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

DO NOT USE THE OPTIONS STAGE 1 NONSENTELN and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.
**Header Text:** c45911001
**Visit:** COHORT_SELECTION
**Form Version:** 22-Apr-2020 21:02
**Site No:** 1083
**Subject No:** 10831194
**Generated By:** (b) (4)

**Form:** MAIN INFORMED CONSENT
**Form Status:** Data Complete, Locked, Frozen, Verified
**Site Name:** (1083) Benchmark Research
**Subject Initials:** ---
**Generated Time (GMT):** 29-Mar-2021 10:11

### eCRF Audit Trail History

#### Informed Consent

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<tr>
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<th>Consent Was:</th>
<th>Date Written Consent Obtained</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>OBTAINED</td>
<td>Sep/4/2020</td>
</tr>
</tbody>
</table>
### Demography

<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>1.</td>
<td>Subject ID</td>
</tr>
<tr>
<td>2.</td>
<td>Birth Date:</td>
</tr>
<tr>
<td>3.</td>
<td>Sex:</td>
</tr>
<tr>
<td>4.</td>
<td>Ethnicity:</td>
</tr>
<tr>
<td>5.</td>
<td>Race: (Check X all that apply):</td>
</tr>
<tr>
<td>6.</td>
<td>Racial Designation:</td>
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</table>
## eCRF Audit Trail History

<table>
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<th>Date of Visit</th>
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</thead>
<tbody>
<tr>
<td>1. Date of Visit</td>
<td>Sep/4/2020</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>
<th></th>
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</thead>
<tbody>
<tr>
<td>1. Date of Completion/Discontinuation/Death</td>
<td>Sep/4/2020</td>
</tr>
<tr>
<td>2. Phase of Disposition:</td>
<td>SCREENING</td>
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<tr>
<td>3. Status:</td>
<td>COMPLETED</td>
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<td>4. Specify Status:</td>
<td>[ ]</td>
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<tr>
<td>Line/MH Number</td>
<td>Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies</td>
</tr>
<tr>
<td>---------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>1.a</td>
<td>[Allergic Rhinitis-Seasonal]</td>
</tr>
<tr>
<td>1.b</td>
<td>[Obesity]</td>
</tr>
<tr>
<td>1.c</td>
<td>[Hypertension]</td>
</tr>
<tr>
<td>1.d</td>
<td>[Sleep Apnea]</td>
</tr>
<tr>
<td>Vital Signs</td>
<td></td>
</tr>
<tr>
<td>---------------------</td>
<td>------------</td>
</tr>
<tr>
<td>Date:</td>
<td>Sep/4/2020</td>
</tr>
<tr>
<td>Weight:</td>
<td>[273.2]</td>
</tr>
<tr>
<td>Unit:</td>
<td>LB</td>
</tr>
<tr>
<td>Height:</td>
<td>[72.5]</td>
</tr>
<tr>
<td>Unit:</td>
<td>in</td>
</tr>
<tr>
<td>Body Mass Index:</td>
<td>[36.5]</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Vital Signs Details</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Record Identifier:</td>
<td>1</td>
</tr>
<tr>
<td>Temperature:</td>
<td>[98.1]</td>
</tr>
<tr>
<td>Unit:</td>
<td>F</td>
</tr>
<tr>
<td>Temperature Location:</td>
<td>ORAL CA VITY</td>
</tr>
<tr>
<td>Disposition</td>
<td></td>
</tr>
<tr>
<td>-------------------</td>
<td>---------</td>
</tr>
<tr>
<td>1. Randomization Date :</td>
<td>Sep/4/2020</td>
</tr>
<tr>
<td>2. Randomization Number:</td>
<td>[81918]</td>
</tr>
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<td>3. Randomization Group:</td>
<td>[ ]</td>
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Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1083
Subject No: 10831194
Generated By: (b) (4)
Form: RANDOMIZATION
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1083) Benchmark Research
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 10:11
**eCRF Audit Trail History**

**Electronic Sample Tracking**

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<tbody>
<tr>
<td>1.</td>
<td>Data Origin</td>
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<tr>
<td>2.</td>
<td>Sample Type</td>
<td>SERUM</td>
</tr>
<tr>
<td>3.</td>
<td>Sample Collected?</td>
<td>YES</td>
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<tr>
<td></td>
<td>Date of Collection:</td>
<td>Sep/4/2020</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>
<td>[ ]</td>
</tr>
</tbody>
</table>

**Aliquot**

Please enter barcode for each aliquot.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>5.a</td>
<td>Sample ID</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td><strong>1.</strong> Data Origin</td>
<td>SITE</td>
</tr>
<tr>
<td><strong>2.</strong> Sample Type</td>
<td>NASAL_SWAB</td>
</tr>
<tr>
<td><strong>3.</strong> Sample Collected?</td>
<td>YES</td>
</tr>
<tr>
<td>Date of Collection:</td>
<td>Sep/4/2020</td>
</tr>
<tr>
<td><strong>4.</strong> If no sample was collected or sample was not collected according to protocol, please provide reason:</td>
<td>[]</td>
</tr>
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</table>

**Aliquot**

Please enter barcode for each aliquot.

<p>| | |</p>
<table>
<thead>
<tr>
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<th></th>
</tr>
</thead>
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<tr>
<td><strong>5.a</strong> Sample ID</td>
<td>[BPZ1N8]</td>
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</table>
### eCRF Audit Trail History

#### Vaccination

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

1. Select appropriate response - Reactogenicity diary collection
   - NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
Date of Visit

1. Date of Visit Sep/23/2020
2. Erroneous Visit

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

**Vital Signs**

<table>
<thead>
<tr>
<th>Date</th>
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</thead>
<tbody>
<tr>
<td>Sep/23/2020</td>
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**Vital Signs Details**

<table>
<thead>
<tr>
<th>Record Identifier</th>
<th>Temperature</th>
<th>Unit</th>
<th>Temperature Location</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>[97.9]</td>
<td>F</td>
<td>ORAL CA VITY</td>
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<tr>
<td>Data Origin</td>
<td>SITE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sample Type</td>
<td>NASAL_SWAB</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sample Collected?</td>
<td>YES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date of Collection:</td>
<td>Sep/23/2020</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If no sample was collected or sample was not collected according to protocol, please provide reason:</td>
<td>[]</td>
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</tr>
</tbody>
</table>

### Aliquot

Please enter barcode for each aliquot.

<table>
<thead>
<tr>
<th>Sample ID</th>
<th>[BLCJWJ]</th>
</tr>
</thead>
</table>
**Vaccination**

1. Was there a temporary delay of vaccination? | NO
2. Treatment Name | [BLINDED THERAPY]
3. Formulation: | INJECTION
4. Dose Date Time: | Sep/23/2020 14:51
5. Anatomical Location: | DELTOID MUSCLE
6. Body Side: | LEFT
7. Route: | INTRAMUSCULAR
8. Actual Dose: | [ ]
9. Unit: |
10. Timeframe Subject Was Observed | THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11. Was the subject observed for at least the protocol specified observation period after investigational product administration? | YES
## eCRF Audit Trail History

<table>
<thead>
<tr>
<th>Date of Visit</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Visit</td>
<td>Oct/22/2020</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
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</tr>
</tbody>
</table>
### eCRF Audit Trail History

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

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

### COVID-19 Illness Visit

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

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

### Symptoms

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

### Symptoms - Other

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>5.</td>
<td>Symptoms - Other Text: [ ]</td>
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</table>
### Electronic Sample Tracking

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

Please enter barcode for each aliquot.

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<table>
<thead>
<tr>
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<tr>
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<td>Electronic Sample Tracking</td>
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<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>
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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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<tr>
<td>5. Sample ID [ ]</td>
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**Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB**

**Site No:** 1083
**Subject No:** 10831194
**Generated By:** (b) (4)

---

**Visit:** POT_COVID_ILL - New Unscheduled Visit
**Form Version:** 22-Apr-2020 21:03
**Form Status:** Not Started
**Site Name:** (1083) Benchmark Research
**Subject Initials:** ---
**Generated Time (GMT):** 29-Mar-2021 10:11

---

**FDA-CBER-2021-5683-0960837**

---

090177e196ae3f98\Final\Final On: 01-Apr-2021 05:19 (GMT)
### Health Care Utilization

1. **Physician or Healthcare Professional:**
   - Occurrence of Visits or Contacts:

### Health Care Utilization Other

2. **Other Type of Practitioner Specify:** [ ]

### Health Care Utilization

3. **Has the subject been hospitalized due to potential COVID-19 illness?**
<table>
<thead>
<tr>
<th>Illness Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Category of Clinical Event:</td>
</tr>
<tr>
<td>2. Was a diagnosis obtained for Potential COVID-19 Illness?</td>
</tr>
<tr>
<td>3. Toxicity Grade:</td>
</tr>
<tr>
<td>Date of Visit</td>
</tr>
<tr>
<td>---------------</td>
</tr>
<tr>
<td>1. Date of Visit</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
</tr>
<tr>
<td>COVID-19 Illness Visit</td>
</tr>
<tr>
<td>3. COVID-19 Illness Visit:</td>
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<tr>
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</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td><strong>Electronic Sample Tracking</strong></td>
</tr>
<tr>
<td>1.</td>
</tr>
<tr>
<td>2.</td>
</tr>
<tr>
<td>3.</td>
</tr>
<tr>
<td>4.</td>
</tr>
<tr>
<td><strong>Aliquot</strong></td>
</tr>
<tr>
<td>Please enter barcode for each aliquot.</td>
</tr>
<tr>
<td>5.</td>
</tr>
<tr>
<td>Date of Visit</td>
</tr>
<tr>
<td>--------------------</td>
</tr>
<tr>
<td>1. Date of Visit</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
</tr>
</tbody>
</table>
Unplanned Assessments

1. Assessments
**Disposition - Treatment**

<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>1.</td>
<td>Date of Completion/Discontinuation/Death:</td>
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<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>
### Disposition - Follow-Up

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<thead>
<tr>
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<tbody>
<tr>
<td>1.</td>
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<tr>
<td>2.</td>
<td>Phase of Disposition:</td>
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<td>3.</td>
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<tr>
<td>4.</td>
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<td>[ ]</td>
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**Site No:** 1083  
**Site Name:** (1083) Benchmark Research  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:11
<table>
<thead>
<tr>
<th>Date of Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Visit //</td>
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<tr>
<td>2. Erroneous Visit</td>
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</table>

### COVID-19 Repeat Swab

<table>
<thead>
<tr>
<th>3. COVID-19 Repeat Swab:</th>
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FDA-CBER-2021-5683-0960846

Page 32 of 162
### Electronic Sample Tracking

<p>| | |</p>
<table>
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<tr>
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<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.

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<table>
<thead>
<tr>
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</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>2.</td>
<td>ADVERSE EVENT</td>
</tr>
<tr>
<td>3.</td>
<td>ADVERSE EVENT</td>
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<td>4.</td>
<td>ADVERSE EVENT</td>
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</table>
### Adverse Event Report

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<table>
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<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>1.</td>
<td>Category: ADVERSE EVENT</td>
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<tr>
<td>2.</td>
<td>AE ID: [1]</td>
</tr>
<tr>
<td>3.</td>
<td>Adverse Event: (If possible specify diagnosis, not individual symptoms) [New Onset Atrial Fibrillation with rapid ventricular response]</td>
</tr>
<tr>
<td>4.</td>
<td>Start Date Time: Oct/26/2020 00:00</td>
</tr>
<tr>
<td>5.</td>
<td>Is the adverse event still ongoing? YES</td>
</tr>
<tr>
<td>6.</td>
<td>Toxicity Grade: 2</td>
</tr>
<tr>
<td>7.</td>
<td>Is the adverse event serious? YES</td>
</tr>
<tr>
<td></td>
<td>Is this serious event associated with congenital anomaly or birth defect? NO</td>
</tr>
<tr>
<td></td>
<td>Did this serious event result in death? NO</td>
</tr>
<tr>
<td></td>
<td>Did this serious event require or prolong hospitalization? YES</td>
</tr>
<tr>
<td></td>
<td>Did this serious event result in persistent or significant disability/incapacity? NO</td>
</tr>
<tr>
<td></td>
<td>Is this serious event life threatening? NO</td>
</tr>
<tr>
<td></td>
<td>Other medically important serious event NO</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>Question</td>
<td>Answer</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td>9. Is this event related to study treatment?</td>
<td>NOT RELATED</td>
</tr>
<tr>
<td>If Not Related to study treatment(s), this event is due to:</td>
<td>OTHER</td>
</tr>
<tr>
<td>If Other, specify:</td>
<td>[Arrhythmia]</td>
</tr>
<tr>
<td>10. Latest Action Taken with Study Treatment:</td>
<td>NOT APPLICABLE</td>
</tr>
<tr>
<td>11. Was a Concomitant Medication given?</td>
<td>YES</td>
</tr>
<tr>
<td>12. Was a Non-Drug Treatment given?</td>
<td>NO</td>
</tr>
<tr>
<td>13. What was the outcome of this adverse event?:</td>
<td>RECOVERING/RESOLVING</td>
</tr>
<tr>
<td>14. Did the adverse event cause the subject to be discontinued from the study?</td>
<td>NO</td>
</tr>
<tr>
<td>15. Serious Adverse Event Number: For Pfizer Use Only</td>
<td>[2020427451]</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) [Chest Pain]
4. Start Date Time: Oct/26/2020 00:00
5. Is the adverse event still ongoing? NO
   End Date Time: Oct/28/2020 00:00
6. Toxicity Grade: 2
7. Is the adverse event serious? NO
   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).
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: [Arrhythmia]
<table>
<thead>
<tr>
<th></th>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.</td>
<td>Latest Action Taken with Study Treatment:</td>
<td>NOT APPLICABLE</td>
</tr>
<tr>
<td>11.</td>
<td>Was a Concomitant Medication given?</td>
<td>YES</td>
</tr>
<tr>
<td>12.</td>
<td>Was a Non-Drug Treatment given?</td>
<td>NO</td>
</tr>
<tr>
<td>13.</td>
<td>What was the outcome of this adverse event?</td>
<td>RECOVERED/RESOLVED</td>
</tr>
<tr>
<td>14.</td>
<td>Did the adverse event cause the subject to be discontinued from the study?</td>
<td>NO</td>
</tr>
<tr>
<td>15.</td>
<td>Serious Adverse Event Number: For Pfizer Use Only</td>
<td>[ ]</td>
</tr>
</tbody>
</table>
### Adverse Event Report

1. **Category:** ADVERSE EVENT
2. **AE ID:** [3]
3. **Adverse Event:**
   - (If possible specify diagnosis, not individual symptoms)
   - [Heart Palpitations]
4. **Start Date Time:** Oct/26/2020 00:20
5. **Is the adverse event still ongoing?**
   - NO
   - **End Date Time:** Oct/28/2020 00:00
6. **Toxicity Grade:** 2
7. **Is the adverse event serious?**
   - NO
   - 
   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).
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:
       - [Arrhythmia]
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>10. Latest Action Taken with Study Treatment:</strong></td>
<td>NOT APPLICABLE</td>
</tr>
<tr>
<td><strong>11. Was a Concomitant Medication given?</strong></td>
<td>YES</td>
</tr>
<tr>
<td><strong>12. Was a Non-Drug Treatment given?</strong></td>
<td>NO</td>
</tr>
<tr>
<td><strong>13. What was the outcome of this adverse event?</strong></td>
<td>RECOVERED/RESOLVED</td>
</tr>
<tr>
<td><strong>14. Did the adverse event cause the subject to be discontinued from the study?</strong></td>
<td>NO</td>
</tr>
<tr>
<td><strong>15. Serious Adverse Event Number:</strong> For Pfizer Use Only</td>
<td>[]</td>
</tr>
</tbody>
</table>
Adverse Event Report

1. Category: ADVERSE EVENT
2. AE ID: [4]
3. Adverse Event: (If possible specify diagnosis, not individual symptoms) [Trivial Mitral Regurgitation]
4. Start Date Time: Oct/26/2020 00:00
5. Is the adverse event still ongoing? YES
6. Toxicity Grade: 1
7. Is the adverse event serious?
   If Yes, NOTIFY PFIZER IMMEDIATELY. NO
   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).
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: [Heart Disease]
10. Latest Action Taken with Study Treatment: NOT APPLICABLE
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>11.</td>
<td>Was a Concomitant Medication given?</td>
</tr>
<tr>
<td>12.</td>
<td>Was a Non-Drug Treatment given?</td>
</tr>
<tr>
<td>13.</td>
<td>What was the outcome of this adverse event?:</td>
</tr>
<tr>
<td>14.</td>
<td>Did the adverse event cause the subject to be discontinued from the study?</td>
</tr>
<tr>
<td>15.</td>
<td>Serious Adverse Event Number: For Pfizer Use Only</td>
</tr>
<tr>
<td>#</td>
<td>Category</td>
</tr>
<tr>
<td>---</td>
<td>----------</td>
</tr>
<tr>
<td>1.</td>
<td></td>
</tr>
</tbody>
</table>

---

FDA-CBER-2021-5683-0960857
## Medication Error

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Category:</td>
</tr>
<tr>
<td>2.</td>
<td>Medication Error (Type of Medication Error): [ ]</td>
</tr>
<tr>
<td>3.</td>
<td>Start Date: //</td>
</tr>
<tr>
<td>4.</td>
<td>Is the medication error still ongoing?</td>
</tr>
<tr>
<td>5.</td>
<td>Latest Action Taken with Study Treatment:</td>
</tr>
<tr>
<td>6.</td>
<td>Was a Concomitant Medication given?</td>
</tr>
<tr>
<td>7.</td>
<td>Was a Non-Drug Treatment given?</td>
</tr>
<tr>
<td>8.</td>
<td>Did the Medication Error cause the subject to be discontinued from the study?</td>
</tr>
<tr>
<td>9.</td>
<td>Was this medication error associated with any adverse events?</td>
</tr>
<tr>
<td>10.</td>
<td>Serious Adverse Event Number: For Pfizer Use Only [ ]</td>
</tr>
<tr>
<td>#</td>
<td>Sponsor-Defined Identifier</td>
</tr>
<tr>
<td>----</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>1.</td>
<td></td>
</tr>
</tbody>
</table>

**Header Text:** c4591001  
**Visit:** Logs  
**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1083  
**Site Name:** (1083) Benchmark Research  
**Subject No:** 10831194  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:11
<table>
<thead>
<tr>
<th></th>
<th>Concomitant Medications</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>What is the medication identifier?</td>
</tr>
<tr>
<td>2.</td>
<td>Category:</td>
</tr>
<tr>
<td>3.</td>
<td>Concomitant Medications Pre-specified:</td>
</tr>
<tr>
<td>4.</td>
<td>Medication:</td>
</tr>
<tr>
<td></td>
<td>Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).</td>
</tr>
<tr>
<td>5.</td>
<td>Date:</td>
</tr>
<tr>
<td></td>
<td>Sponsor-Defined Identifier</td>
</tr>
<tr>
<td>---</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>1.</td>
<td></td>
</tr>
</tbody>
</table>
## Concomitant Medications

1. What is the medication identifier?  
2. Category:  
3. Concomitant Medications  
   Pre-specified:  
4. Medication:  
   Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).  
5. Dose:  
6. Dose Unit:  
7. Dose Frequency:  
8. Route:  
9. Start Date:  
10. Ongoing?
<table>
<thead>
<tr>
<th>#</th>
<th>Category</th>
<th>Treatment Identifier</th>
<th>Con Non-Drug Treatments Pre-specified</th>
<th>Treatment</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?
<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>Repeating Pages</td>
</tr>
<tr>
<td>Back to Form</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>--------------</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Transfusion Type:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Date of Transfusion:</td>
<td>//</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Header Text:** c4591001  
**Visit:** Logs - Unscheduled  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1083  
**Subject No:** 10831194  
**Generated By:** (b) (4)  
**Site Name:** (1083) Benchmark Research  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:11
**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>

**Form Details**

- **Header Text:** c4591001
- **Visit:** Unplanned Vaccination - Unscheduled
- **Form Version:** 22-Apr-2020 21:02
- **Form Status:** Not Started
- **Site No:** 1083
- **Subject No:** 10831194
- **Generated By:** (b) (4)
- **Generated Time (GMT):** 29-Mar-2021 10:11
- **Site Name:** (1083) Benchmark Research
- **Subject Initials:** ---
### Vital Signs

1. Date: //

### Vital Signs Details

<table>
<thead>
<tr>
<th>2.</th>
<th>Record Identifier:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Temperature:</td>
</tr>
<tr>
<td></td>
<td>[ ]</td>
</tr>
<tr>
<td></td>
<td>Unit:</td>
</tr>
<tr>
<td></td>
<td>Temperature Location:</td>
</tr>
</tbody>
</table>

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**Header Text:** c4591001  
**Visit:** Unplanned Vaccination - Unscheduled  
**Form Version:** 20-Feb-2021 02:16  
**Site No:** 1083  
**Subject No:** 10831194  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:11
## Vaccination

1. Was there a temporary delay of vaccination?  

2. Treatment Name  

3. Formulation:  

4. Dose Date Time:  //  

5. Anatomical Location:  

6. Body Side:  

7. Route:  

8. Actual Dose:  []  

9. Unit:  

10. Timeframe Subject Was Observed  

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?
<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>
<tr>
<td>Contact Outcome</td>
</tr>
<tr>
<td>-----------------</td>
</tr>
<tr>
<td>1. Contact Type:</td>
</tr>
<tr>
<td>2. Was contact made?</td>
</tr>
<tr>
<td>3. Comments: [ ]</td>
</tr>
</tbody>
</table>
### Date of Visit

<table>
<thead>
<tr>
<th></th>
<th>Date of Visit</th>
<th>Jan/13/2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Date of Visit</td>
<td>Jan/13/2021</td>
</tr>
<tr>
<td>2</td>
<td>Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>

**eCRF Audit Trail History**

1. Date of Visit: Jan/13/2021
2. Erroneous Visit
**eCRF Audit Trail History**

### Further Vaccination Confirmation

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Select appropriate response - Is participant willing to return for Vaccination 3?</td>
</tr>
<tr>
<td></td>
<td>Participant is willing to return for Vaccination 3</td>
</tr>
<tr>
<td></td>
<td>Participant is:</td>
</tr>
<tr>
<td></td>
<td>eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2</td>
</tr>
</tbody>
</table>
**Treatment Unblinded**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>1.</td>
<td>Date Treatment Unblinded :</td>
</tr>
<tr>
<td>2.</td>
<td>Primary Reason for Unblinding:</td>
</tr>
</tbody>
</table>
Withdrawal Of Consent

1. Withdrawal of Consent Date: //
<table>
<thead>
<tr>
<th>Death Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Collection / Notification of Death: //</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cause of Death</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Cause of Death Status:</td>
</tr>
<tr>
<td>Cause of Death: [ ]</td>
</tr>
</tbody>
</table>
### eCRF Audit Trail History

#### Date of Visit

<table>
<thead>
<tr>
<th></th>
<th>Date of Visit</th>
<th>Jan/22/2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Date of Visit</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>
**Informed Consent - Further Vaccination**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>1.</td>
<td>Consent Was:</td>
</tr>
<tr>
<td></td>
<td>OBTAINED</td>
</tr>
<tr>
<td></td>
<td>Date Written Consent Obtained</td>
</tr>
<tr>
<td></td>
<td>Jan/22/2021</td>
</tr>
</tbody>
</table>
### Inclusion Comments

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

<table>
<thead>
<tr>
<th></th>
<th>Description of Exclusion Criterion Met</th>
<th>Not Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Description of Exclusion Criterion Met</td>
<td>Not Applicable</td>
</tr>
<tr>
<td><strong>Disposition - Screening for Further Vaccination</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Date of Completion/Discontinuation/Death:</td>
<td>Jan/22/2021</td>
<td></td>
</tr>
<tr>
<td>2. Phase of Disposition:</td>
<td>REPEAT SCREENING 1</td>
<td></td>
</tr>
<tr>
<td>3. Status:</td>
<td>COMPLETED</td>
<td></td>
</tr>
<tr>
<td>4. Specify Status:</td>
<td>[ ]</td>
<td></td>
</tr>
</tbody>
</table>
### eCRF Audit Trail History

**Electronic Sample Tracking**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Data Origin</td>
</tr>
<tr>
<td>2.</td>
<td>Sample Type</td>
</tr>
<tr>
<td>3.</td>
<td>Sample Collected?</td>
</tr>
<tr>
<td></td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td>Date of Collection: Jan/22/2021</td>
</tr>
<tr>
<td></td>
<td>[ ]</td>
</tr>
</tbody>
</table>

#### Aliquot

Please enter barcode for each aliquot.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5.a</td>
<td>Sample ID</td>
</tr>
<tr>
<td></td>
<td>[BM3MB7]</td>
</tr>
<tr>
<td>5.b</td>
<td>Sample ID</td>
</tr>
<tr>
<td></td>
<td>[BM3MB5]</td>
</tr>
<tr>
<td>5.c</td>
<td>Sample ID</td>
</tr>
<tr>
<td></td>
<td>[BKN2FX]</td>
</tr>
</tbody>
</table>
### eCRF Audit Trail History

#### Electronic Sample Tracking

<table>
<thead>
<tr>
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<th>Data Origin</th>
<th>Sample Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>SITE</td>
<td>NASAL_SWAB</td>
</tr>
</tbody>
</table>

3. **Sample Collected?**

   **YES**
   
   **Date of Collection:**
   
   Jan/22/2021

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

   [ ]

### Aliquot

Please enter barcode for each aliquot.

5.a **Sample ID**

   [BKN2FG]
1. Was there a temporary delay of vaccination?
   - NO

2. Treatment Name
   - [BNT162b2]

3. Formulation:
   - INJECTION

4. Dose Date Time:
   - Jan/22/2021 09:16

5. Anatomical Location:
   - DELTOID MUSCLE

6. Body Side:
   - LEFT

7. Route:
   - INTRAMUSCULAR

8. Actual Dose:
   - [30.0]

9. Unit:
   - ug

10. Timeframe Subject Was Observed
    - 30 MINUTES

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?
    - YES
**Header Text:** c4591001  
**Visit:** V102_VAX4  
**Form:** DATE OF VISIT  
**Form Version:** 22-Apr-2020 21:02  
**Form Status:** Data Complete, Frozen, Verified  
**Site No:** 1083  
**Site Name:** (1083) Benchmark Research  
**Subject No:** 10831194  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:11

### eCRF Audit Trail History

<table>
<thead>
<tr>
<th>Date of Audit</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Visit</td>
<td>Feb/12/2021</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>
**eCRF Audit Trail History**

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

#### Vaccination

1. **Was there a temporary delay of vaccination?**  
   - **NO**

2. **Treatment Name**  
   - [BNT162b2]

3. **Formulation:**  
   - INJECTION

4. **Dose Date Time:**  
   - Feb/12/2021 09:05

5. **Anatomical Location:**  
   - DELTOID MUSCLE

6. **Body Side:**  
   - LEFT

7. **Route:**  
   - INTRAMUSCULAR

8. **Actual Dose:**  
   - [30.0]

9. **Unit:**  
   - ug

10. **Timeframe Subject Was Observed**  
    - 30 MINUTES

11. **Was the subject observed for at least the protocol specified observation period after investigational product administration?**  
    - YES
### Date of Visit

1. Date of Visit
   //

2. Erroneous Visit

---

**Header Text:** c4591001  
**Visit:** V103_MONTH1  
**Form:** DATE OF VISIT  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1083  
**Subject No:** 10831194  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:11  
**Site Name:** (1083) Benchmark Research  

**Form Status:** Not Started  

---

**FDA-CBER-2021-5683-0960887**
<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>
<tr>
<td>Date of Visit</td>
</tr>
<tr>
<td>---------------</td>
</tr>
<tr>
<td>1. Date of Visit</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
</tr>
</tbody>
</table>
## Contact Outcome

1. **Contact Type:**

2. **Was contact made?**

3. **Comments:** [ ]
<table>
<thead>
<tr>
<th>Date of Visit</th>
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<tbody>
<tr>
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<td>//</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
<tr>
<td>Contact Outcome</td>
<td></td>
</tr>
<tr>
<td>-----------------</td>
<td></td>
</tr>
<tr>
<td>1. Contact Type:</td>
<td></td>
</tr>
<tr>
<td>2. Was contact made?</td>
<td></td>
</tr>
<tr>
<td>3. Comments: [ ]</td>
<td></td>
</tr>
</tbody>
</table>
### Disposition - Treatment

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

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**Header Text:** c4591001

**Visit:** FURTHER_VACCINATION_EOT - Unscheduled

**Form:** DISPOSITION - TREATMENT

**Form Version:** 20-Feb-2021 02:26

**Site No:** 1083

**Subject No:** 10831194

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

**Form Status:** Not Started

**Site Name:** (1083) Benchmark Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:11
Subject Status

1. Subject Status FOLLOW-UP
2. Subject Status Date Oct/22/2020
### eCRF Audit Trail History

#### Casebook Signature Form

<table>
<thead>
<tr>
<th></th>
<th>Casebook Signature</th>
<th>Click Here to Enable</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This form requires signing by a member of each of the following signature groups:
- CRF_Sign

<table>
<thead>
<tr>
<th>Name</th>
<th>Signature Meaning</th>
<th>Date</th>
<th>Type</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laurence Chu</td>
<td>Approved</td>
<td>Mar-12-2021 09:13:40 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>BOOK</td>
<td>Signed</td>
</tr>
</tbody>
</table>

**Affidavit:**

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

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

To this I do attest by supplying my user name and password and clicking the button marked Submit below.
<table>
<thead>
<tr>
<th>Item</th>
<th>Date</th>
<th>User</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form</td>
<td>Sep-04-2020 17:28:20 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>(b) (4), (b) (6)</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Item</td>
<td>Date</td>
<td>User</td>
<td>Comment</td>
</tr>
<tr>
<td>------</td>
<td>------</td>
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<td>---------</td>
</tr>
<tr>
<td>Form</td>
<td>Jan-22-2021 17:33:28 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>(b) (4), (b) (6)</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>
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<th>Action</th>
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</thead>
<tbody>
<tr>
<td>Laurence Chu</td>
<td>Approved</td>
<td>Mar-12-2021 09:13:40 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>BOOK</td>
<td>Signed</td>
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</tbody>
</table>

**Affidavit:**
N/A

<table>
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<tr>
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<th>Signature Meaning</th>
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<th>Type</th>
<th>Action</th>
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</thead>
<tbody>
<tr>
<td>Laurence Chu</td>
<td>Approved</td>
<td>Jan-25-2021 09:50:06 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>BOOK</td>
<td>Signed</td>
</tr>
</tbody>
</table>

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

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<table>
<thead>
<tr>
<th>Name</th>
<th>Signature Meaning</th>
<th>Date</th>
<th>Type</th>
<th>Action</th>
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</thead>
<tbody>
<tr>
<td>Laurence Chu</td>
<td>Approved</td>
<td>Jan-22-2021 17:33:03 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>BOOK</td>
<td>Signed</td>
</tr>
</tbody>
</table>
Affidavit:
By my dated signature below, I, Laurence Chu, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

<table>
<thead>
<tr>
<th>(b) (6)</th>
<th>N/A</th>
<th>Dec-04-2020 14:33:14 (UTC-06:00) Central Time (US &amp; Canada)</th>
<th>Edit - All signatures invalidated</th>
</tr>
</thead>
</table>

Affidavit:
N/A

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

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

<table>
<thead>
<tr>
<th>(b) (6)</th>
<th>N/A</th>
<th>Nov-06-2020 15:33:53 (UTC-06:00) Central Time (US &amp; Canada)</th>
<th>Edit - All signatures invalidated</th>
</tr>
</thead>
</table>

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

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

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

| (b) (6) | N/A | Nov-04-2020 16:35:27 (UTC-06:00) Central Time (US & Canada) | Edit - All signatures invalidated |

Affidavit:
Laurence Chu
Approved
Oct-26-2020 14:08:09 (UTC-06:00) Central Time (US & Canada)
BOOK
Signed

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

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

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-04-2020 17:24:20</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> 24 JUL 2020</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-04-2020 17:24:20</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> STAGE 3 COHORTS</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>
### 1. Consent Was:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-04-2020 17:24:26</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Obtained Date Written Consent Obtained Sep/4/2020</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>
## 1. Subject ID

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-04-2020 17:24:13</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td>Data Entry: 10831194</td>
<td>Item copied from previous form</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td></td>
<td>(autocalc)</td>
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</table>

## 2. Birth Date:

<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>Sep-04-2020 17:24:09</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td>Data Entry: (b) (6)/1972</td>
<td>Enrollment Entry</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td></td>
<td>(autocalc)</td>
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## 3. Sex:

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<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-04-2020 17:24:37</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>MALE</td>
<td>Initial Entry</td>
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<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
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## 4. Ethnicity:

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<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-04-2020 17:24:37</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
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<td></td>
<td></td>
<td></td>
</tr>
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## 5. Race: (Check X all that apply):

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<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>WHITE</td>
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</table>
### 1. Date of Visit

<table>
<thead>
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<th>Reason</th>
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<tbody>
<tr>
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<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Sep/4/2020</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
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</tbody>
</table>
## 1. Date of Completion/Discontinuation/Death

<table>
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<tr>
<th>Date</th>
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<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-04-2020 17:28:45 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEMP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Sep/4/2020</td>
<td>Initial Entry</td>
</tr>
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</table>

## 2. Phase of Disposition:

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<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-04-2020 17:28:45 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEMP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: SCREENING</td>
<td>Initial Entry</td>
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## 3. Status:

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<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-04-2020 17:28:45 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEMP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: COMPLETED</td>
<td>Initial Entry</td>
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</table>
### 1.a

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-04-2020 17:32:47 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> Line/MH Num 1</td>
<td>Initial Entry</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Medical History: Allergic Rhinitis</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Start Date: UNK/UNK/2016</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Ongoing: YES</td>
<td></td>
</tr>
</tbody>
</table>

### 1.a Line/MH Number:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-04-2020 17:32:47 (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>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-04-2020 17:32:47 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Allergic Rhinitis-Seasonal</td>
<td>Initial Entry</td>
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</table>

### 1.a Start Date:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-04-2020 17:32:47 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> UNK/UNK/2016</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

### 1.a Ongoing:

<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-04-2020 17:32:47 (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>Initial Entry</td>
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### 1.b

<table>
<thead>
<tr>
<th>Date</th>
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<th>Value</th>
<th>Reason</th>
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<tbody>
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<td>Initial Entry</td>
</tr>
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<td>(UTC-06:00) Central</td>
<td>(b) (4) (b) (6)</td>
<td></td>
<td>Line/MH Number 2</td>
<td></td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td>: Medical History Term: Obesity</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
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### 1.b Line/MH Number:

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<th>Reason</th>
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<tbody>
<tr>
<td>Sep-04-2020 17:33:56</td>
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<td>auto calc (autocalc)</td>
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<td>Initial Entry</td>
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<td>(UTC-06:00) Central</td>
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### 1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

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<tbody>
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### 1.b Start Date:

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

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### 1.c Ongoing:

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### 1.d

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<tr>
<td>Sep-04-2020 17:34:40</td>
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<td>Sep-04-2020 17:34:40</td>
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### 1.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

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### 1.d Ongoing:

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<td>Initial Entry</td>
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<td>Sep-04-2020 17:31:21</td>
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### 3. Unit:

<table>
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<tbody>
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### 4. Height:

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### 5. Unit:

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<td>(b) (4), (b) (6)</td>
<td>[Data Entry: in]</td>
<td>Initial Entry</td>
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### 6. Body Mass Index:

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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Sep-04-2020 17:31:21</td>
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<td>36.5</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>Date</td>
<td>Location</td>
<td>User</td>
<td>Value</td>
<td>Reason</td>
</tr>
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<td>-------------------</td>
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</tr>
<tr>
<td>Sep-04-2020 17:31:21 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Record Identifier 1 ::</td>
<td>Initial Entry</td>
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<td></td>
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<td>Temperature: 98.1</td>
<td><strong>Temperature Unit:</strong> F</td>
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<tr>
<td></td>
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<td>Temperature Location:: ORAL CAVITY</td>
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**7.a Record Identifier:**

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<th>Reason</th>
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</table>

**7.a Temperature:**

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<th>Value</th>
<th>Reason</th>
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<tbody>
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**7.a Unit:**

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<th>Value</th>
<th>Reason</th>
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**7.a Temperature Location:**

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<th>Value</th>
<th>Reason</th>
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**Back to Form**

1. **Randomization Date**:

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<th>Value</th>
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<tbody>
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2. **Randomization Number**:

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<tr>
<td>Sep-04-2020 18:16:05 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: SITE</td>
<td>Initial Entry</td>
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### 2. Sample Type

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<th>Reason</th>
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### 3. Sample Collected?

<table>
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<td>Query 1: Deleted</td>
<td>Close Auto Query</td>
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### 5.a

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<td>(b) (4), (b) (6)</td>
<td>Data Entry: Sample ID: BPZ1N0</td>
<td>Initial Entry</td>
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<tr>
<td>Date</td>
<td>Location</td>
<td>User</td>
<td>Value</td>
<td>Reason</td>
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**5.a Sample ID**
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### 2. Sample Type

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### 3. Sample Collected?

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### 5.a

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

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<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-04-2020 17:29:33 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

### 2. Treatment Name

<table>
<thead>
<tr>
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<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-04-2020 17:29:33 (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>
</tr>
</tbody>
</table>

### 3. Formulation:

<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-04-2020 17:29:33 (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>
</tr>
</tbody>
</table>

### 4. Dose Date Time:

<table>
<thead>
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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-04-2020 17:29:33 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Sep/4/2020 12:40</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

### 5. Anatomical Location:

<table>
<thead>
<tr>
<th>Date</th>
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<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-04-2020 17:29:33 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: DELTOID MUSCLE</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

### 6. Body Side:

<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>Sep-04-2020 17:29:33 (UTC-06:00) Central</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: LEFT</td>
<td>Initial Entry</td>
</tr>
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</table>
### 7. Route:

<table>
<thead>
<tr>
<th>Date</th>
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<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-04-2020 17:29:33</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: INTRAMUSCULAR</td>
<td>Initial Entry</td>
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### 10. Timeframe Subject Was Observed

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-04-2020 17:29:33</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-04-2020 17:29:33</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: YES</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>
1. Select appropriate response - Reactogenicity diary collection

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-04-2020 17:28:54 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>
### 1. Date of Visit

<table>
<thead>
<tr>
<th>Date</th>
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<th>Reason</th>
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<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Sep/23/2020</td>
</tr>
</tbody>
</table>

Initial Entry
<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 18:33:16</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>97.9</td>
<td>Data Entry: Sep/23/2020</td>
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</table>

**2.a**

<table>
<thead>
<tr>
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<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tr>
<td>Sep-23-2020 18:33:16</td>
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**2.a Temperature:**

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<th>Reason</th>
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<tbody>
<tr>
<td>Sep-23-2020 18:33:16</td>
<td>ACV0PFEINFP6000</td>
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**2.a Unit:**

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<tbody>
<tr>
<td>Sep-23-2020 18:33:16</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>F</td>
<td>Data Entry: F</td>
</tr>
</tbody>
</table>
### 2.a Temperature Location:

<table>
<thead>
<tr>
<th>Date</th>
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<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Sep-23-2020 18:33:16</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> ORAL CAVITY</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
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</table>
### 1. Data Origin

<table>
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<tr>
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<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Sep-23-2020 18:35:28</td>
<td>(UTC-06:00) Central Time</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td>Data Entry: SITE, Initial Entry</td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
<td></td>
<td>(autocalc)</td>
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### 2. Sample Type

<table>
<thead>
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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Sep-23-2020 18:35:28</td>
<td>(UTC-06:00) Central Time</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td>Data Entry: NASAL_SWAB, Initial Entry</td>
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<tr>
<td>(US &amp; Canada)</td>
<td></td>
<td>(autocalc)</td>
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### 3. Sample Collected?

<table>
<thead>
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<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Sep-23-2020 18:35:42</td>
<td>(UTC-06:00) Central Time</td>
<td>ACV0PFEINFP6000</td>
<td>auto query</td>
<td>Query 1: Deleted, Close Auto Query</td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
<td></td>
<td>(autoquery)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sep-23-2020 18:35:28</td>
<td>(UTC-06:00) Central Time</td>
<td>ACV0PFEINFP6000</td>
<td>auto query</td>
<td>Query 1: Candidate</td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
<td></td>
<td>(autoquery)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sep-23-2020 18:35:28</td>
<td>(UTC-06:00) Central Time</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: YES, Date of Collection: Sep/23/2020, Initial Entry</td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
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### 5.a

<table>
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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Sep-25-2020 17:59:58</td>
<td>(UTC-06:00) Central Time</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Sample ID: BLCJWJ, Transcription Error</td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
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### 5. a Sample ID

<table>
<thead>
<tr>
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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Sep-26-2020 08:01:08</td>
<td>ACV0PFEINFP6000.InFormAdapter.Discrepancy</td>
<td>DMW QUERY</td>
<td>(b) (4)</td>
<td>Auto closed by Validation Check: VC_BEETRK001_06</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td></td>
<td>Query 2: Closed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sep-25-2020 17:59:58</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 2: Answered</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Sep-25-2020 17:59:58</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
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<td>BLCJWJ</td>
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<tr>
<td>Sep-25-2020 04:33:09</td>
<td>ACV0PFEINFP6000.InFormAdapter.Discrepancy</td>
<td>DMW QUERY</td>
<td>(b) (4)</td>
<td>DMW4811490: The Barcode BLCJWH is recorded for two subjects 10831189 and 10831194, Please review and update as appropriate.</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
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<td>Query 2: Opened</td>
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<tr>
<td>Sep-23-2020 18:36:54</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Closed</td>
<td>Close Auto Query</td>
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<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
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<tr>
<td>Date/Time</td>
<td>User ID</td>
<td>Description</td>
<td>Notes</td>
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<td>Sep-23-2020 18:36:54</td>
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<td>Data Entry</td>
<td>(b) (4), (b) (6)</td>
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<tr>
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<td></td>
<td>Transcription Error</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sep-23-2020 18:35:42</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Opened&lt;br&gt;Barcode contains lower case letters which is not the correct format. Please review and correct as appropriate.</td>
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<tr>
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<td>Data Entry</td>
<td>(b) (4), (b) (6)</td>
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<td>Initial Entry</td>
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<tr>
<td>Sep-23-2020 18:35:42</td>
<td>ACV0PFEINFP6000</td>
<td>Data Entry</td>
<td>(b) (4), (b) (6)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Initial Entry</td>
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</table>
1. **Was there a temporary delay of vaccination?**

<table>
<thead>
<tr>
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<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-23-2020 18:38:15</td>
<td>ACV0PFEINFP6000 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> NO</td>
<td>Initial Entry</td>
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</table>

2. **Treatment Name**

<table>
<thead>
<tr>
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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Sep-23-2020 18:38:15</td>
<td>ACV0PFEINFP6000 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> BLINDED THERAPY</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

3. **Formulation:**

<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 18:38:15</td>
<td>ACV0PFEINFP6000 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> INJECTION</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

4. **Dose Date Time:**

<table>
<thead>
<tr>
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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Sep-23-2020 18:38:15</td>
<td>ACV0PFEINFP6000 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Sep/23/2020 14:51</td>
<td>Initial Entry</td>
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5. **Anatomical Location:**

<table>
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<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Sep-23-2020 18:38:15</td>
<td>ACV0PFEINFP6000 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> DELTOID MUSCLE</td>
<td>Initial Entry</td>
</tr>
</tbody>
</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>Sep-23-2020 18:38:15</td>
<td>ACV0PFEINFP6000 (UTC-06:00) Central</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> LEFT</td>
<td>Initial Entry</td>
</tr>
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</table>
### 7. Route:
<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-23-2020 18:38:15 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: INTRAMUSCULAR</td>
<td>Initial Entry</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>
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<tbody>
<tr>
<td>Sep-23-2020 18:38:15 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

### 11. Was the subject observed for at least the protocol specified observation period after investigational product administration?
<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-23-2020 18:38:15 (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>
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</table>
### 1. Date of Visit

<table>
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<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Nov-05-2020 05:00:31</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Closed</td>
<td>event downgraded in SDB</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td></td>
<td></td>
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<tr>
<td>Nov-05-2020 00:43:13</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Reissued:Opened</td>
<td>SAE RECON 1: ae#2 indicates CHEST PAIN as the AE term however, reported as non serious while serious in Inform. Please confirm event seriousness. If safety update is required, submit a follow-up SAE Form.</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nov-04-2020 13:16:19</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Answered</td>
<td>Site will be receiving medical records from hospital and will review and send a follow up report by end of business day</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
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<tr>
<td>Nov-04-2020 06:08:13</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Opened</td>
<td>SAE RECON:AER#2020427451 Chest pain(onset date:26Oct2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Oct-22-2020 13:05:01</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Oct/22/2020</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>
### 1. Data Origin

<table>
<thead>
<tr>
<th>Date</th>
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<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-22-2020 13:05:06 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> SITE</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

### 2. Sample Type

<table>
<thead>
<tr>
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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Oct-22-2020 13:05:06 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> SERUM</td>
<td>Initial Entry</td>
</tr>
</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>Oct-22-2020 17:13:04 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Deleted</td>
<td>Close Auto Query</td>
</tr>
<tr>
<td>Oct-22-2020 13:05:06 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Candidate</td>
<td>‘Sample Collected?’ is Yes, however no barcodes are entered. Please review and correct as appropriate.</td>
</tr>
<tr>
<td>Oct-22-2020 13:05:06 (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>Date of Collection: Oct/22/2020</td>
</tr>
</tbody>
</table>

### 5.a

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-22-2020 17:13:04 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Sample ID: BP21WF</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>
**5.a Sample ID**

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
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<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-22-2020 17:13:04 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> BP21WF</td>
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</table>

**5.b**

<table>
<thead>
<tr>
<th>Date</th>
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<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec-04-2020 14:33:14 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Sample ID: BPHMSX</td>
<td>Initial Entry</td>
</tr>
</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>Dec-04-2020 14:33:14 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> BPHMSX</td>
<td>Initial Entry</td>
</tr>
</tbody>
</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>Dec-04-2020 14:33:29 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Sample ID: BPHMSY</td>
<td>Initial Entry</td>
</tr>
</tbody>
</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>Dec-04-2020 14:33:29 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> BPHMSY</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>
**Back to Form**

1. Date of Completion/Discontinuation/Death:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-22-2020 13:05:18 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Oct/22/2020</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

2. Phase of Disposition:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-22-2020 13:05:18 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: VACCINATION</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

3. Status:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-22-2020 13:05:18 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: COMPLETED</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-04-2020 16:35:27</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Form Created</td>
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### ADVERSE EVENT REPORT - Audit Trail

**Visit:** Logs - Unscheduled  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1083  
**Subject No:** 10831194  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:11

<table>
<thead>
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<th>Date</th>
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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Nov-04-2020 16:38:58 (UTC-06:00) Central Time (US &amp; Canada)</td>
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<td>(b) (4), (b) (6)</td>
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### Back to Form

<table>
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<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Nov-04-2020 16:40:21</td>
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<td>(b) (4), (b) (6)</td>
<td>Form Created</td>
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<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
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<tr>
<td>Date</td>
<td>Location</td>
<td>User</td>
<td>Value</td>
<td>Reason</td>
</tr>
<tr>
<td>---------------------</td>
<td>---------------------------</td>
<td>---------------</td>
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<td>Nov-04-2020 16:41:39</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Form Created</td>
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<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
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Back to Form
### 1. Category:

<table>
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<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Nov-04-2020 16:35:27 (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>
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</table>

### 2. AE ID:

<table>
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<tr>
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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
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<tbody>
<tr>
<td>Nov-04-2020 16:35:27 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> 1</td>
<td>Initial Entry</td>
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</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>
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<tbody>
<tr>
<td>Nov-09-2020 12:07:20 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Nov-09-2020 11:03:23 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Answered</td>
<td>Per PI NCS</td>
</tr>
<tr>
<td>Nov-05-2020 17:36:40 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Opened</td>
<td>CLINICAL -SAE report includes 3 platelet volume results all elevated; please submit the rest of CBC including platelet count to the SAE, as pertinent info. Please consider clinical significance, and report an event if appropriate.</td>
</tr>
<tr>
<td>Nov-04-2020 16:35:27 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> New Onset Atrial Fibrillation with rapid ventricular response</td>
<td>Initial Entry</td>
</tr>
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</table>
4. Start Date Time:

<table>
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<tr>
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<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Nov-04-2020 16:35:27</td>
<td>(UTC-06:00) Central Time</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Oct/26/2020 00:00</td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
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5. Is the adverse event still ongoing?

<table>
<thead>
<tr>
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<th>User</th>
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<th>Reason</th>
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<tbody>
<tr>
<td>Mar-05-2021 06:18:46</td>
<td>(UTC-06:00) Central Time</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4)</td>
<td>Query 1: Closed</td>
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<tr>
<td>(US &amp; Canada)</td>
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<td></td>
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<td></td>
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<tr>
<td>Mar-04-2021 15:12:35</td>
<td>(UTC-06:00) Central Time</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Answered</td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mar-04-2021 13:12:02</td>
<td>(UTC-06:00) Central Time</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4)</td>
<td>Query 1: Opened</td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nov-04-2020 16:35:27</td>
<td>(UTC-06:00) Central Time</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: YES</td>
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<tr>
<td>(US &amp; Canada)</td>
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6. Toxicity Grade:

<table>
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<tr>
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<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Nov-05-2020 11:15:12</td>
<td>(UTC-06:00) Central Time</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: 2</td>
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<tr>
<td>(US &amp; Canada)</td>
<td></td>
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</tr>
<tr>
<td>Nov-04-2020 16:35:27</td>
<td>(UTC-06:00) Central Time</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: 3</td>
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<tr>
<td>(US &amp; Canada)</td>
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</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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</table>

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***Confidential***

FDA-CBER-2021-5683-0960938
**Header Text:** c4591001  
**Visit:** Logs - Unscheduled  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1083  
**Subject No:** 10831194  
**Generated By:** (b) (4)  

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History  
**Form Status:** Data Complete, Verified  
**Site Name:** (1083) Benchmark Research  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:11

<table>
<thead>
<tr>
<th>Date/Time</th>
<th>User ID</th>
<th>Query Status</th>
<th>Notes</th>
</tr>
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<tbody>
<tr>
<td>Nov-07-2020 07:02:03</td>
<td>ACV0PFEINFP6000</td>
<td>Query 3: Closed</td>
<td>Thanks - will close query.</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time</td>
<td>Charu Sabharwal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
<td>(b) (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nov-06-2020 15:29:53</td>
<td>ACV0PFEINFP6000</td>
<td>Query 3: Answered</td>
<td>Good catch. Newest SAE Follow Up Letter #3 will have the correct date.</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time</td>
<td>(b) (4), (b) (6)</td>
<td></td>
<td>Site has made update to previously sent SAE follow up letter source</td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nov-06-2020 01:44:03</td>
<td>ACV0PFEINFP6000</td>
<td>Query 3: Opened</td>
<td>CLINICAL - Injection #1 log states performed on 04Sep20; however, Injection date in SAE report is 09Sep20. Please review, and update in the appropriate location</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time</td>
<td>(b) (4), (b) (6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nov-05-2020 17:26:51</td>
<td>ACV0PFEINFP6000</td>
<td>Query 3: Candidate</td>
<td>CLINICAL - Injection #1 log states performed on 04Sep20; however, Injection date in SAE report is 09Sep20. Please review, and update in the appropriate location</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time</td>
<td>(b) (4), (b) (6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nov-05-2020 11:02:22</td>
<td>ACV0PFEINFP6000</td>
<td>Query 1: Closed</td>
<td>Close Auto Query</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time</td>
<td>auto query</td>
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<td></td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
<td>(autoquery)</td>
<td></td>
<td></td>
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<tr>
<td>Nov-05-2020 11:02:22</td>
<td>ACV0PFEINFP6000</td>
<td>Data Entry: YES</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time</td>
<td>(b) (4), (b) (6)</td>
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</tr>
<tr>
<td>(US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Data Entry:**

- **YES**
  - Is this serious event associated with congenital anomaly or birth defect?
  - **NO**

---

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<table>
<thead>
<tr>
<th>Date/Time</th>
<th>Site Name</th>
<th>Event</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-05-2020 05:02:39 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 2: Deleted</td>
</tr>
<tr>
<td>Nov-04-2020 16:35:27 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 2: Candidate</td>
</tr>
<tr>
<td>Nov-04-2020 16:35:27 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Opened</td>
</tr>
</tbody>
</table>
least one seriousness criterion is expected to be YES for serious events. Please review and update as appropriate.

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>
</table>
| ACV0PFEINFP6000    | (b) (4), (b) (6) | Data Entry: YES  
Is this serious event associated with congenital anomaly or birth defect?  
NO  
Did this serious event result in death?  
NO  
Did this serious event require or prolong hospitalization?  
NO  
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 |

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### 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-04-2020 16:35:27 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NOT RELATED</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>Nov-05-2020 11:15:44 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
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<td>New Information</td>
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<tr>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: NOT RELATED</td>
<td>New Information</td>
</tr>
</tbody>
</table>

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

- OTHER

If Other, specify:

- Arrhythmia

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
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<tbody>
<tr>
<td>Nov-04-2020 16:35:27 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
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### 11. Was a Concomitant Medication given?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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</table>
### 12. Was a Non-Drug Treatment given?

<table>
<thead>
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<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Nov-04-2020 16:35:27</td>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry:</td>
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<tr>
<td>(UTC-06:00) Central</td>
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<td>Initial Entry</td>
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<tr>
<td>Time (US &amp; Canada)</td>
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### 13. What was the outcome of this adverse event?:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
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<tbody>
<tr>
<td>Nov-07-2020 09:43:48</td>
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<td>(b) (4), (b) (6)</td>
<td>Query 1: Closed</td>
<td>Response satisfies query</td>
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<tr>
<td>(UTC-06:00) Central</td>
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</tr>
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<td>Time (US &amp; Canada)</td>
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<table>
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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-06-2020 15:33:53</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Answered</td>
<td>New Information</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>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-04-2020 16:35:27</td>
<td>ACV0PFIEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry:</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td></td>
<td></td>
<td>NOT RECOVERED/NOT RESOLVED</td>
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<tr>
<td>Time (US &amp; Canada)</td>
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14. Did the adverse event cause the subject to be discontinued from the study?

<table>
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<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Nov-04-2020 16:35:27</td>
<td>ACV0PFIEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry:</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
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<td></td>
<td>NO</td>
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<tr>
<td>Time (US &amp; Canada)</td>
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</table>

15. Serious Adverse Event Number: For Pfizer Use Only

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-05-2020 05:02:39</td>
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<td>(b) (4), (b) (6)</td>
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<td>Initial Entry</td>
</tr>
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<td>(UTC-06:00) Central</td>
<td></td>
<td></td>
<td>2020427451</td>
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</table>
## 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>Nov-04-2020 16:38:58</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td>Data Entry: ADVERSE EVENT</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td>(autocalc)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
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</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-04-2020 16:38:58</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td>2</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td>(autocalc)</td>
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<td>Time (US &amp; Canada)</td>
<td></td>
<td></td>
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</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-09-2020 13:59:41</td>
<td>ACV0PFEINFP6000</td>
<td>Ahmed Hassan</td>
<td>Query 1: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td>(b) (4)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nov-09-2020 10:43:27</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Answered</td>
<td>Symptom related to SAE #1 Atrial Fibrillation</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Time (US &amp; Canada)</td>
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<tr>
<td>Nov-06-2020 18:37:22</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Opened</td>
<td>ClinQuery: Chest Pain : Is a diagnosis available thanks</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
<td></td>
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</tr>
<tr>
<td>Time (US &amp; Canada)</td>
<td></td>
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</tr>
<tr>
<td>Nov-04-2020 16:38:58</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Chest Pain</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-06:00) Central</td>
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<tr>
<td>Time (US &amp; Canada)</td>
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<td></td>
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</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-04-2020 16:38:58</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Oct/26/2020 00:00</td>
<td>Initial Entry</td>
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<td>(UTC-06:00) Central</td>
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</tr>
<tr>
<td>Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></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>Nov-04-2020 16:38:58 (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:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Oct/28/2020 00:00</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-05-2020 11:16:55 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: 2</td>
<td>Transcription Error</td>
</tr>
<tr>
<td></td>
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</tr>
<tr>
<td>Nov-04-2020 16:38:58 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: 3</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>Nov-04-2020 16:38:58 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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-04-2020 16:38:58 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

9. Is this event related to study treatment:
### 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>Nov-04-2020 16:38:58</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> NOT APPLICABLE</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Nov-04-2020 16:38:58</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> NOT APPLICABLE</td>
<td>Initial Entry</td>
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</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>Nov-04-2020 16:38:58</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> YES</td>
<td>Initial Entry</td>
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</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Nov-04-2020 16:38:58</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> NO</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

**Data Entry:**

- **NOT RELATED**
  - If Not Related to study treatment(s), this event is due to:
    - **OTHER**
      - *If Other, specify:*
        - Arrhythmia
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-04-2020 16:38:58</td>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: RECOVERED/RESOLVED</td>
<td>Initial Entry</td>
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<td>(UTC-06:00) Central</td>
<td>Time (US &amp; Canada)</td>
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<td>Value</td>
<td>Reason</td>
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<td>Time (US &amp; Canada)</td>
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<td>(UTC-06:00) Central</td>
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<td>Time (US &amp; Canada)</td>
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<tr>
<td>3. Adverse Event:</td>
<td>(If possible specify diagnosis, not individual symptoms)</td>
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<tr>
<td></td>
<td></td>
<td>Nov-10-2020 04:02:54</td>
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<td></td>
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<td>Ahmed Hassan</td>
<td></td>
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<td></td>
<td>Time (US &amp; Canada)</td>
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<td></td>
<td>Nov-09-2020 14:05:27</td>
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<td>Query 1: Answered</td>
</tr>
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<td></td>
<td></td>
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<td>(b) (4), (b) (6)</td>
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<td>Time (US &amp; Canada)</td>
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<td></td>
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<tr>
<td></td>
<td></td>
<td>Time (US &amp; Canada)</td>
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</table>
and LM site returned call with no answer. Site left another message to return call.

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
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<td>Query 1: Opened</td>
<td>ClinQuery: Heart Palpitations: is a diagnosis available?</td>
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<tr>
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</table>

4. **Start Date Time:**

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<tbody>
<tr>
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5. **Is the adverse event still ongoing?**

<table>
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<tr>
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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Nov-04-2020 16:40:21</td>
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<td>Oct/28/2020 00:00</td>
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6. **Toxicity Grade:**

<table>
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<th>Reason</th>
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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).

### 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>
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<tbody>
<tr>
<td>Nov-04-2020 16:40:21 (UTC-06:00) Central Time (US &amp; Canada)</td>
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### 9. Is this event related to study treatment:

<table>
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<td>New Information</td>
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<tr>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: NOT RELATED if Not Related to study treatment(s), this event is due to: OTHER If Other, specify: Arrhythmia</td>
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### 10. Latest Action Taken with Study Treatment:

<table>
<thead>
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<th>Date</th>
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<th>User</th>
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### 11. Was a Concomitant Medication given?

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<tbody>
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### 12. Was a Non-Drug Treatment given?

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

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### 14. Did the adverse event cause the subject to be discontinued from the study?

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<td>Data Entry: Oct/26/2020 00:00</td>
<td>Initial Entry</td>
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<table>
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</table>
7. Is the adverse event serious?

*If Yes, NOTIFY PFIZER IMMEDIATELY.*

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

<table>
<thead>
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<td>ACV0PFEINFP6000</td>
<td>Ahmed Hassan</td>
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<td>Response satisfies query</td>
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<td>ClinQuery: Trivial Mitral Regurgitation: Please can you review the toxicity grade of this AE as currently it pertains to 'does not interfere with subjects' usual function'. Thanks</td>
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</table>

8. Is this adverse event the result of a study Medication Error?

*If Yes, record the type of medication error on the Medication Error Log.*

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tr>
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<td>Time (US &amp; Canada)</td>
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### 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>
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<tbody>
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<td>(b) (4), (b) (6)</td>
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<td>If Not Related to study treatment(s), this event is due to:</td>
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<td>If Not Related to study treatment(s), this event is due to:</td>
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<td>If Other, specify:</td>
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### 10. Latest Action Taken with Study Treatment:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
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### 11. Was a Concomitant Medication given?

<table>
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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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### 12. Was a Non-Drug Treatment given?
### 13. What was the outcome of this adverse event?

<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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<td>Time (US &amp; Canada)</td>
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### 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>
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<tbody>
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### 1. Date of Visit

<table>
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I. Select appropriate response - Is participant willing to return for Vaccination 3?

<table>
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<th>Reason</th>
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<td></td>
<td>Participant is willing to return</td>
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<tr>
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<td></td>
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<td></td>
<td>for Vaccination 3</td>
</tr>
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<td>Participant is:</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td>eligible per local/national</td>
</tr>
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<td>recommendations and confirmed to</td>
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<td></td>
<td></td>
<td></td>
<td>have received only placebo at</td>
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<td></td>
<td></td>
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<td>Vaccination 1/2</td>
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**Data Entry:**
Participant is willing to return for Vaccination 3
Participant is:
eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
### 1. Date Treatment Unblinded:

<table>
<thead>
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### 2. Primary Reason for Unblinding:

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<td>Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION</td>
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1. Date of Visit

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## 1. Consent Was:

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<tr>
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<td><strong>Data Entry:</strong> OBTAINED Date Written Consent Obtained Jan/22/2021</td>
<td>Initial Entry</td>
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### 1. Date of Completion/Discontinuation/Death:

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<tbody>
<tr>
<td>Jan-22-2021 17:33:41 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Jan/22/2021</td>
<td>Initial Entry</td>
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### 2. Phase of Disposition:

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<td>Jan-22-2021 17:33:41 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
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### 3. Status:

<table>
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<td>ACV0PFEINFP6000</td>
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**1. Data Origin**

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

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<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> SERUM</td>
<td>Initial Entry</td>
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**3. Sample Collected?**

<table>
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<tr>
<td>Jan-22-2021 18:12:17 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Deleted</td>
<td>Close Auto Query</td>
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<tr>
<td>Jan-22-2021 17:34:43 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Candidate</td>
<td>'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.</td>
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</tbody>
</table>

Jan-22-2021 17:34:43 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000     | (b) (4), (b) (6) | **Data Entry:** YES Date of Collection: Jan/22/2021 | Initial Entry |

**5.a**

<table>
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<tr>
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<td>ACV0PFEINFP6000</td>
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<td><strong>Data Entry:</strong> Sample ID: BM3MB7</td>
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<td>Date</td>
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<td>Data Entry: BM3MB7</td>
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### 1. Data Origin

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### 2. Sample Type

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### 3. Sample Collected?

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### 5.a

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

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<td>Jan-22-2021 17:35:22</td>
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### 2. Treatment Name

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### 3. Formulation:

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### 4. Dose Date Time:

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### 5. Anatomical Location:

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### 6. Body Side:

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7. Route:

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<td>auto calc (autocalc)</td>
<td>Data Entry: INTRAMUSCULAR</td>
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8. Actual Dose:

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<tbody>
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<td>auto calc (autocalc)</td>
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<td>Initial Entry</td>
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9. Unit:

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<th>Value</th>
<th>Reason</th>
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<td>Initial Entry</td>
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10. Timeframe Subject Was Observed

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<td>auto calc (autocalc)</td>
<td>Data Entry: 30 MINUTES</td>
<td>Initial Entry</td>
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11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

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<th>User</th>
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<td>Initial Entry</td>
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### 1. Date of Visit

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<tbody>
<tr>
<td>Mar-04-2021 10:43:47 (UTC-06:00) Central Time (US &amp; Canada)</td>
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<td>Data Entry: Feb/12/2021</td>
<td>Initial Entry</td>
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### 1. Data Origin

<table>
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<td>ACV0PFEINFP6000</td>
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### 2. Sample Type

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### 3. Sample Collected?

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<tr>
<td>Mar-10-2021 10:23:25</td>
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<td>Close Auto Query</td>
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<tr>
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<td>ACV0PFEINFP6000</td>
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<td>'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.</td>
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<td>Initial Entry</td>
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**FDA-CBER-2021-5683-0960970**
5.a

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Data Entry:
Sample ID: BKN2J6

5.a Sample ID

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<td>(b) (4), (b) (6)</td>
<td>Initial Entry</td>
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Data Entry:
BKN2J6
### 1. Was there a temporary delay of vaccination?

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<tr>
<td>Mar-04-2021 10:48:59</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
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### 2. Treatment Name

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<tr>
<td>Mar-04-2021 10:48:59</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
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### 3. Formulation:

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<td>Mar-04-2021 10:48:59</td>
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<td>Data Entry: INJECTION</td>
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### 4. Dose Date Time:

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<tbody>
<tr>
<td>Mar-04-2021 10:48:59</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Feb/12/2021 09:05</td>
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### 5. Anatomical Location:

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<tbody>
<tr>
<td>Mar-04-2021 10:48:59</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: DELTOID MUSCLE</td>
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### 6. Body Side:

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<td>Mar-04-2021 10:48:59</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: LEFT</td>
<td>Initial Entry</td>
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### 7. Route:

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<tbody>
<tr>
<td>Mar-04-2021 10:48:59</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td>Data Entry: INTRAMUSCULAR</td>
<td>Initial Entry</td>
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<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
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### 8. Actual Dose:

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<td>Mar-04-2021 10:48:59</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
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<td>Initial Entry</td>
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### 9. Unit:

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<td>auto calc</td>
<td>ug</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
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<td>(autocalc)</td>
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### 10. Timeframe Subject Was Observed

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<tbody>
<tr>
<td>Mar-04-2021 10:48:59</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td>Data Entry: 30 MINUTES</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
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<td>(autocalc)</td>
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### 11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Mar-04-2021 10:48:59</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: YES</td>
<td>Initial Entry</td>
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<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
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</table>
**1. Subject Status**

<table>
<thead>
<tr>
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<th>Reason</th>
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<tbody>
<tr>
<td>Mar-11-2021 04:18:00 (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-10-2021 14:23:21 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Answered</td>
<td>V102 was completed 12FEB2021</td>
</tr>
<tr>
<td>Mar-10-2021 09:16:57 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Rivkah Rosen (b) (4)</td>
<td>Query 1: Reissued:Opened</td>
<td>DM: Thank you for your response. V102 is entered as occurring 12Feb2021. Can you confirm whether visit was completed 12Feb or 06Mar? Thank you.</td>
</tr>
<tr>
<td>Mar-09-2021 23:43:29 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Answered</td>
<td>V102 was completed 06MAR2021 and been entered</td>
</tr>
<tr>
<td>Mar-05-2021 02:30:57 (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 Requery 1: As per response, please reschedule V102 on 6Mar2021 and record the visit details in inform. Further, please answer to this query. Thank you.</td>
</tr>
<tr>
<td>Mar-04-2021 15:12:53 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Answered</td>
<td>Visit pushed OOW due to inclement weather and IP TE. Visit V102 was re-scheduled for 06MAR2021</td>
</tr>
<tr>
<td>Mar-04-2021 00:44:14 (UTC-06:00) Central</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Opened</td>
<td>DM: V102 overdue based on expected</td>
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2. Subject Status Date

<table>
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<tbody>
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<td>Oct-22-2020 13:05:18 (UTC-06:00) Central Time (US &amp; Canada)</td>
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<td>auto calc (autocalc)</td>
<td>Data Entry: Initial Entry</td>
<td></td>
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<tr>
<td>Sep-04-2020 17:30:59 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: Initial Entry</td>
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<td>Sep-04-2020 17:28:45 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
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### 1. Casebook Signature

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<td>Oct-26-2020 13:50:29 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Laurence Chu (b) (4)</td>
<td><strong>Data Entry:</strong> Click Here to Enable</td>
<td>Initial Entry</td>
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