**
By my dated signature below, I, Paul Pickrell, 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.

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**Affidavit:**

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

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

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

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

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<td>(b) (4), (6)</td>
<td><strong>Data Entry:</strong> STAGE 3 COHORTS</td>
<td>Initial Entry</td>
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<td>Date</td>
<td>Location</td>
<td>User</td>
<td>Value</td>
<td>Reason</td>
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<td>(UTC-06:00) Central Time</td>
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<td>Data Entry: Obtained Date Written Consent Obtained Aug/29/2020</td>
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**1. Consent Was:**
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<td>Query 1: Answered</td>
<td>This has been updated</td>
</tr>
<tr>
<td>Sep-23-2020 04:25:12 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Reissued:Opened</td>
<td>SAE RECON 2:'Coronary artery occlusion' (onset date:05SEP2020)is still missing in AE CRF. Please confirm and update accordingly</td>
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<td>Sep-22-2020 20:36:19 (UTC-06:00) Central Time (US &amp; Canada)</td>
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<td>Query 2: Closed</td>
<td>event added</td>
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<td>Sep-22-2020 11:28:31 (UTC-06:00) Central Time (US &amp; Canada)</td>
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<td>(b) (4), (b) (6)</td>
<td>Query 2: Answered</td>
<td>this has been updated</td>
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<td>Sep-22-2020 07:51:28 (UTC-06:00) Central Time (US &amp; Canada)</td>
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<td>more information is forthcoming</td>
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<td>Query 2: Opened</td>
<td>SAE RECON:AER#2020365372R sided coronary blockage resulting in MI PT Myocardial infarction' (onset date:05SEP2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a form</td>
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<td>SAE RECON:AER#2020365372R sided coronary blockage resulting in MI PT 'Coronary artery occlusion'(onset date:05SEP2020)was</td>
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reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a form

### Data Entry: 10951173

| Item copied from previous form |

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### 2. Birth Date:

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### 3. Sex:

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<td><strong>Data Entry:</strong> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN</td>
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#### 1. Date of Completion/Discontinuation/Death

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2. **Phase of Disposition:**

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**Medical History Term:**

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**Non-Drug Allergies/Drug Allergies:**

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**Ongoing:**

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### 1.b

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<tr>
<td>Aug-29-2020 15:20:20</td>
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<td>auto calc (autocalc)</td>
<td>Initial Entry</td>
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### 1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

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### 6. Body Mass Index:

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**7.a**
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**7.a Record Identifier:**

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**7.a Temperature Location:**

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<tr>
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<td>Initial Entry</td>
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### 2. Sample Type

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### 3. Sample Collected?

<table>
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<th>Value</th>
<th>Reason</th>
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<td>Query 1: Closed</td>
<td>Close Auto Query</td>
</tr>
<tr>
<td>Aug-31-2020 01:53:28 (UTC-06:00) Central Time (US &amp; Canada)</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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## 3. Sample Collected?

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**Header Text:** c4591001  
**Visit:** V1_DAY1_VAX1_L  
**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF

---

**Audit Trail History**

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

**Site No:** 1095  
**Site Name:** (1095) Tekton Research  
**Subject No:** 10951173  
**Subject Initials:** ---

**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:39
### 5.a Sample ID

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<td>Sep-01-2020 10:06:24</td>
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<td>Initial Entry</td>
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<td>(UTC-06:00) Central Time</td>
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<td>(b) (6)</td>
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<td>(US &amp; Canada)</td>
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*Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1095
Site Name: (1095) Tekton Research
Subject No: 10951173
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 10:39

ACV0PF6INFP6000 (b) (4), (b) (6)
Data Entry: Sample ID: BP3BHM
Initial Entry
1. Was there a temporary delay of vaccination?

<table>
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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Aug-29-2020 15:19:07 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
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<td>Data Entry: NO</td>
<td>Initial Entry</td>
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2. Treatment Name

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<th>Reason</th>
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<tbody>
<tr>
<td>Aug-29-2020 15:19:07 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: BLINDED THERAPY</td>
<td>Initial Entry</td>
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3. Formulation:

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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>Data Entry: INJECTION</td>
<td>Initial Entry</td>
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4. Dose Date Time:

<table>
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<th>Reason</th>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4) (6)</td>
<td>Data Entry: Aug/29/2020 15:16</td>
<td>Initial Entry</td>
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5. Anatomical Location:

<table>
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<th>Reason</th>
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<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: DELTOID MUSCLE</td>
<td>Initial Entry</td>
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6. Body Side:

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<th>Reason</th>
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<tbody>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4) (6)</td>
<td>Data Entry: LEFT</td>
<td>Initial Entry</td>
</tr>
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</table>

7. Route:
### 10. Timeframe Subject Was Observed

<table>
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<th>User</th>
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<th>Reason</th>
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<tbody>
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<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: INTRAMUSCULAR</td>
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### 11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

<table>
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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Aug-29-2020 15:19:07</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: YES</td>
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</table>
### 1. Select appropriate response - Reactogenicity diary collection

<table>
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<th>Value</th>
<th>Reason</th>
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<tr>
<td>Aug-29-2020 14:26:23</td>
<td>(UTC-06:00) Central Time</td>
<td>ACV0PF00060000</td>
<td>Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT</td>
<td>Initial Entry</td>
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<td>(US &amp; Canada)</td>
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</tbody>
</table>
### Date of Visit

<table>
<thead>
<tr>
<th>Date</th>
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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Nov-15-2020 10:49:12 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 3: Closed</td>
<td>barcode has been entered</td>
</tr>
<tr>
<td>Nov-14-2020 07:45:55 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 3: Reissued: Opened</td>
<td>Hold recon: Nasal swab with barcode BP1N5T received at Lab; however missing in database. Please provide missing data or else update SCF.</td>
</tr>
<tr>
<td>Nov-13-2020 16:47:38 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 3: Answered</td>
<td>Please unfreeze and requery</td>
</tr>
<tr>
<td>Nov-13-2020 03:04:14 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 3: Opened</td>
<td>Hold recon: Nasal swab with barcode BP1N5T received at Lab; however missing in database. Please provide missing data or else update SCF.</td>
</tr>
<tr>
<td>Oct-14-2020 00:19:41 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Closed</td>
<td>As per site confirmation - updated PD tracker</td>
</tr>
<tr>
<td>Oct-13-2020 09:16:28 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Answered</td>
<td>Data is correct, due to SAE visit out of window</td>
</tr>
<tr>
<td>Oct-13-2020 05:09:29 (UTC-06:00)</td>
<td>ACV0PFEINFP6000.InFormAdapter.Discrepancy</td>
<td>PFE SDQ PROD (b) (4)</td>
<td>Query 2: Opened</td>
<td>PDQ: Date of visit at V2_VAX2_L is out of window for 21</td>
</tr>
<tr>
<td>Date Time</td>
<td>User ID</td>
<td>Data Entry</td>
<td>Query 1</td>
<td>DM Note</td>
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<tr>
<td>---------------------------</td>
<td>------------------</td>
<td>------------------</td>
<td>----------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------</td>
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<tr>
<td>Oct-12-2020 09:48:17</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Initial Entry</td>
<td>days from V1_DAY1_VAX1_L Dose Date. Please verify and update. Else, confirm in query response appropriately. (b) (4)</td>
</tr>
<tr>
<td>Sep-27-2020 02:43:54</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Response satisfies query</td>
<td></td>
</tr>
<tr>
<td>Sep-25-2020 17:38:08</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>This pt has not come in for visit yet. Will complete once visit occurs.</td>
<td></td>
</tr>
<tr>
<td>Sep-25-2020 05:48:06</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Opened</td>
<td>DM: Kindly review and complete 'Date of Visit, Nasal Swab, Vaccination, Vital Signs' forms at this visit. Thank you.</td>
</tr>
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### 1. Date

<table>
<thead>
<tr>
<th>Date</th>
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<tr>
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<td>(b)</td>
<td>Data Entry: Oct/12/2020</td>
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### 2.a

#### 2.a Record Identifier:

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### 2.a Temperature:

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### 2.a Unit:

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<td>ACV0PFEINFP6000</td>
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### 2.a Temperature Location:

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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
<td>Data Entry: ORAL CAVITY</td>
<td>Initial Entry</td>
</tr>
<tr>
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### 1. Data Origin

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

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<td>auto calc (autocalc)</td>
<td>Data Entry: NASAL_SWAB</td>
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### 3. Sample Collected?

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<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 3: Closed</td>
<td>Close Auto Query</td>
</tr>
<tr>
<td>Nov-14-2020 12:01:37 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Data Entry: YES Date of Collection: Oct/12/2020</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Nov-14-2020 12:00:59 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 3: Opened</td>
<td>Response to &quot;Sample Collected?&quot; is No, but Barcodes are present on the page.</td>
</tr>
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<td>Oct-14-2020 10:41:01 (UTC-06:00) Central Time (US &amp; Canada)</td>
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<td>auto query (autoquery)</td>
<td>Query 2: Closed</td>
<td>Close Auto Query</td>
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<td>auto query (autoquery)</td>
<td>Query 2: Opened</td>
<td>'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please</td>
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</table>
**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
**Audit Trail History**

<table>
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<td>Oct-13-2020 05:54:20</td>
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<td>Sample Collected? is Yes, however no barcodes are entered. Please review and correct as appropriate.</td>
</tr>
<tr>
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<td>(US &amp; Canada)</td>
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<td>(b) (4), (b)</td>
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<td>(autoquery)</td>
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<td>(UTC-06:00) Central Time</td>
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4. **If no sample was collected or sample was not collected according to protocol, please provide reason:**

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<th>User</th>
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<th>Reason</th>
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<td>Data Entry: No nasal swab or vaccine administred due to SAE</td>
</tr>
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<td>(US &amp; Canada)</td>
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<td>(b) (4), (b)</td>
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5.a

<table>
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<th>Reason</th>
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5.a **Sample ID**

<table>
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<th>Value</th>
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<tbody>
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<td>Data Entry: BP1N5T</td>
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</tbody>
</table>

**Generated By:** (b) (4)  
**Data Entry:** BP1N5T  
**Initial Entry:**

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### Audit Trail History

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
**Audit Trail History**

**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site Name:** (1095) Tekton Research  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:39
1. Was there a temporary delay of vaccination?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-12-2020 09:50:03 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b), (4), (6)</td>
<td>Data Entry: Not Done</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

2. Treatment Name

<table>
<thead>
<tr>
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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
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<tbody>
<tr>
<td>Oct-12-2020 09:50:03 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b), (4), (6)</td>
<td>Data Entry: Not Done</td>
<td>Initial Entry</td>
</tr>
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3. Formulation:

<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-12-2020 09:50:03 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b), (4), (6)</td>
<td>Data Entry: Not Done</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

4. Dose Date Time:

<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>Oct-12-2020 09:50:03 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b), (4), (6)</td>
<td>Data Entry: Not Done</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

5. Anatomical Location:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-12-2020 09:50:03 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b), (4), (6)</td>
<td>Data Entry: Not Done</td>
<td>Initial Entry</td>
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</table>

6. Body Side:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-12-2020 09:50:03 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b), (4), (6)</td>
<td>Data Entry: Not Done</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

7. Route:
### 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>Oct-12-2020 09:50:03</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4)</td>
<td>Data Entry: Not Done</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>Oct-12-2020 09:50:03</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4)</td>
<td>Data Entry: Not Done</td>
</tr>
</tbody>
</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>Oct-12-2020 09:50:03</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4)</td>
<td>Data Entry: Not Done</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>Oct-12-2020 09:50:03</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4)</td>
<td>Data Entry: Not Done</td>
</tr>
</tbody>
</table>
### 1. Date of Visit

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-11-2020 09:47:27</td>
<td>(UTC-06:00) Central Time</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Nov/11/2020</td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 1. Data Origin

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-11-2020 09:47:35</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td><strong>Data Entry:</strong> SITE</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td>(autocalc)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 2. Sample Type

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-11-2020 09:47:35</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td><strong>Data Entry:</strong> SERUM</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td>(autocalc)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

### 3. Sample Collected?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-12-2020 08:00:55</td>
<td>ACV0PFEINFP6000</td>
<td>auto query</td>
<td>Query 1: Closed</td>
<td>Close Auto Query</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td>(autoquery)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nov-11-2020 11:42:05</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
<td>Query 1: Opened</td>
<td>Please enter missing barcodes or provide date (or estimated date) as to when the missing information is available. Please provide DATE as to when we can expect the information. Thank you!</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td>(6)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nov-11-2020 09:47:35</td>
<td>ACV0PFEINFP6000</td>
<td>auto query</td>
<td>Query 1: Candidate</td>
<td>'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td>(autoquery)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nov-11-2020 09:47:35</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
<td><strong>Data Entry:</strong> YES</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td>(6)</td>
<td></td>
<td>Date of Collection:</td>
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<tr>
<td>(US &amp; Canada)</td>
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<td></td>
<td>Nov/11/2020</td>
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</tr>
<tr>
<td>Date</td>
<td>Location</td>
<td>User</td>
<td>Value</td>
<td>Reason</td>
</tr>
<tr>
<td>-------------------</td>
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<td>-----------------</td>
</tr>
<tr>
<td>Nov-12-2020 08:00:55 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Sample ID: BPLJWV</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

**5.a Sample ID**

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-12-2020 08:00:55 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Sample ID: BPLJWV</td>
<td>Initial Entry</td>
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</table>

**5.b**

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-12-2020 08:04:28 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Sample ID: BRDG1M</td>
<td>Initial Entry</td>
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</tbody>
</table>

**5.b Sample ID**

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-12-2020 08:04:28 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Sample ID: BRDG1M</td>
<td>Initial Entry</td>
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</table>

**5.c**

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-12-2020 08:04:37 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Sample ID: BRDG1N</td>
<td>Initial Entry</td>
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</table>

**5.c Sample ID**

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-12-2020 08:04:37 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: BRDG1N</td>
<td>Initial Entry</td>
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**5.d**

<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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**Header Text:** c4591001

**Visit:** V3_MONTH1_POSTVAX2_L

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

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

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

**Site No:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951173

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39
### 5.d Sample ID

<table>
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<th>Date</th>
<th>Location</th>
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<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Nov-12-2020 08:04:47 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Sample ID: BRDG1P</td>
<td>Initial Entry</td>
</tr>
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</table>

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

**Site No:** 1095
**Subject No:** 10951173
**Generated By:** (b) (4)
1. Date of Completion/Discontinuation/Death:

<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>Nov-12-2020</td>
<td>ACV0PFEINFP6000</td>
<td>(b)</td>
<td>Query 2: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Nov-11-2020</td>
<td>ACV0PFEINFP6000</td>
<td>(b)</td>
<td>Query 2: Answered</td>
<td>This has been updated</td>
</tr>
<tr>
<td>Nov-11-2020</td>
<td>ACV0PFEINFP6000</td>
<td>(b)</td>
<td>Query 2: Reissued:Opened</td>
<td>DM: Form is not frozen. Please review query and update as appropriate.</td>
</tr>
<tr>
<td>Nov-11-2020</td>
<td>ACV0PFEINFP6000</td>
<td>(b)</td>
<td>Data Entry:</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Nov-11-2020</td>
<td>ACV0PFEINFP6000</td>
<td>(b)</td>
<td>Query 2: Answered</td>
<td>please unfreeze and re-query so this can be updated</td>
</tr>
<tr>
<td>Nov-10-2020</td>
<td>ACV0PFEINFP6000</td>
<td>(b)</td>
<td>Query 2: Opened</td>
<td>The discontinuation date of 29AUG2020 should be relative to the AE causing the withdrawal of the study vaccine, AE start 05SEP2020 and end 09SEP2020 (date should not be PRIOR to start of AE). Please adjust Discontinuation da</td>
</tr>
<tr>
<td>Oct-30-2020</td>
<td>ACV0PFEINFP6000</td>
<td>(b)</td>
<td>Query 1: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Oct-29-2020</td>
<td>ACV0PFEINFP6000</td>
<td>(b)</td>
<td>Query 1: Answered</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>Oct-29-2020</td>
<td>ACV0PFEINFP6000</td>
<td>(b)</td>
<td>Data Entry:</td>
<td>Initial Entry</td>
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</table>
**2. Phase of Disposition:**

<table>
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<th>Reason</th>
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<tbody>
<tr>
<td>Oct-29-2020 14:20:43</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: VACCINATION</td>
<td>Initial Entry</td>
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**3. Status:**

<table>
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<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-08-2020 09:52:41</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 4: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Nov-06-2020 15:08:14</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 5: Closed</td>
<td>Close Auto Query</td>
</tr>
<tr>
<td>Nov-06-2020 15:07:50</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 5: Opened</td>
<td>Response to &quot;Status&quot; is ADVERSE EVENT but &quot;Specify Status&quot; is Provided.</td>
</tr>
<tr>
<td>Time</td>
<td>Date</td>
<td>Auto Query</td>
<td>Data Entry</td>
<td>Notes</td>
</tr>
<tr>
<td>------</td>
<td>------</td>
<td>------------</td>
<td>------------</td>
<td>-------</td>
</tr>
<tr>
<td>Nov-06-2020 15:07:50 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td><strong>Data Entry:</strong> ADVERSE EVENT</td>
<td>Action taken for the SAE “STEMI: ST elevation Myocardial Infarction” is reported as &quot;DRUG WITHDRAWN&quot;, however status is reported as &quot;OTHER&quot;. Please verify and confirm whether this needs to be updated as 'Adverse event'. Else clarify.</td>
</tr>
<tr>
<td>Nov-04-2020 05:14:10 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Balaji Prabu R (b) (4)</td>
<td>Query 4: Opened</td>
<td></td>
</tr>
<tr>
<td>Nov-02-2020 14:27:40 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td></td>
<td>Query 2: Answered</td>
<td>Response to &quot;Status&quot; is OTHER but &quot;Specify Status&quot; is missing.</td>
</tr>
<tr>
<td>Nov-02-2020 14:27:29 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 3: Closed</td>
<td>Close Auto Query</td>
</tr>
<tr>
<td>Nov-02-2020 14:26:42 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 3: Opened</td>
<td>Response to &quot;Status&quot; is OTHER but &quot;Specify Status&quot; is missing.</td>
</tr>
<tr>
<td>Nov-02-2020 14:26:42 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> OTHER</td>
<td>updated</td>
</tr>
<tr>
<td>Nov-01-2020 04:48:17 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Reissued:Opened</td>
<td>DM 1: There is no Adverse Event with 'Did the adverse event cause the subject to be discontinued from the study' reported as YES. Please recheck</td>
</tr>
<tr>
<td>Date/Time (Central Time (US &amp; Canada))</td>
<td>ACV0PFEINFP6000</td>
<td>Query</td>
<td>Notes</td>
<td></td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>-----------------</td>
<td>-------</td>
<td>-------</td>
<td></td>
</tr>
<tr>
<td>Oct-30-2020 15:25:34</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Answered</td>
<td>Per CRM, participant will remain in the study although he chooses to not receive the second vaccine.</td>
<td></td>
</tr>
<tr>
<td>Oct-30-2020 00:04:40</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Reissued:Opened</td>
<td>DM: Status is recorded as ADVERSE EVENT. However, Response to Did the adverse event cause the subject to be discontinued from the study? Is not recorded as YES on AE Log page. Please review and update. Else, clarify.</td>
<td></td>
</tr>
<tr>
<td>Oct-29-2020 14:22:20</td>
<td>auto query (autoquery)</td>
<td>Query 1: Closed</td>
<td>Close Auto Query</td>
<td></td>
</tr>
<tr>
<td>Oct-29-2020 14:20:43</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Answered</td>
<td>Participant is not discontinuing from study only from second vaccine. Please clarify if this should be answered dif.</td>
<td></td>
</tr>
<tr>
<td>Oct-29-2020 14:20:43</td>
<td>auto query (autoquery)</td>
<td>Query 2: Opened</td>
<td>Status is reported as Adverse Event, but there is no Adverse Event with 'Did the adverse event cause the subject to be discontinued from the study' reported as YES. Please check and correct the data.</td>
<td></td>
</tr>
<tr>
<td>Oct-29-2020 14:20:43</td>
<td>auto query (autoquery)</td>
<td>Query 1: Opened</td>
<td>Response to &quot;Status&quot; is ADVERSE EVENT but &quot;Specify Status&quot; is Provided.</td>
<td></td>
</tr>
</tbody>
</table>
**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site Name:** (1095) Tekton Research  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:39

### 4. Specify Status:

<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 14:20:43</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b), (4), (6)</td>
<td>Data Entry: updated, (b) (4), (b) (6)</td>
</tr>
<tr>
<td>Nov-02-2020 14:22:20</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b), (4), (6)</td>
<td>Data Entry: Participant is choosing to not receive 2nd vaccine, per CRM, participant is okay to continue in study</td>
</tr>
<tr>
<td>Oct-29-2020 14:20:43</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b), (4), (6)</td>
<td>Data Entry: updated</td>
</tr>
<tr>
<td>Oct-29-2020 14:20:43</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b), (4), (6)</td>
<td>Data Entry: Patient to continue without second vaccine</td>
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</tbody>
</table>
**Header Text:** c4591001  
**Visit:** Logs - Unscheduled  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1095  
**Subject No:** 10951173  
**Generated By:** (b) (4)  

**Form:** ADVERSE EVENT REPORT - Audit Trail  
**Form Status:**  
**Site Name:** (1095) Tekton Research  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:39

<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>Sep-22-2020 07:50:18 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Form Created</td>
<td></td>
</tr>
</tbody>
</table>
### Back to Form

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
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<tr>
<td>Oct-12-2020 13:28:34</td>
<td>(UTC-06:00) Central Time</td>
<td>ACV0PFEINFP6000</td>
<td>Form Deleted</td>
<td>New Information</td>
</tr>
<tr>
<td></td>
<td>(US &amp; Canada)</td>
<td>(b) (4)</td>
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</tr>
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<td>Oct-02-2020 07:52:31</td>
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</tr>
<tr>
<td></td>
<td>(US &amp; Canada)</td>
<td>(b) (4)</td>
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**Header Text:** c4591001  
**Visit:** Logs - Unscheduled  
**Form:** ADVERSE EVENT REPORT - Audit Trail  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1095  
**Subject No:** 10951173  
**Generated By:** (b) (4)  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:39

*** THIS REPEATING FORM HAS BEEN DELETED ***

---

**FDA-CBER-2021-5683-1022512**
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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>Nov-16-2020 18:10:45</td>
<td>(UTC-06:00) Central Time</td>
<td>ACV0PF61F6000</td>
<td>(b) (4)</td>
<td>Form Created</td>
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**Header Text:** c4591001
**Visit:** Logs - Unscheduled
**Form Version:** 22-Apr-2020 21:02
**Site No:** 1095
**Subject No:** 10951173
**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail
**Site Name:** (1095) Tekton Research
**Subject Initials:** ---
**Generated Time (GMT):** 29-Mar-2021 10:39
### 1. Category:

<table>
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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-22-2020 07:50:18 (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>

### 2. AE ID:

<table>
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<tr>
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<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-22-2020 07:50:18 (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>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-13-2020 17:33:39 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 4: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Oct-13-2020 15:16:05 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 4: Answered</td>
<td>Changed Information</td>
</tr>
<tr>
<td>Oct-13-2020 15:16:05 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> STEMI: ST elevation Myocardial Infarction</td>
<td>Changed Information</td>
</tr>
<tr>
<td>Oct-13-2020 10:41:15 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 4: Opened</td>
<td>CLINICAL recent SAE safety update changed the event term to STEMI; please harmonize the event term on the AE CRF</td>
</tr>
<tr>
<td>Date/Time</td>
<td>Event Description</td>
<td>Type</td>
<td>Operation</td>
<td>Result</td>
</tr>
<tr>
<td>---------------------</td>
<td>------------------------------------------------------------------------------------</td>
<td>------------</td>
<td>----------------------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>Sep-28-2020 05:01:12 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4)</td>
<td>Query 3: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Sep-26-2020 00:30:40 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000.InFormAdapter.Discrepancy</td>
<td>PFETMS Oracle (b) (4)</td>
<td>Query 2: Closed</td>
<td>Discrepancy has been closed.</td>
</tr>
<tr>
<td>Sep-25-2020 17:31:26 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 3: Answered</td>
<td>updated</td>
</tr>
<tr>
<td>Sep-25-2020 17:31:26 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 2: Answered</td>
<td>updated</td>
</tr>
<tr>
<td>Sep-25-2020 17:31:26 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Myocardial Infarction</td>
<td>updated</td>
</tr>
<tr>
<td>Sep-25-2020 07:17:22 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 3: Opened</td>
<td>SAE RECON:AER#2020365372,term was updated to MYOCARDIAL INFARCTION in Safety database while retained as 'Right sided coronary blockage resulting in Myocardial Infarction' in AE CRF. Please confirm. If safety update is required, please submit a follow-up form</td>
</tr>
<tr>
<td>Sep-24-2020 10:04:53 (UTC-06:00) Central Time</td>
<td>ACV0PFEINFP6000</td>
<td>Quan Jason Gong (b) (4)</td>
<td>Query 1: Closed</td>
<td>This will be addressed by the response to a separate query which requesting coronary blockage and MI to be listed as...</td>
</tr>
<tr>
<td>Date/Time</td>
<td>Event Description</td>
<td>Query Status</td>
<td>Query Text</td>
<td>Entry Status</td>
</tr>
<tr>
<td>------------------</td>
<td>-----------------------------------------------------------------------------------</td>
<td>--------------</td>
<td>---------------------------------------------------------------------------</td>
<td>----------------</td>
</tr>
<tr>
<td>Sep-24-2020 00:42:32 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000.InFormAdapter.Discrepancy</td>
<td>Query 2: Open</td>
<td>Multiple concepts in the term RIGHT SIDED CORONARY BLOCKAGE RESULTING IN MYOCARDIAL INFARCTION. Split the term into RIGHT SIDED CORONARY BLOCKAGE and MYOCARDIAL INFARCTION and submit separately. Thank you.</td>
<td>2 separate events.</td>
</tr>
<tr>
<td>Sep-23-2020 18:42:25 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Answered</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Sep-23-2020 18:42:25 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6) Data Entry: Right sided coronary blockage resulting in myocardial infarction</td>
<td>Data Entry:</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Sep-23-2020 15:14:10 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Quan Jason Gong (b) (4)</td>
<td>Query 1: Opened</td>
<td>GPDClin: The SAE reporting term &quot;right sided coronary blockage resulting in myocardial infarction (MI)&quot; includes 2 SAEs. Please add &quot;right sided coronary blockage&quot; as a separate SAE.</td>
</tr>
<tr>
<td>Sep-22-2020 11:26:09 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6) Data Entry: Myocardial Infarction</td>
<td>Data Entry:</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Sep-22-2020 11:24:23 (UTC-06:00)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6) Data Entry: Undiag</td>
<td>Data Entry:</td>
<td>Transcription Error</td>
</tr>
</tbody>
</table>
### 4. Start Date Time:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-11-2020 09:23:04</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Nov-10-2020 17:39:59</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Answered</td>
<td>Please unfreeze and query/date will be entered as 21SEP2020</td>
</tr>
<tr>
<td>Nov-10-2020 15:01:24</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Reissued: Opened</td>
<td>The status date on EOT should be the date when the subject was withdrawn from the treatment, therefore equal to or after the AE start date since drug was withdrawn due to this AE.</td>
</tr>
<tr>
<td>Nov-10-2020 13:40:34</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Answered</td>
<td>The date of completion is representing last treatment received. Please advise on how to enter this if this is incorrect. Participant received 1 injection and prior to vaccine 2 had an MI. Participant is choosing to not receive 2nd vaccine.</td>
</tr>
<tr>
<td>Date/Time</td>
<td>Event Description</td>
<td>Query ID</td>
<td>Query Description</td>
<td></td>
</tr>
<tr>
<td>-------------------------------</td>
<td>------------------------------------------------------------------------------------</td>
<td>----------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Nov-09-2020 05:40:41</td>
<td>ACV0PFEINFP6000.InFormAdapter.Discrepancy</td>
<td>DMW QUERY</td>
<td>Op: DMW5308222; The Latest Action to Study Treatment is DRUG WITHDRAWN, but the Start Date of this AE is AFTER the Date of Completion/Discontinuation/Death on Disposition-Treatment Form. Please review and update as appropriate.</td>
<td></td>
</tr>
<tr>
<td>Nov-02-2020 19:41:04</td>
<td>ACV0PFEINFP6000.InFormAdapter.Discrepancy</td>
<td>DMW QUERY</td>
<td>Closed: Auto closed by Validation Check: VC_AE001_33</td>
<td></td>
</tr>
<tr>
<td>Nov-02-2020 00:22:55</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Reissued: Opened: DM: Date of Completion/Discontinuation/Death (29/Aug/2020) on EOT is prior to AE start date (5/Sep/2020). Please review and update. Else, clarify.</td>
<td></td>
</tr>
<tr>
<td>Oct-30-2020 13:23:43</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Answered: Please clarify if you would like the date to be last date of vaccine (being vaccine 1) or date of second visit, although no vaccine took place. Please advise.</td>
<td></td>
</tr>
<tr>
<td>Oct-30-2020 02:41:01</td>
<td>ACV0PFEINFP6000.InFormAdapter.Discrepancy</td>
<td>DMW QUERY</td>
<td>Op: DMW5223299; The Latest Action to Study Treatment is DRUG WITHDRAWN, but the Start Date of this AE is AFTER the Date of Completion/Discontinuation/Death on Disposition-Treatment Form. Please review and update as appropriate.</td>
<td></td>
</tr>
<tr>
<td>Sep-22-2020 07:50:18</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Initial Entry</td>
<td></td>
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</table>
5. Is the adverse event still ongoing?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Sep-22-2020 11:31:16</td>
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<td>(b) (4), (6)</td>
<td>NO</td>
<td>New Information</td>
</tr>
<tr>
<td>Sep/9/2020</td>
<td></td>
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<td></td>
<td>End Date Time:</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time</td>
<td></td>
<td></td>
<td></td>
<td>Sep/9/2020 UNK:UNK</td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
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</tr>
<tr>
<td>Sep-22-2020 07:50:18</td>
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<td>YES</td>
<td>Initial Entry</td>
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<tr>
<td>(UTC-06:00) Central Time</td>
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<tr>
<td>(US &amp; Canada)</td>
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6. Toxicity Grade:

<table>
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<th>Date</th>
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<th>Reason</th>
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<tr>
<td>(US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

7. Is the adverse event serious?

*If Yes, NOTIFY PFIZER IMMEDIATELY.*

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
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<tr>
<td>Mar-04-2021 01:42:44</td>
<td>ACV0PFEINFP6000</td>
<td>Quan Jason Gong (4)</td>
<td>Query 5: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mar-03-2021 15:18:33</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 5: Answered</td>
<td>EDC updated, SAE will be updated and sent</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mar-03-2021 15:18:33</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
<td>YES</td>
<td>EDC updated, SAE will be updated and sent</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time</td>
<td></td>
<td></td>
<td></td>
<td>Is this serious event associated with congenital anomaly or birth defect?</td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did this serious event result in death?</td>
<td></td>
<td></td>
<td></td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>NO</td>
</tr>
<tr>
<td>Date</td>
<td>Time</td>
<td>Timezone</td>
<td>Event ID</td>
<td>Event Time</td>
</tr>
<tr>
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<td>----------------</td>
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<tr>
<td>Mar-02-2021 20:28:38</td>
<td>UTC-06:00 Central</td>
<td>ACV0PFEINFP6000</td>
<td>Quan Jason Gong</td>
<td>(b) (4)</td>
</tr>
<tr>
<td>Nov-10-2020 22:41:43</td>
<td>UTC-06:00 Central</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 3: Closed</td>
</tr>
<tr>
<td>Nov-10-2020 17:44:52</td>
<td>UTC-06:00 Central</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 3: Answered</td>
</tr>
<tr>
<td>Oct-30-2020 19:17:39</td>
<td>UTC-06:00 Central</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 3: Reissued:Opened</td>
</tr>
<tr>
<td>Date/Time</td>
<td>Event Type</td>
<td>Time Zone</td>
<td>Event Details</td>
<td>Notes</td>
</tr>
<tr>
<td>-------------------------</td>
<td>-------------------</td>
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<td>------------------------</td>
</tr>
<tr>
<td>Oct-30-2020 03:00:31</td>
<td>ACV0PF6000</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>COVID testing was performed (yes/no) and if yes, the results.</td>
<td></td>
</tr>
<tr>
<td>Oct-29-2020 14:23:42</td>
<td>ACV0PF6000</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>Query 4: Closed</td>
<td>Data amended</td>
</tr>
<tr>
<td>Oct-29-2020 14:23:42</td>
<td>auto query</td>
<td>(autoquery)</td>
<td>Query 4: Answered</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Oct-29-2020 14:23:42</td>
<td>auto query</td>
<td>(autoquery)</td>
<td>Query 3: Answered</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Oct-29-2020 14:23:42</td>
<td>ACV0PF6000</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>Data Entry: YES</td>
<td>Transcription Error</td>
</tr>
</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 disability/incapacity?  
NO

Is this serious event life threatening?  
NO

Other medically important serious event  
NO
<table>
<thead>
<tr>
<th>Date/Time</th>
<th>User</th>
<th>Query Type</th>
<th>Response Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-29-2020 13:31:46</td>
<td>ACV0PFEINFP6000</td>
<td>Query 4: Opened</td>
<td>Only the seriousness criteria &quot;Did this serious event require or prolong hospitalization?&quot; is answered, all other serious criterias are left blank. Please answer all seriousness criteria questions with &quot;Yes&quot; or &quot;No&quot; response. Thank you.</td>
</tr>
<tr>
<td>Oct-21-2020 10:26:18</td>
<td>ACV0PFEINFP6000</td>
<td>Query 3: Opened</td>
<td>Clinical COVID testing has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form [#2020365372] to provide whether COVID testing was performed (yes/no) and if yes, the results.</td>
</tr>
<tr>
<td>Sep-23-2020 02:48:50</td>
<td>ACV0PFEINFP6000</td>
<td>Query 2: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Sep-22-2020 20:37:09</td>
<td>ACV0PFEINFP6000</td>
<td>Query 1: Deleted</td>
<td>Close Auto Query</td>
</tr>
<tr>
<td>Sep-22-2020 11:27:25</td>
<td>ACV0PFEINFP6000</td>
<td>Query 2: Answered</td>
<td>updated</td>
</tr>
<tr>
<td>Sep-22-2020 11:26:43</td>
<td>ACV0PFEINFP6000</td>
<td>Data Entry:</td>
<td>Transcription Error</td>
</tr>
<tr>
<td></td>
<td></td>
<td>YES</td>
<td>Did this serious event require or prolong hospitalization?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>YES</td>
<td>Is this serious event life threatening?</td>
</tr>
</tbody>
</table>
7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-22-2020 11:25:14</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) YES</td>
<td>Transcription Error: Did this serious event require or prolong hospitalization? YES Is this serious event life threatening? YES</td>
</tr>
<tr>
<td>Sep-22-2020 11:24:23</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4) auto query</td>
<td>For AE Undiagnosed obstructive CAD causing Myocardial Infarction: Response to &quot;Is the adverse event serious?&quot; is 'Yes' but &quot;Serious Adverse Event Number&quot; is blank.</td>
</tr>
<tr>
<td>Sep-22-2020 07:50:18</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query</td>
<td>Is this adverse event serious? is reported 'Yes', but at least one seriousness criteria is missing. Please review and update as appropriate.</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>Data Entry</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-22-2020 07:50:18 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
<td>YES</td>
<td>Initial Entry</td>
<td></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>Oct-08-2020 21:57:54 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Katherine Puig</td>
<td>Query 1: Closed Captured under AE2</td>
<td></td>
</tr>
<tr>
<td>Oct-06-2020 08:16:40 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
<td>Query 1: Answered Please clarify - All data collected has been entered.</td>
<td></td>
</tr>
<tr>
<td>Oct-03-2020 01:25:19 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000.InFormAdapter.Discrepancy</td>
<td>PFE SDQ PROD</td>
<td>Query 1: Opened Please review &quot;If not related to study treatment other&quot; field, the following text was indicated in the comment field [Obstructive CAD]. Any</td>
<td></td>
</tr>
</tbody>
</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>
</thead>
<tbody>
<tr>
<td>Mar-12-2021</td>
<td>ACV0PFEINFP6000</td>
<td>auto query</td>
<td>Query 6: Answered</td>
<td>New Information</td>
</tr>
<tr>
<td>13:38:09 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td></td>
<td>(autoquery)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mar-12-2021</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NOT APPLICABLE</td>
<td>New Information</td>
</tr>
<tr>
<td>13:38:09 (UTC-06:00) Central</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
<td>Event Time (UTC)</td>
<td>Site No: 1095</td>
<td>Subject No: 10951173</td>
<td>Generated By: (b) (4)</td>
</tr>
<tr>
<td>------------------</td>
<td>-----------------</td>
<td>---------------</td>
<td>----------------------</td>
<td>----------------------</td>
</tr>
<tr>
<td>Mar-12-2021</td>
<td>02:49:39 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 6: Reissued:Opened</td>
</tr>
<tr>
<td>Mar-11-2021</td>
<td>08:09:43 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 6: Answered</td>
</tr>
<tr>
<td>Mar-11-2021</td>
<td>04:43:46 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 6: Opened</td>
</tr>
<tr>
<td>Nov-18-2020</td>
<td>13:01:12 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 4: Closed</td>
</tr>
<tr>
<td>Nov-18-2020</td>
<td>10:28:01 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 4: Answered</td>
</tr>
<tr>
<td>Nov-14-2020</td>
<td>09:36:33 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 4: Reissued:Opened</td>
</tr>
<tr>
<td>Nov-13-2020</td>
<td>16:38:48 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 4: Answered</td>
</tr>
<tr>
<td>Nov-13-2020</td>
<td>05:31:23 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 4: Reissued:Opened</td>
</tr>
</tbody>
</table>
### ADVERSE EVENT REPORT - eCRF Audit Trail History

<table>
<thead>
<tr>
<th>Date/Time</th>
<th>Action Taken</th>
<th>Query/Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-10-2020 13:36:07</td>
<td>Technically drug is not withdrawn, however participant is requesting to not receive. Per sponsor participant can continue in the study.</td>
<td>Query 4: Answered</td>
</tr>
<tr>
<td>Nov-10-2020 10:05:01</td>
<td>Response satisfies query</td>
<td>Query 5: Closed</td>
</tr>
<tr>
<td>Nov-04-2020 02:04:29</td>
<td>Clinical The reported action taken with study drug is withdrawn for AE (as reported under the AE); however End of Treatment does NOT state study drug was withdrawn for AE. Please review and harmonize the AE/Study drug reporting in AE/SAE/EOT</td>
<td>Query 5: Opened</td>
</tr>
<tr>
<td>Nov-04-2020 01:54:22</td>
<td>Clinical The reported action taken with study drug is withdrawn for AE (as reported under the AE); however End of Treatment does NOT state study drug was withdrawn for AE. Please review and harmonize the AE/Study drug reporting in AE/SAE/EOT</td>
<td>Query 5: Candidate</td>
</tr>
<tr>
<td>Oct-30-2020 06:40:33</td>
<td>SAE RECON:AER#2020365372, action taken was updated to DRUG WITHDRAWN in AE CRF while retained as Not applicable in Safety database. Please confirm if a follow up AEM form was sent to update action taken in Safety.</td>
<td>Query 4: Opened</td>
</tr>
<tr>
<td>Date/Time (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ID</td>
<td>Query &amp; Action</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>----</td>
<td>----------------</td>
</tr>
<tr>
<td>Oct-29-2020 14:23:07</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
</tr>
<tr>
<td>Oct-29-2020 14:23:07</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
</tr>
<tr>
<td>Oct-27-2020 09:23:46</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
</tr>
<tr>
<td>Oct-23-2020 18:12:34</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
</tr>
<tr>
<td>Oct-22-2020 12:10:12</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
</tr>
<tr>
<td>Oct-22-2020 12:09:24</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
</tr>
<tr>
<td>Oct-22-2020 12:04:16</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
</tr>
<tr>
<td>Oct-08-2020 10:59:24</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
</tr>
<tr>
<td>Oct-06-2020 08:14:57</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
</tr>
</tbody>
</table>

Please unfreeze and query

Response satisfies query

updated - participant will be given the option to move forward with second vaccine or discontinue vaccine. Attempts have been made to reach participant have
<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-06-2020 08:14:57 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NOT APPLICABLE</td>
<td>updated - participant will be given the option to move forward with second vaccine or discontinue vaccine. Attempts have been made to reach participant have been unsuccessful.</td>
</tr>
<tr>
<td>Sep-29-2020 09:50:40 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Opened</td>
<td>CLINQUERY If study drug is withdrawn for this AE, please complete the End of Treatment CRF</td>
</tr>
<tr>
<td>Sep-22-2020 07:50:18 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: DRUG WITHDRAWN</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

### 11. Was a Concomitant Medication given?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-22-2020 07:50:18 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: YES</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-22-2020 07:50:18 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: YES</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-22-2020 11:31:16 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Closed</td>
<td>Close Auto Query</td>
</tr>
<tr>
<td>Sep-22-2020 11:30:09 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Opened</td>
<td>For AE Myocardial Infarction: Response to &quot;What was the outcome of this adverse event?&quot; is 3 but End Date/Time is missing.</td>
</tr>
</tbody>
</table>
### 14. Did the adverse event cause the subject to be discontinued from the study?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-23-2020 10:15:05 (UTC-06:00 Central Time (US &amp; Canada))</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Sep-23-2020 08:58:34 (UTC-06:00 Central Time (US &amp; Canada))</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Answered</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Sep-23-2020 08:58:34 (UTC-06:00 Central Time (US &amp; Canada))</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Sep-23-2020 00:41:25 (UTC-06:00 Central Time (US &amp; Canada))</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Opened</td>
<td>DM: The response for &quot;Did the adverse event cause the subject to be discontinued from the study?&quot; is missing. Kindly review and update.</td>
</tr>
<tr>
<td>Date</td>
<td>Location</td>
<td>User</td>
<td>Value</td>
<td>Reason</td>
</tr>
<tr>
<td>---------------------</td>
<td>---------------------------</td>
<td>----------</td>
<td>---------------</td>
<td>----------------</td>
</tr>
<tr>
<td>Sep-22-2020 20:37:09</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINF6000</td>
<td>2020365372</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**Site Name:** (1095) Tekton Research

**Subject No:** 10951173

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

**Form Status:** Data Complete, Answered Queries

**Site No:** 1095

**Visit:** Logs - Unscheduled

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

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**FDA-CBER-2021-5683-1022531**
### 1. Category:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-02-2020 07:52:31</td>
<td>(UTC-06:00) Central Time</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: ADVERSE EVENT</td>
</tr>
<tr>
<td></td>
<td>(US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 2. AE ID:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-02-2020 07:52:31</td>
<td>(UTC-06:00) Central Time</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: 2</td>
</tr>
<tr>
<td></td>
<td>(US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 3. Adverse Event:

**(If possible specify diagnosis, not individual symptoms)**

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-11-2020 19:30:10</td>
<td>(UTC-06:00) Central Time</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4)</td>
<td>Query 1: Closed</td>
</tr>
<tr>
<td></td>
<td>(US &amp; Canada)</td>
<td></td>
<td>(6)</td>
<td></td>
</tr>
<tr>
<td>Oct-06-2020 14:02:54</td>
<td>(UTC-06:00) Central Time</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4)</td>
<td>Query 1: Answered</td>
</tr>
<tr>
<td></td>
<td>(US &amp; Canada)</td>
<td></td>
<td>(6)</td>
<td></td>
</tr>
<tr>
<td>Oct-05-2020 20:36:34</td>
<td>(UTC-06:00) Central Time</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4)</td>
<td>Query 1: Opened</td>
</tr>
<tr>
<td></td>
<td>(US &amp; Canada)</td>
<td></td>
<td>(6)</td>
<td></td>
</tr>
<tr>
<td>Oct-02-2020 07:52:31</td>
<td>(UTC-06:00) Central Time</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4)</td>
<td>Data Entry: Right sided coronary artery blockage</td>
</tr>
<tr>
<td></td>
<td>(US &amp; Canada)</td>
<td></td>
<td>(6)</td>
<td></td>
</tr>
</tbody>
</table>
### 4. Start Date Time:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-02-2020 07:52:31 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Sep/5/2020 UNK:UNK</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-02-2020 07:52:31 (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>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>End Date Time:  Sep/9/2020 UNK:UNK</td>
</tr>
</tbody>
</table>

### 6. Toxicity Grade:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-02-2020 07:52:31 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: 2</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

### 7. Is the adverse event serious?

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-12-2020 14:33:20 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Closed</td>
<td>Data was deleted.</td>
</tr>
<tr>
<td>Oct-12-2020 13:28:11 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Answered</td>
<td>will delete</td>
</tr>
<tr>
<td>Oct-07-2020 05:39:52 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Reissued:Opened</td>
<td>SAE RECON 1: The term in Safety database was updated to Myocardial Infarction which matches AE#1 hence,</td>
</tr>
</tbody>
</table>
right sided coronary artery blockage was not captured. If event should be added as separate AE in SDB, submit a follow up form.

<table>
<thead>
<tr>
<th>Date/Time</th>
<th>Query/Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-06-2020 16:57:46</td>
<td>An SAE has been submitted for this. If you are looking for something else, please clarify.</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td></td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
<td></td>
</tr>
<tr>
<td>ACV0PFEINFP6000</td>
<td></td>
</tr>
<tr>
<td>(b) (4), (b) (6)</td>
<td></td>
</tr>
<tr>
<td>Query 1: Answered</td>
<td></td>
</tr>
</tbody>
</table>

SAE RECON: Right sided coronary artery blockage (Onset date: 05Sep2020) is not reported to Safety database but marked serious on AE CRF. Please confirm if event should be added in SDB as separate SAE. If this event is not serious, downgrade the event on AE CRF

<table>
<thead>
<tr>
<th>Date/Time</th>
<th>Query/Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-03-2020 07:19:42</td>
<td>SAE RECON: Right sided coronary artery blockage (Onset date: 05Sep2020) is not reported to Safety database but marked serious on AE CRF. Please confirm if event should be added in SDB as separate SAE. If this event is not serious, downgrade the event on AE CRF</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td></td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
<td></td>
</tr>
<tr>
<td>ACV0PFEINFP6000</td>
<td></td>
</tr>
<tr>
<td>(b) (4), (b) (6)</td>
<td></td>
</tr>
<tr>
<td>Query 1: Opened</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date/Time</th>
<th>Query/Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-02-2020 09:50:51</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td></td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
<td></td>
</tr>
<tr>
<td>ACV0PFEINFP6000</td>
<td></td>
</tr>
<tr>
<td>(b) (4), (b) (6)</td>
<td></td>
</tr>
<tr>
<td>Query 2: Closed</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date/Time</th>
<th>Query/Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-02-2020 07:53:21</td>
<td>Prolonged hospitalization required is marked as YES</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td></td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
<td></td>
</tr>
<tr>
<td>ACV0PFEINFP6000</td>
<td></td>
</tr>
<tr>
<td>(b) (4), (b) (6)</td>
<td></td>
</tr>
<tr>
<td>Query 2: Answered</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date/Time</th>
<th>Query/Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-02-2020 07:52:31</td>
<td>Is this adverse event serious? 'Yes', but at least one seriousness criteria is missing. Please review and update as appropriate.</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td></td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
<td></td>
</tr>
<tr>
<td>ACV0PFEINFP6000</td>
<td></td>
</tr>
<tr>
<td>auto query (autoquery)</td>
<td></td>
</tr>
<tr>
<td>Query 2: Opened</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date/Time</th>
<th>Query/Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-02-2020 07:52:31</td>
<td>For AE Right sided coronary artery blockage: Response</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td></td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
<td></td>
</tr>
<tr>
<td>ACV0PFEINFP6000</td>
<td></td>
</tr>
<tr>
<td>auto query (autoquery)</td>
<td></td>
</tr>
<tr>
<td>Query 1: Candidate</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>Oct-02-2020 07:52:31 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> YES</td>
<td><strong>Reason:</strong> Initial Entry</td>
</tr>
</tbody>
</table>

#### Data Entry:
Did this serious event require or prolong hospitalization?

- **YES**

**Initial Entry**

---

### 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>Oct-02-2020 07:52:31 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> NOT RELATED</td>
<td><strong>Reason:</strong> Initial Entry</td>
</tr>
</tbody>
</table>

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

- **OTHER**
  - *If Other, specify:*
    - CAD

**Initial Entry**

---

### 10. Latest Action Taken with Study Treatment:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-06-2020 16:27:57 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Hayley Wyper (b) (4)</td>
<td>Query 1: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Oct-06-2020 14:01:46 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Answered</td>
<td>Transcription Error</td>
</tr>
</tbody>
</table>

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***THIS REPEATING FORM HAS BEEN DELETED***

to "Is the adverse event serious?" is *Yes* but "Serious Adverse Event Number" is blank.
11. Was a Concomitant Medication given?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-02-2020 07:52:31 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: YES</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

12. Was a Non-Drug Treatment given?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-02-2020 07:52:31 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: YES</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-02-2020 07:52:31 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: RECOVERED/RESOLVED</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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>Oct-02-2020 07:52:31 (UTC-06:00) Central Time</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>Date</td>
<td>Location</td>
<td>User</td>
<td>Value</td>
<td>Reason</td>
</tr>
<tr>
<td>----------------------</td>
<td>---------------------------------</td>
<td>------------</td>
<td>----------------</td>
<td>----------------------------</td>
</tr>
<tr>
<td>Nov-16-2020 18:10:45 (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>
</tr>
</tbody>
</table>

2. AE ID:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-16-2020 18:10:45 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>3</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-16-2020 18:10:45 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
<td><strong>Data Entry:</strong> Coronary Artery Disease</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

4. Start Date Time:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-16-2020 18:10:45 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
<td><strong>Data Entry:</strong> Sep/5/2020 UNK:UNK</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

5. Is the adverse event still ongoing?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
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<tbody>
<tr>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
<td><strong>Data Entry:</strong> YES</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

6. Toxicity Grade:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-16-2020 18:10:45 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
<td><strong>Data Entry:</strong> 2</td>
<td>Initial Entry</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).

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<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-16-2020 18:10:45</td>
<td></td>
<td>(b)</td>
<td>NO</td>
<td>Initial Entry</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>Nov-16-2020 18:10:45</td>
<td></td>
<td>(b)</td>
<td>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>Nov-16-2020 18:10:45</td>
<td></td>
<td>(b)</td>
<td>NOT RELATED</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

   OTHER

   *If Other, specify:*

   CAD

10. Latest Action Taken with Study Treatment:

<table>
<thead>
<tr>
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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
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11. Was a Concomitant Medication given?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mar-09-2021 11:18:14</td>
<td></td>
<td>Quan Jason</td>
<td>Query 1: Closed</td>
<td>Response satisfies</td>
</tr>
<tr>
<td>Date</td>
<td>Location</td>
<td>User</td>
<td>Value</td>
<td>Reason</td>
</tr>
<tr>
<td>------------------------</td>
<td>---------------------</td>
<td>-----------</td>
<td>----------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>Nov-16-2020 18:10:45</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4),</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td></td>
<td>(b) (6)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

12. Was a Non-Drug Treatment given?

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<tr>
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<th>User</th>
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<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-16-2020 18:10:45</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4),</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td></td>
<td>(b) (6)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-16-2020 18:10:45</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4),</td>
<td>Data Entry: NOT RECOVERED/NOT RESOLVED</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td></td>
<td>(b) (6)</td>
<td></td>
<td></td>
</tr>
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</table>

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>Nov-16-2020 18:10:45</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4),</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td></td>
<td>(b) (6)</td>
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**Header Text:**
c4591001

**Visit:** Logs - Unscheduled

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

**Form Status:**

**Site No:** 1095

**Site Name:** (1095) Tekton Research

**Subject No:** 10951173

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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<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>Nov-11-2020 09:46:58 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4)</td>
<td>Form Created</td>
<td>(b) (6)</td>
</tr>
</tbody>
</table>
### 1. What is the medication identifier?

<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>Nov-11-2020 09:46:58 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINF6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> Data Entry: Initial Entry</td>
<td></td>
</tr>
</tbody>
</table>

### 2. Category:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-11-2020 09:46:58 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINF6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> VACCINATIONS Initial Entry</td>
<td></td>
</tr>
</tbody>
</table>

### 3. Concomitant Medications Pre-specified:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-11-2020 09:46:58 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINF6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> NO Initial Entry</td>
<td></td>
</tr>
</tbody>
</table>

### 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).*

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-12-2020 01:04:12 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINF6000.InFormAdapter.Discrepancy</td>
<td>PFETMS Oracle (b) (4)</td>
<td>Query 1: Closed Discrepancy has been closed.</td>
<td></td>
</tr>
<tr>
<td>Nov-11-2020 15:04:30 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINF6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Answered Transcription Error</td>
<td></td>
</tr>
<tr>
<td>Nov-11-2020 15:04:30 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINF6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Influenza vaccine 1 dose IM once f or influenza prev ention Transcription Error</td>
<td></td>
</tr>
</tbody>
</table>
Clarify INFLUENZA VACCINE 1 DOSE UN ONCE FOR INFLUENZA PREVENTION as follows: Please spell out the abbreviation UN. If reporting INFLUENZA VACCINE 1 DOSE IN ONCE FOR INFLUENZA PREVENTION update the verbatim term as such. Otherwise clarify and update the term as appropriate or provide reference/label. Thank you.

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-11-2020 09:46:58 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
<td>Influenza vaccine 1 dose UN once for influenza prevention</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

### 5. Date:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-11-2020 09:46:58 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
<td>Data Entry: Oct/28/2020</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>
### 1. Date of Visit

<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>
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<td>(b), (4), (6)</td>
<td>Data Entry: Feb/4/2021</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

**User:** ACV0PFEINFP6000

**Reason:** Initial Entry
### 1. Date:

<table>
<thead>
<tr>
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<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Feb-25-2021 16:40:04 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
<td>Data Entry: Feb/4/2021</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

### 2.a

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
<td>Data Entry: Record Identifier: 1, Temperature: 98.0, Temperature Unit: F, Temperature Location: ORAL CAVI</td>
<td>Initial Entry</td>
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#### 2.a Record Identifier:

<table>
<thead>
<tr>
<th>Date</th>
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<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-25-2021 16:40:04 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
<td>Data Entry: 1</td>
<td>Initial Entry</td>
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</table>

#### 2.a Temperature:

<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-25-2021 16:40:04 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
<td>Data Entry: 98.0</td>
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#### 2.a Unit:

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<th>Value</th>
<th>Reason</th>
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<tbody>
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<td>Feb-25-2021 16:40:04 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
<td>Data Entry: F</td>
<td>Initial Entry</td>
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</table>

#### 2.a Temperature Location:

<table>
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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Date</td>
<td>Time</td>
<td>ACV0PFEINFP6000</td>
<td>Data Entry</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>--------------</td>
<td>----------------</td>
<td>-----------------</td>
<td>------------</td>
<td>---------------</td>
</tr>
<tr>
<td>Feb-25-2021</td>
<td>16:40:04</td>
<td>(b) (4)</td>
<td>ORAL CAVITY</td>
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Header Text: c4591001
Visit: Unplanned Vaccination - Unscheduled
Form Version: 20-Feb-2021 02:16
Site No: 1095
Subject No: 10951173
Generated By: (b) (4)
Form: VITAL SIGNS - TEMP - eCRF Audit Trail History
Form Status: Data Complete, Frozen, Verified
Site Name: (1095) Tekton Research
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 10:39

ACV0PFEINFP6000

ORAL CAVITY

Initial Entry

FDA-CBER-2021-5683-1022546
### 1. Was there a temporary delay of vaccination?

<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-25-2021 16:41:46 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
<td>Data Entry: YES</td>
<td>Initial Entry</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Date of First Delay:</td>
<td>Oct/12/2020</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Reason(s) for Temporary Delay of Vaccination</td>
<td>FEVER OR ACUTE ILLNESS</td>
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</table>

### 2. Treatment Name

<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-25-2021 16:41:46 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: BLINDED THERAPY</td>
<td>Initial Entry</td>
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</table>

### 3. Formulation:

<table>
<thead>
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<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Feb-25-2021 16:41:46 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: INJECTION</td>
<td>Initial Entry</td>
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</table>

### 4. Dose Date Time:

<table>
<thead>
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<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Feb-25-2021 16:41:46 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
<td>Data Entry: Feb/4/2021 11:01</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

### 5. Anatomical Location:

<table>
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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
<tr>
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<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: DELTOID MUSCLE</td>
<td>Initial Entry</td>
</tr>
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</table>

### 6. Body Side:

---
### Date

<table>
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<th>Location</th>
<th>User</th>
<th>Value</th>
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<tbody>
<tr>
<td>Feb-25-2021 16:41:46</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4)</td>
<td>Data Entry: LEFT</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time</td>
<td>(US &amp; Canada)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
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<td></td>
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</tr>
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</table>

### 7. Route:

<table>
<thead>
<tr>
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<th>Location</th>
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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Feb-25-2021 16:41:46</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td>Data Entry: INTRAMUSCULAR</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>( UTC-06:00) Central Time</td>
<td>(US &amp; Canada)</td>
<td>(autocalc)</td>
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<tr>
<td>(US &amp; Canada)</td>
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### 10. Timeframe Subject Was Observed

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
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<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Feb-25-2021 16:41:46</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td>Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time</td>
<td>(US &amp; Canada)</td>
<td>(autocalc)</td>
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<tr>
<td>(US &amp; Canada)</td>
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</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Feb-25-2021 16:41:46</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4)</td>
<td>Data Entry: YES</td>
<td>Initial Entry</td>
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<tr>
<td>(UTC-06:00) Central Time</td>
<td>(US &amp; Canada)</td>
<td>(b) (6)</td>
<td></td>
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<tr>
<td>(US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
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</tr>
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</table>
### 1. Date of Visit

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Mar-02-2021 23:13:58</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Closed</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Mar-02-2021 15:57:08</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Answered</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>uploaded consent with coordinator signature.</td>
</tr>
<tr>
<td>Feb-24-2021 20:06:18</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Opened</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Person obtaining consent signature is not on ICF V6.0, instead the subject signed. It is either because Pg 20 not uploaded properly or subjects signed. Please re-upload or correct the error, thanks</td>
</tr>
<tr>
<td>Feb-02-2021 17:11:12</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Feb/2/2021</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td>Initial Entry</td>
</tr>
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</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>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-08-2021 10:52:27 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b)</td>
<td>Data Entry: Participant is willing to return for Vaccination 3</td>
<td>Transcription Error</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(4),</td>
<td>Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(b)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(6)</td>
<td></td>
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<tr>
<td>Feb-02-2021 17:11:31 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b)</td>
<td>Data Entry: Participant is willing to return for Vaccination 3</td>
<td>Initial Entry</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(4),</td>
<td>Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(b)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(6)</td>
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<td></td>
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</table>
### 1. Date Treatment Unblinded:

<table>
<thead>
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<th>Date</th>
<th>Location</th>
<th>User</th>
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<th>Reason</th>
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<tbody>
<tr>
<td>Feb-02-2021 17:11:04</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Feb/2/2021 Initial Entry</td>
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### 2. Primary Reason for Unblinding:

<table>
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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Feb-02-2021 17:11:04</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION Initial Entry</td>
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</table>
## Date of Visit

<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>Mar-04-2021 02:50:14 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Mar-03-2021 14:20:26 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Answered</td>
<td>This has been added</td>
</tr>
<tr>
<td>Feb-26-2021 05:38:47 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Reissued:Opened</td>
<td>DM: REVAX IE form has been unfrozen. Please update.</td>
</tr>
<tr>
<td>Feb-25-2021 14:44:03 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Answered</td>
<td>unfreeze &amp; query please.</td>
</tr>
<tr>
<td>Feb-25-2021 05:28:38 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Reissued:Opened</td>
<td>DM2: Thank you for response. Kindly confirm if visit is erroneous visit if yes add form level comment as Not Applicable on REVAX IE form of this visit by referring CCG section 4.10. Else clarify.</td>
</tr>
<tr>
<td>Feb-24-2021 10:54:52 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Answered</td>
<td>data updated</td>
</tr>
<tr>
<td>Feb-10-2021 03:58:56 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Reissued:Opened</td>
<td>DM1: Thank you for your reply. However, form level comment is not present on rest for forms. Kindly consider to add form level comment by selecting Not Done or Not Applicable option on rest of</td>
</tr>
</tbody>
</table>
### 2. Erroneous Visit

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Feb-08-2021 10:52:54</td>
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<td>(b)</td>
<td>(4), (b) (6)</td>
<td>Data Entry: ERRONEOUS VISIT</td>
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<tr>
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<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>(b)</td>
<td>(4), (b) (6)</td>
<td>Data Entry: Feb/4/2021</td>
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4. If no sample was collected or sample was not collected according to protocol, please provide reason:

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`Sample Collected?` is Yes, however no barcodes are entered. Please review and correct as appropriate.
1. Data Origin

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3. Sample Collected?

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**Visit:** V101_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF

**Audit Trail History**

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

**Site No:** 1095

**Subject No:** 10951173

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

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4. If no sample was collected or sample was not collected according to protocol, please provide reason:

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Page 213 of 220
### 1. Was there a temporary delay of vaccination?

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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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Page 219 of 220
### 1. Casebook Signature

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**Form Version:** 22-Apr-2020 21:04

**Site No:** 1095

**Subject No:** 10951173

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

**Site Name:** (1095) Tekton Research

**Subject Initials:** ---

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