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

1. Select appropriate response - Protocol version 08 SEP 2020

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

<table>
<thead>
<tr>
<th></th>
<th>Consent Was:</th>
<th>OBTAINED Date Written Consent Obtained Sep/23/2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>OBTAINED</td>
<td>Sep/23/2020</td>
</tr>
</tbody>
</table>
**eCRF Audit Trail History**

**Demography**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Subject ID</td>
</tr>
<tr>
<td>2.</td>
<td>Birth Date:</td>
</tr>
<tr>
<td>3.</td>
<td>Sex:</td>
</tr>
<tr>
<td>4.</td>
<td>Ethnicity:</td>
</tr>
<tr>
<td>5.</td>
<td>Race: (Check X all that apply):</td>
</tr>
<tr>
<td>6.</td>
<td>Racial Designation:</td>
</tr>
</tbody>
</table>
**Header Text:** c4591001  
**Visit:** V1_DAY1_VAX1_L  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1054  
**Subject No:** 10541186  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 04:44

**eCRF Audit Trail History**

<table>
<thead>
<tr>
<th>Date of Visit</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Visit</td>
<td>Sep/23/2020</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>

***Confidential***  
FDA-CBER-2021-5683-0916192
**Inclusion Criteria Not Met**

1. Description of Inclusion Criterion Not Met

**Exclusion Criteria Met**

2. Description of Exclusion Criterion Met

Not Applicable
<table>
<thead>
<tr>
<th>Disposition - Screening</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Completion/Discontinuation/Death</td>
</tr>
<tr>
<td>2. Phase of Disposition:</td>
</tr>
<tr>
<td>3. Status:</td>
</tr>
<tr>
<td>4. Specify Status:</td>
</tr>
<tr>
<td>Line/MH Number:</td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>Start Date:</td>
</tr>
<tr>
<td>Ongoing:</td>
</tr>
<tr>
<td>End Date:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Line/MH Number:</th>
<th>2</th>
<th>Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:</th>
<th>[appendectomy]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start Date:</td>
<td>Feb/14/2017</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ongoing:</td>
<td>NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>End Date:</td>
<td>Feb/14/2017</td>
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<table>
<thead>
<tr>
<th>Line/MH Number:</th>
<th>3</th>
<th>Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:</th>
<th>[lactose intolerance]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start Date:</td>
<td>UNK/UNK/2016</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ongoing:</td>
<td>YES</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Line/MH Number:</th>
<th>4</th>
<th>Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:</th>
<th>[cyst, R axilla]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start Date:</td>
<td>UNK/UNK/2019</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ongoing:</td>
<td>YES</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## HIV Status

1. Select appropriate response - What is the subject HIV status?

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<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>The subject is NOT known to be HIV POSITIVE</td>
<td></td>
</tr>
</tbody>
</table>

**eCRF Audit Trail History**

**HIV Status**

1. Select appropriate response - What is the subject HIV status?

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<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>The subject is NOT known to be HIV POSITIVE</td>
<td></td>
</tr>
</tbody>
</table>
## Vital Signs

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>1.</td>
<td>Date: Sep/23/2020</td>
</tr>
<tr>
<td>2.</td>
<td>Weight: [84.35]</td>
</tr>
<tr>
<td>3.</td>
<td>Unit: kg</td>
</tr>
<tr>
<td>4.</td>
<td>Height: [172.72]</td>
</tr>
<tr>
<td>5.</td>
<td>Unit: cm</td>
</tr>
<tr>
<td>6.</td>
<td>Body Mass Index: [28.3]</td>
</tr>
</tbody>
</table>

### Vital Signs Details

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>7.a</td>
<td>Record Identifier: 1</td>
</tr>
<tr>
<td></td>
<td>Temperature: [97.7]</td>
</tr>
<tr>
<td></td>
<td>Unit: F</td>
</tr>
<tr>
<td></td>
<td>Temperature Location: ORAL CAVITY</td>
</tr>
</tbody>
</table>
### Lab Urinalysis

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Lab Panel:</td>
<td>Not Applicable</td>
<td>Comments</td>
</tr>
<tr>
<td>2. Lab Sub-Panel:</td>
<td>Not Applicable</td>
<td>Comments</td>
</tr>
<tr>
<td>3. Collection Date:</td>
<td>Not Applicable</td>
<td>Comments</td>
</tr>
<tr>
<td>4. Laboratory Name and Address (Derived)</td>
<td>Not Applicable</td>
<td>Comments</td>
</tr>
<tr>
<td>5. Specimen Type:</td>
<td>Not Applicable</td>
<td>Comments</td>
</tr>
</tbody>
</table>

### Lab Result

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>6.a Sponsor ID:</td>
<td>Not Applicable</td>
<td>Comments</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test:</td>
<td>Not Applicable</td>
<td>Comments</td>
</tr>
<tr>
<td>Choriogonadotropin Beta_PX113</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Result:</td>
<td>Not Applicable</td>
<td>Comments</td>
</tr>
<tr>
<td>Not Done:</td>
<td>Not Applicable</td>
<td>Comments</td>
</tr>
<tr>
<td>Disposition</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------------------------</td>
<td>--------</td>
<td></td>
</tr>
<tr>
<td>1. Randomization Date:</td>
<td>Sep/23/2020</td>
<td></td>
</tr>
<tr>
<td>2. Randomization Number:</td>
<td>[264594]</td>
<td></td>
</tr>
<tr>
<td>3. Randomization Group:</td>
<td>[ ]</td>
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</tr>
</tbody>
</table>
### eCRF Audit Trail History

**Electronic Sample Tracking**

<table>
<thead>
<tr>
<th></th>
<th>Data Origin</th>
<th>Sample Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>SITE</td>
<td>SERUM</td>
</tr>
<tr>
<td>2</td>
<td>Sample Type</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Sample Collected?</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td>Date of Collection:</td>
<td>Sep/23/2020</td>
</tr>
<tr>
<td>4</td>
<td>If no sample was collected or sample was not collected according to protocol, please provide reason:</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

**Aliquot**

Please enter barcode for each aliquot.

<table>
<thead>
<tr>
<th></th>
<th>Sample ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.a</td>
<td>[BPYWXM]</td>
</tr>
<tr>
<td>5.b</td>
<td>[BPYWXM]</td>
</tr>
</tbody>
</table>
### Electronic Sample Tracking

1. **Data Origin**: SITE  
2. **Sample Type**: NASAL SWAB  
3. **Sample Collected?** YES  
   - **Date of Collection:** Sep/23/2020  
4. If no sample was collected or sample was not collected according to protocol, please provide reason: [ ]

### Aliquot

Please enter barcode for each aliquot.

<table>
<thead>
<tr>
<th>5.a</th>
<th>Sample ID</th>
<th>[BPYWXP]</th>
</tr>
</thead>
</table>

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Status: Data Complete, Locked, Frozen, Verified
<table>
<thead>
<tr>
<th></th>
<th>Vaccination</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Was there a temporary delay of vaccination?</td>
</tr>
<tr>
<td></td>
<td>NO</td>
</tr>
<tr>
<td>2.</td>
<td>Treatment Name</td>
</tr>
<tr>
<td></td>
<td>[BLINDED THERAPY]</td>
</tr>
<tr>
<td>3.</td>
<td>Formulation:</td>
</tr>
<tr>
<td></td>
<td>INJECTION</td>
</tr>
<tr>
<td>4.</td>
<td>Dose Date Time:</td>
</tr>
<tr>
<td></td>
<td>Sep/23/2020 12:32</td>
</tr>
<tr>
<td>5.</td>
<td>Anatomical Location:</td>
</tr>
<tr>
<td></td>
<td>DELTOID MUSCLE</td>
</tr>
<tr>
<td>6.</td>
<td>Body Side:</td>
</tr>
<tr>
<td></td>
<td>LEFT</td>
</tr>
<tr>
<td>7.</td>
<td>Route:</td>
</tr>
<tr>
<td></td>
<td>INTRAMUSCULAR</td>
</tr>
<tr>
<td>8.</td>
<td>Actual Dose:</td>
</tr>
<tr>
<td></td>
<td>[ ]</td>
</tr>
<tr>
<td>9.</td>
<td>Unit:</td>
</tr>
<tr>
<td>10.</td>
<td>Timeframe Subject Was Observed</td>
</tr>
<tr>
<td></td>
<td>THE PROTOCOL SPECIFIED OBSERVATION PERIOD</td>
</tr>
<tr>
<td>11.</td>
<td>Was the subject observed for at least the protocol specified observation period after investigational product administration?</td>
</tr>
<tr>
<td></td>
<td>YES</td>
</tr>
</tbody>
</table>
1. Select appropriate response - Reactogenicity diary collection
   NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
## eCRF Audit Trail History

<table>
<thead>
<tr>
<th>Date of Visit</th>
<th>Oct/14/2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Visit</td>
<td></td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
<tr>
<td>Vital Signs Details</td>
<td></td>
</tr>
<tr>
<td>---------------------</td>
<td></td>
</tr>
<tr>
<td>2.a</td>
<td></td>
</tr>
<tr>
<td>Record Identifier:</td>
<td>1</td>
</tr>
<tr>
<td>Temperature:</td>
<td>[98.3]</td>
</tr>
<tr>
<td>Unit:</td>
<td>F</td>
</tr>
<tr>
<td>Temperature Location:</td>
<td>ORAL CAVITY</td>
</tr>
</tbody>
</table>
## Lab Urinalysis

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Lab Panel:</td>
<td>Not Applicable</td>
<td>Comments</td>
</tr>
<tr>
<td>2. Lab Sub-Panel:</td>
<td>Not Applicable</td>
<td>Comments</td>
</tr>
<tr>
<td>3. Collection Date:</td>
<td>Not Applicable</td>
<td>Comments</td>
</tr>
<tr>
<td></td>
<td>//</td>
<td></td>
</tr>
<tr>
<td>4. Laboratory Name and Address (Derived)</td>
<td>Not Applicable</td>
<td>Comments</td>
</tr>
<tr>
<td></td>
<td>[ ]</td>
<td></td>
</tr>
<tr>
<td>5. Specimen Type:</td>
<td>Not Applicable</td>
<td>Comments</td>
</tr>
</tbody>
</table>

## Lab Result

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>6.a Sponsor ID:</td>
<td>Not Applicable</td>
<td>Comments</td>
</tr>
<tr>
<td></td>
<td>[ ]</td>
<td></td>
</tr>
<tr>
<td>Test:</td>
<td>Not Applicable</td>
<td>Comments</td>
</tr>
<tr>
<td></td>
<td>Choriogonadotropin Beta_PX113</td>
<td></td>
</tr>
<tr>
<td>Result:</td>
<td>Not Applicable</td>
<td>Comments</td>
</tr>
<tr>
<td>Not Done:</td>
<td>Not Applicable</td>
<td>Comments</td>
</tr>
<tr>
<td><strong>eCRF Audit Trail History</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------------------------</td>
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</table>

**Electronic Sample Tracking**

<p>| | |</p>
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>1. Data Origin</td>
<td>SITE</td>
</tr>
<tr>
<td>2. Sample Type</td>
<td>NASAL_SWAB</td>
</tr>
<tr>
<td>3. Sample Collected?</td>
<td>NO</td>
</tr>
<tr>
<td>4. If no sample was collected or sample was not collected according to protocol, please provide reason:</td>
<td>[Pt refused the 2nd vaccine and NP swab due to AEs and discomfort respectively, but is willing to come for future study visits.]</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. Sample ID</td>
<td>[ ]</td>
</tr>
</tbody>
</table>
Vaccination

1. Was there a temporary delay of vaccination? Not Done

2. Treatment Name Not Done

3. Formulation: Not Done

4. Dose Date Time: Not Done

5. Anatomical Location: Not Done

6. Body Side: Not Done

7. Route: Not Done

8. Actual Dose: Not Done

9. Unit: Not Done

10. Timeframe Subject Was Observed Not Done

11. Was the subject observed for at least the protocol specified observation period after investigational product administration? Not Done
### eCRF Audit Trail History

<table>
<thead>
<tr>
<th>Date of Visit</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Visit</td>
<td>Nov/11/2020</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>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Data Origin</td>
<td>SITE</td>
</tr>
<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>Nov/11/2020</td>
</tr>
<tr>
<td>4.</td>
<td>If no sample was collected or sample was not collected according to protocol, please provide reason:</td>
<td></td>
</tr>
</tbody>
</table>

### Aliquot

Please enter barcode for each aliquot.

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5.a</td>
<td>Sample ID</td>
<td>[BM98DC]</td>
</tr>
<tr>
<td>5.b</td>
<td>Sample ID</td>
<td>[BM98DD]</td>
</tr>
<tr>
<td>5.c</td>
<td>Sample ID</td>
<td>[BM98DF]</td>
</tr>
<tr>
<td>Date of Visit</td>
<td></td>
<td></td>
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<td>--------------</td>
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<td></td>
</tr>
<tr>
<td>1. Date of Visit</td>
<td>//</td>
<td></td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
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<td></td>
</tr>
</tbody>
</table>
### Electronic Sample Tracking

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

### Aliquot

Please enter barcode for each aliquot.

<p>| | |</p>
<table>
<thead>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5.</td>
<td>Sample ID [ ]</td>
</tr>
<tr>
<td>Date of Visit</td>
<td></td>
</tr>
<tr>
<td>------------------------</td>
<td></td>
</tr>
<tr>
<td>1. Date of Visit</td>
<td></td>
</tr>
<tr>
<td>//</td>
<td></td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>
### Electronic Sample Tracking

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

### Aliquot

Please enter barcode for each aliquot.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5.</td>
<td>Sample ID</td>
</tr>
<tr>
<td>Date of Visit</td>
<td></td>
</tr>
<tr>
<td>-----------------------</td>
<td>-------</td>
</tr>
<tr>
<td>1. Date of Visit</td>
<td>//</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>
### Electronic Sample Tracking

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

### Aliquot

Please enter barcode for each aliquot.

5. **Sample ID**  
   - [ ]
**Date of Visit**

1. Date of Visit
2. Erroneous Visit

**COVID-19 Illness Visit**

3. COVID-19 Illness Visit:
### Signs and Symptoms

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

### Symptoms - Other

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

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

### Aliquot

Please enter barcode for each aliquot.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5.</td>
<td>Sample ID [ ]</td>
</tr>
</tbody>
</table>
**Electronic Sample Tracking**

1. **Data Origin**

2. **Sample Type**

3. **Sample Collected?**

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

   [ ]

**Aliquot**

Please enter barcode for each aliquot.

5. **Sample ID**

   [ ]
### Health Care Utilization

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

### Health Care Utilization Other

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

### Health Care Utilization

3. **Has the subject been hospitalized due to potential COVID-19 illness?**
**Illness Details**

1. **Category of Clinical Event:**
   -

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

3. **Toxicity Grade:**
   -
<table>
<thead>
<tr>
<th><strong>Date of Visit</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Visit</td>
<td>//</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>

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

1. **Data Origin**

2. **Sample Type**

3. **Sample Collected?**

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

   

5. **Sample ID**

### Aliquot

Please enter barcode for each aliquot.

5. **Sample ID**

---

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Visit:** POT_COVID_CONV A - New Unscheduled Visit

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

**Site No:** 1054

**Subject No:** 10541186

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

**Form Status:** Not Started

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Generated Time (GMT):** 29-Mar-2021 04:44
### Header Text:
- **c4591001**
- **Visit:** POT_COVID_REPEAT_SWAB - New Unscheduled Visit
- **Form Version:** 10-Oct-2020 15:57
- **Site No:** 1054
- **Subject No:** 10541186
- **Generated By:** (b) (4)
- **Form:** DATE OF VISIT - REPEAT SWAB
- **Form Status:** Not Started
- **Site Name:** (1054) Collaborative Neuroscience Network, LLC.
- **Subject Initials:** ---
- **Generated Time (GMT):** 29-Mar-2021 04:44

### Date of Visit

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

### COVID-19 Repeat Swab

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>3.</td>
<td>COVID-19 Repeat Swab:</td>
</tr>
</tbody>
</table>
### Electronic Sample Tracking

1. **Data Origin**

2. **Sample Type**

3. **Sample Collected?**

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

### Aliquot

Please enter barcode for each aliquot.

5. **Sample ID**

---

**Header Text:** c4591001  
**Visit:** POT_COVID_REPEAT_SWAB - New Unscheduled Visit  
**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB  
**Form Version:** 10-Oct-2020 15:57  
**Site No:** 1054  
**Subject No:** 10541186  
**Generated By:** (b) (4)  
**Site Name:** (1054) Collaborative Neuroscience Network, LLC.  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 04:44
### Date of Visit

<table>
<thead>
<tr>
<th></th>
<th>Date of Visit</th>
<th>Erroneous Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Unplanned Assessments</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------------------------</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>1. Assessments</td>
<td></td>
<td></td>
</tr>
<tr>
<td>#</td>
<td>Category</td>
<td>AE Identifier</td>
</tr>
<tr>
<td>----</td>
<td>---------------</td>
<td>---------------</td>
</tr>
<tr>
<td>1</td>
<td>ADVERSE EVENT</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>ADVERSE EVENT</td>
<td>2</td>
</tr>
</tbody>
</table>
### Adverse Event Report

1. **Category:**   ADVERSE EVENT  
2. **AE ID:**       [1]  
3. **Adverse Event:**   (If possible specify diagnosis, not individual symptoms)  
   [lightheadedness]  
4. **Start Date Time:**  Sep/23/2020 12:40  
5. **Is the adverse event still ongoing?**  NO  
   **End Date Time:**  Sep/23/2020 14:40  
6. **Toxicity Grade:**  1  
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:**  RELATED  
10. **Latest Action Taken with Study Treatment:**  DRUG WITHDRAWN  
11. **Was a Concomitant Medication given?**  NO  
12. **Was a Non-Drug Treatment given?**  NO  
13. **What was the outcome of this adverse event?**  RECOVERED/RESOLVED
### Form: ADVERSE EVENT REPORT

**Form Status:** Data Complete, Locked, Frozen  
**Site Name:** (1054) Collaborative Neuroscience Network, LLC.  
**Generated Time (GMT):** 29-Mar-2021 04:44

<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<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>[ ]</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td><strong>Category:</strong></td>
<td>ADVERSE EVENT</td>
</tr>
<tr>
<td><strong>AE ID:</strong></td>
<td>[2]</td>
</tr>
<tr>
<td><strong>Adverse Event:</strong></td>
<td>[nausea]</td>
</tr>
<tr>
<td><strong>Start Date Time:</strong></td>
<td>Sep/23/2020 12:40</td>
</tr>
<tr>
<td><strong>Is the adverse event still ongoing?</strong></td>
<td>NO</td>
</tr>
<tr>
<td><strong>End Date Time:</strong></td>
<td>Sep/23/2020 14:40</td>
</tr>
<tr>
<td><strong>Toxicity Grade:</strong></td>
<td>1</td>
</tr>
<tr>
<td><strong>Is the adverse event serious?</strong></td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).</td>
</tr>
<tr>
<td><strong>Is this adverse event the result of a study Medication Error?</strong></td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Is this event related to study treatment:</strong></td>
<td>RELATED</td>
</tr>
<tr>
<td><strong>Latest Action Taken with Study Treatment:</strong></td>
<td>DRUG WITHDRAWN</td>
</tr>
<tr>
<td><strong>Was a Concomitant Medication given?</strong></td>
<td>NO</td>
</tr>
<tr>
<td><strong>Was a Non-Drug Treatment given?</strong></td>
<td>NO</td>
</tr>
<tr>
<td><strong>What was the outcome of this adverse event?:</strong></td>
<td>RECOVERED/RESOLVED</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</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>[]</td>
</tr>
<tr>
<td>#</td>
<td>Category</td>
</tr>
<tr>
<td>----</td>
<td>----------</td>
</tr>
<tr>
<td>1.</td>
<td></td>
</tr>
</tbody>
</table>

---

(b) (4)
<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Category</td>
<td></td>
</tr>
<tr>
<td>2. Medication Error (Type of Medication Error):</td>
<td>[ ]</td>
</tr>
<tr>
<td>3. Start Date</td>
<td>//</td>
</tr>
<tr>
<td>4. Is the medication error still ongoing?</td>
<td></td>
</tr>
<tr>
<td>5. Latest Action Taken with Study Treatment:</td>
<td></td>
</tr>
<tr>
<td>6. Was a Concomitant Medication given?</td>
<td></td>
</tr>
<tr>
<td>7. Was a Non-Drug Treatment given?</td>
<td></td>
</tr>
<tr>
<td>8. Did the Medication Error cause the subject to be discontinued from the study?</td>
<td></td>
</tr>
<tr>
<td>9. Was this medication error associated with any adverse events?</td>
<td></td>
</tr>
<tr>
<td>10. Serious Adverse Event Number: For Pfizer Use Only</td>
<td>[ ]</td>
</tr>
<tr>
<td>#</td>
<td>Sponsor-Defined Identifier</td>
</tr>
<tr>
<td>---</td>
<td>---------------------------</td>
</tr>
<tr>
<td>1.</td>
<td></td>
</tr>
<tr>
<td>Concomitant Medications</td>
<td></td>
</tr>
<tr>
<td>-------------------------</td>
<td></td>
</tr>
<tr>
<td>1. What is the medication identifier?</td>
<td>[]</td>
</tr>
<tr>
<td>2. Category:</td>
<td></td>
</tr>
<tr>
<td>3. Concomitant Medications Pre-specified:</td>
<td></td>
</tr>
<tr>
<td>4. Medication:</td>
<td>[]</td>
</tr>
<tr>
<td>Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).</td>
<td></td>
</tr>
<tr>
<td>5. Date:</td>
<td>//</td>
</tr>
<tr>
<td>#</td>
<td>Sponsor-Defined Identifier</td>
</tr>
<tr>
<td>---</td>
<td>---------------------------</td>
</tr>
<tr>
<td>1.</td>
<td></td>
</tr>
</tbody>
</table>

---

**Note:** The table above is from a form titled **CONCOMITANT MEDICATIONS - PROHIBITED**. It appears to be a record of concomitant medications, with columns for sponsor-defined identifier, category for medication, concomitant medications pre-specified, name of medication, dose description, and form instance. The form version is noted as 22-Apr-2020 21:03. The site name is (1054) Collaborative Neuroscience Network, LLC. The subject number is 10541186, and the subject initials are ---. The generated time is 29-Mar-2021 04:44.
<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: 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>Dose:</td>
</tr>
<tr>
<td>6.</td>
<td>Dose Unit:</td>
</tr>
<tr>
<td>7.</td>
<td>Dose Frequency:</td>
</tr>
<tr>
<td>8.</td>
<td>Route:</td>
</tr>
<tr>
<td>9.</td>
<td>Start Date: //</td>
</tr>
<tr>
<td>10.</td>
<td>Ongoing?</td>
</tr>
<tr>
<td>#</td>
<td>Category</td>
</tr>
<tr>
<td>---</td>
<td>----------</td>
</tr>
<tr>
<td>1.</td>
<td></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></td>
</tr>
<tr>
<td></td>
<td>Transfusion Type:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Date of Transfusion: //</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**eCRF Audit Trail History**

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

**Header Text:** c4591001
**Visit:** End of Treatment - Unscheduled
**Form:** DISPOSITION - TREATMENT
**Form Version:** 15-Sep-2020 21:55
**Form Status:** Data Complete, Locked, Frozen, Verified
**Site No:** 1054
**Site Name:** (1054) Collaborative Neuroscience Network, LLC.
**Subject No:** 10541186
**Subject Initials:** ---
**Generated By:** (b) (4)
**Generated Time (GMT):** 29-Mar-2021 04:44

**Site No:** 1054
**Site Name:** (1054) Collaborative Neuroscience Network, LLC.
**Subject No:** 10541186
**Subject Initials:** ---
**Generated By:** (b) (4)
**Generated Time (GMT):** 29-Mar-2021 04:44
<table>
<thead>
<tr>
<th>Date of Visit</th>
</tr>
</thead>
</table>
| 1. Date of Visit
| 2. Erroneous Visit |
**Vital Signs**

1. Date: //

**Vital Signs Details**

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

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

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

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Date of Visit //</td>
</tr>
<tr>
<td>2.</td>
<td>Erroneous Visit</td>
</tr>
<tr>
<td>1. Consent Was:</td>
<td></td>
</tr>
<tr>
<td>----------------</td>
<td>---</td>
</tr>
</tbody>
</table>

**Header Text:** c4591001  
**Visit:** V201_SURVEIL_CONSENT - Unscheduled  
**Form Version:** 14-Jan-2021 02:29  
**Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE  
**Form Status:** Not Started  
**Site No:** 1054  
**Site Name:** (1054) Collaborative Neuroscience Network, LLC.  
**Subject No:** 10541186  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 04:44
Electronic Sample Tracking

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

Aliquot

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

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

<table>
<thead>
<tr>
<th>Disposition - Follow-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Completion/Discontinuation /Death:</td>
</tr>
<tr>
<td>2. Phase of Disposition:</td>
</tr>
<tr>
<td>3. Status:</td>
</tr>
<tr>
<td>4. Specify Status:</td>
</tr>
</tbody>
</table>
**eCRF Audit Trail History**

<table>
<thead>
<tr>
<th>Date of Visit</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Visit</td>
<td>Jan/20/2021</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>
| 1. | Select appropriate response - Is participant willing to return for Vaccination 3? | Participant is willing to return for Vaccination 3  
|   |                               | Participant is:  
|   |                               | eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2 |
### Treatment Unblinded

<table>
<thead>
<tr>
<th></th>
<th>Date Treatment Unblinded</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Jan/20/2021</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION</td>
<td></td>
</tr>
<tr>
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FDA-CBER-2021-5683-0916259
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**Exclusion Criteria Met**

2. **Description of Exclusion Criterion Met**
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**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

**Form Status:** Not Started

**Visit:** V101_VAX3

**Form Version:** 10-Dec-2020 02:31

**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION

**Site No:** 1054

**Subject No:** 10541186

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eCRF Audit Trail History

Subject Status

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2. Subject Status Date

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- CRF_Sign
- CRF_Sign_1

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**Form Version:** 15-Sep-2020 21:51
**Site No:** 1054
**Subject No:** 10541186
**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments
**Form Status:** Data Complete, Locked, Frozen, Verified
**Site Name:** (1054) Collaborative Neuroscience Network, LLC.
**Subject Initials:** ---
**Generated Time (GMT):** 29-Mar-2021 04:44

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- CRF_Sign
- CRF_Sign_1

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

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

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

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**Affidavit:**
By my dated signature below, I, Mark Leibowitz, 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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Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

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

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

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**Form:** DATE OF VISIT - eCRF Audit Trail History  
**Form Status:** Data Complete, Locked, Frozen, Verified  
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**Subject No:** 10541186  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 04:44
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**1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

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

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### 1.c

**[Page 123 of 179](#)**
### Medical History Term:

**1.c Line/MH Number:**

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

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

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### 1.d Start Date:

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### 1.d Ongoing:

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### 1. Select appropriate response - What is the subject HIV status?

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**2. Lab Sub-Panel:**

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### 6.a Not Done:

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**Data Entry:** NEGATIVE

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1. Randomization Date:

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2. Randomization Number:

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<td><strong>Data Entry:</strong> SITE</td>
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**1. Data Origin**

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**2. Sample Type**

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<td>auto query (autoquery)</td>
<td>Query 1: Candidate</td>
<td>'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.</td>
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<tr>
<td>Sep-24-2020 08:14:41 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
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**3. Sample Collected?**

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**5.a**

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**5.a Sample ID**

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### 1. Data Origin

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### 2. Sample Type

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### 3. Sample Collected?

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<td>auto query (autoquery)</td>
<td>Query 1: Candidate</td>
<td>'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.</td>
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<td>ACV0PFEINFP6000</td>
<td>Steven Choi (b) (4)</td>
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### 5.a

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<td>Steven Choi (b) (4)</td>
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### 5.a Sample ID

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Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit
Trail History
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1054) Collaborative Neuroscience Network, LLC.
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 04:44

**Page 137 of 179**

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

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### 5. Anatomical Location:

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### 10. Timeframe Subject Was Observed

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

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<td>Steven Choi (b) (4)</td>
<td><strong>Data Entry:</strong> YES</td>
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### 1. Select appropriate response - Reactogenicity diary collection

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<th>Reason</th>
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<tr>
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### 1. Date of Visit

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### 2.a

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<td>Temperature:: 98.3</td>
<td></td>
</tr>
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<td>Temperature Unit:: F</td>
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<td>Temperature Location:: ORAL CAVITY:</td>
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### 2.a Record Identifier:

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<th>Reason</th>
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<tbody>
<tr>
<td>Oct-16-2020 15:56:02 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
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### 2.a Temperature:

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<th>Value</th>
<th>Reason</th>
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### 1. Lab Panel:

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### 2. Lab Sub-Panel:

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

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### 5. Specimen Type:

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### 6.a

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## 1. Data Origin

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

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<th>Reason</th>
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<tr>
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<td>ACV0PFEINFP6000</td>
<td>Steven Choi (b) (4)</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
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## 4. If no sample was collected or sample was not collected according to protocol, please provide reason:

<table>
<thead>
<tr>
<th>Date</th>
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<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
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<td>Oct-16-2020 15:57:08 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi (b) (4)</td>
<td>Data Entry: Pt refused the 2nd vaccine and NP swab due to AEs and discomfort respectively, but is willing to come for future study visits.</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Oct-16-2020 15:57:20 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Closed</td>
<td>Close Auto Query</td>
</tr>
<tr>
<td>Oct-16-2020 15:57:20 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi (b) (4)</td>
<td>Data Entry: Pt withdrew consent at time of V2 NP swab.</td>
<td>Transcription Error</td>
</tr>
</tbody>
</table>
| Oct-16-2020 15:57:08 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | Entered text has either a carriage return (line break) or extra spaces at the end of the text or between words. Please correct by removing all data in
<table>
<thead>
<tr>
<th>Date/Time</th>
<th>User ID</th>
<th>Data Entry</th>
<th>Initial Entry</th>
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<tr>
<td>Oct-16-2020 15:57:08</td>
<td>ACV0PFEINFP6000</td>
<td>Pt withdrew consent at time of V2 NP swab.</td>
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<td>Steven Choi</td>
<td>(b) (4)</td>
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<td>(US &amp; Canada)</td>
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- The field and re-enter without adding extra spaces or using enter or tab keys.
1. Was there a temporary delay of vaccination?

<table>
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<th>Reason</th>
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<tbody>
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2. Treatment Name

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<td><strong>Data Entry:</strong> Not Done</td>
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3. Formulation:

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<th>Reason</th>
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<td>ACV0PFEINFP6000</td>
<td>Steven Choi (b) (4)</td>
<td><strong>Data Entry:</strong> Not Done</td>
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4. Dose Date Time:

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<tbody>
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<td>Oct-21-2020 19:58:33 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000.InFormAdapter.Discrepancy</td>
<td>DMW QUERY (b) (4)</td>
<td>Query 1: Closed</td>
<td>Auto closed by Validation Check: VC_EC001_2_06_AN</td>
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<td>ACV0PFEINFP6000</td>
<td>Steven Choi (b) (4)</td>
<td>Query 1: Answered</td>
<td>Query is ambiguous</td>
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<tr>
<td>Oct-21-2020 02:39:09 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Reissued: Opened</td>
<td>DM: Randomization number is recorded and the final disposition date is present on the Disposition - Follow-up eCRF, but there is no dosing date present on the Treatment eCRF. Please review and update as appropriate.</td>
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### 5. Anatomical Location:

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<tr>
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<td>Initial Entry</td>
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Oct-19-2020 08:20:03
(UCT-08:00)
Pacific Time
(US & Canada)

Oct-17-2020 01:07:25
(UCT-08:00)
Pacific Time
(US & Canada)

### 6. Body Side:

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### 7. Route:

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### 8. Actual Dose:

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**Query 1: Answered**

Changed data per query

DMW5060540; Randomization number is recorded and the final disposition date is present on the Disposition - Follow-up eCRF, but there is no dosing date present on the Treatment eCRF. Please review and update as appropriate.
### 9. Unit:

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<td>Initial Entry</td>
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### 10. Timeframe Subject Was Observed

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

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### 1. Date of Visit

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### 1. Data Origin

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### 2. Sample Type

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<th>Reason</th>
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<tbody>
<tr>
<td>Nov-11-2020 11:35:26</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td>Data Entry:</td>
<td>Initial Entry</td>
</tr>
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<td>(autocalc)</td>
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<td>(US &amp; Canada)</td>
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### 3. Sample Collected?

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<tbody>
<tr>
<td>Nov-11-2020 14:09:24</td>
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<td>Close Auto Query</td>
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<td>barcodes are entered.</td>
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<td>Please review and</td>
</tr>
<tr>
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<td>correct as appropriate.</td>
</tr>
<tr>
<td>Nov-11-2020 11:35:26</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi</td>
<td>Data Entry:</td>
<td>Initial Entry</td>
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### 5.a

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<th>Reason</th>
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<td>ACV0PFEINFP6000</td>
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<td>Data Entry:</td>
<td>Initial Entry</td>
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### 5.a Sample ID

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<td>Initial Entry</td>
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<td>Nov-11-2020 14:09:47</td>
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<td>Data Entry: Sample ID: BM98DF</td>
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<td>Steven Choi (b) (4)</td>
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<td>(UTC-08:00) Pacific Time (US &amp; Canada)</td>
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</tr>
<tr>
<td>Date</td>
<td>Location</td>
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<td>Value</td>
<td>Reason</td>
</tr>
<tr>
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Back to Form

**Header Text:**
- **c4591001**

**Visit:** Logs - Unscheduled

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

**Site No:** 1054

**Subject No:** 10541186

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

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

**Form Status:**

**Site Name:** (1054) Collaborative Neuroscience Network, LLC.

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

Page 154 of 179
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<th>Reason</th>
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### 1. Category:

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<th>Reason</th>
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### 2. AE ID:

<table>
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<th>Reason</th>
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<tbody>
<tr>
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<td>Initial Entry</td>
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<tr>
<td></td>
<td></td>
<td>(autocalc)</td>
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</tr>
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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>Oct-16-2020 16:03:13</td>
<td>(UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>Steven Choi</td>
<td>lightheadedness</td>
<td>Initial Entry</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(b) (4)</td>
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</table>

### 4. Start Date Time:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-16-2020 16:03:13</td>
<td>(UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>Steven Choi</td>
<td>Sep/23/2020 12:40</td>
<td>Initial Entry</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(b) (4)</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>Oct-16-2020 16:03:13</td>
<td>(UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>Steven Choi</td>
<td>NO</td>
<td>Initial Entry</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(b) (4)</td>
<td>End Date Time:</td>
<td>Sep/23/2020 14:40</td>
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### 6. Toxicity Grade:

<table>
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<tr>
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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-16-2020 16:03:13</td>
<td>(UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>Steven Choi</td>
<td>1</td>
<td>Initial Entry</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(b) (4)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
7. **Is the adverse event serious?**

If Yes, **NOTIFY PFIZER IMMEDIATELY.**

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-16-2020 16:03:13</td>
<td>(UTC-08:00) Pacific Time</td>
<td>Steven Choi</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
<td></td>
<td>(b) (4)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-16-2020 16:03:13</td>
<td>(UTC-08:00) Pacific Time</td>
<td>Steven Choi</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
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<td>(US &amp; Canada)</td>
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<td>(b) (4)</td>
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</table>

9. **Is this event related to study treatment:**

<table>
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<tr>
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<th>User</th>
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<th>Reason</th>
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<tbody>
<tr>
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<td>(UTC-08:00) Pacific Time</td>
<td>Steven Choi</td>
<td>Data Entry: RELATED</td>
<td>Initial Entry</td>
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<tr>
<td>(US &amp; Canada)</td>
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<td>(b) (4)</td>
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10. **Latest Action Taken with Study Treatment:**

<table>
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<tr>
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<th>Reason</th>
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<tbody>
<tr>
<td>Nov-16-2020 05:18:58</td>
<td>(UTC-08:00) Pacific Time</td>
<td>(b) (4)</td>
<td>Query 3: Closed</td>
<td>STAT, SPA confirmed it's OK to have more than 1 AE with DRUG WITHDRAWN</td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
<td></td>
<td>(b) (6)</td>
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<tr>
<td>Nov-15-2020 08:42:19</td>
<td>(UTC-08:00) Pacific Time</td>
<td>(b) (4)</td>
<td>Query 3: Reissued:Opened</td>
<td>Only 1 AE should have DRUG WITHDRAWN as Action Taken. Please have the PI decide which one would be the most appropriate.</td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
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<td>(b) (6)</td>
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<tr>
<td>Nov-11-2020 14:03:31</td>
<td>(UTC-08:00) Pacific Time</td>
<td>(b) (4)</td>
<td>Query 3: Reissued:Candidate</td>
<td>DM: Do not issue query. Sending to Triad team for CRA assistance.</td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
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<td>(b) (6)</td>
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<tr>
<td>Date/Time</td>
<td>User ID</td>
<td>Event Type</td>
<td>Description</td>
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<tr>
<td>---------------------------------</td>
<td>-----------------------</td>
<td>------------</td>
<td>-----------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Nov-11-2020 08:44:36</td>
<td>Steven Choi</td>
<td>Query 3: Answered</td>
<td>As written. Both AEs have the same start and stop date/time. Designating one AE to be DRUG WITHDRAWN as the LATEST ACTION TAKEN WITH STUDY DRUG and the other as NOT APPLICABLE would be arbitrary at best.</td>
<td></td>
</tr>
<tr>
<td>Nov-10-2020 19:13:07</td>
<td>Steven Choi</td>
<td>Query 3: Opened</td>
<td>Only one primary Adverse Event should be chosen to have question 'LATEST ACTION TAKEN WITH STUDY DRUG' that would indicate DRUG WITHDRAWN. Multiple are selected at this time, please select ONLY Primary Adverse Event.</td>
<td></td>
</tr>
<tr>
<td>Nov-10-2020 19:12:43</td>
<td>Steven Choi</td>
<td>Query 2: Closed</td>
<td>issued in error</td>
<td></td>
</tr>
<tr>
<td>Nov-10-2020 18:27:36</td>
<td>Steven Choi</td>
<td>Query 2: Opened</td>
<td>Only one primary Adverse Event should be chosen to have question 'Did the adverse event cause the subject to be discontinued from the study?' answered as YES if applicable. Please chose Primary Adverse Event.</td>
<td></td>
</tr>
<tr>
<td>Oct-20-2020 12:25:36</td>
<td>Hayley Wyper</td>
<td>Query 1: Closed</td>
<td>Response satisfies query</td>
<td></td>
</tr>
<tr>
<td>Oct-20-2020 08:34:54</td>
<td>Steven Choi</td>
<td>Query 1: Answered</td>
<td>Changed data per query</td>
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<tr>
<td>Date</td>
<td>Location</td>
<td>User</td>
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<td>Reason</td>
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<td>-----------------------------</td>
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<tr>
<td>Oct-16-2020 16:03:13</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi</td>
<td><strong>Drug Withdrawn</strong></td>
<td>Initial Entry</td>
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<td>(UTC-08:00) Pacific Time</td>
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11. Was a Concomitant Medication given?

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<tbody>
<tr>
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<td>ACV0PFEINFP6000</td>
<td>Steven Choi</td>
<td>NO</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-08:00) Pacific Time</td>
<td>(US &amp; Canada)</td>
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12. Was a Non-Drug Treatment given?

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<th>Reason</th>
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<tbody>
<tr>
<td>Oct-16-2020 16:03:13</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi</td>
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<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-08:00) Pacific Time</td>
<td>(US &amp; Canada)</td>
<td>(b) (4)</td>
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</table>

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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<tbody>
<tr>
<td>Oct-16-2020 16:03:13</td>
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<td>Steven Choi</td>
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<td>Initial Entry</td>
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<tr>
<td>(UTC-08:00) Pacific Time</td>
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### 14. Did the adverse event cause the subject to be discontinued from the study?

<table>
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<tr>
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<th>Reason</th>
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<tbody>
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<td>Steven Choi</td>
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- **Data Entry:** RECOVERED/RESOLVED
1. Category:

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<th>User</th>
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<th>Reason</th>
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<tbody>
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2. AE ID:

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<th>User</th>
<th>Value</th>
<th>Reason</th>
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3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

<table>
<thead>
<tr>
<th>Date (UTC-08:00)</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-16-2020 16:03:54</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi (b) (4)</td>
<td>Data Entry: nausea</td>
<td>Initial Entry</td>
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4. Start Date Time:

<table>
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<tr>
<th>Date (UTC-08:00)</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-16-2020 16:03:54</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi (b) (4)</td>
<td>Data Entry: Sep/23/2020 12:40</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

5. Is the adverse event still ongoing?

<table>
<thead>
<tr>
<th>Date (UTC-08:00)</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-16-2020 16:03:54</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi (b) (4)</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

6. Toxicity Grade:

<table>
<thead>
<tr>
<th>Date (UTC-08:00)</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-16-2020 16:03:54</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi (b) (4)</td>
<td>Data Entry: 1</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>
### 7. Is the adverse event serious?  
**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-16-2020 16:03:54</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td></td>
<td>(b) (4)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-16-2020 16:03:54</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td></td>
<td>(b) (4)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 9. Is this event related to study treatment:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-16-2020 16:03:54</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi</td>
<td>Data Entry: RELATED</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td></td>
<td>(b) (4)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-16-2020 05:19:12</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 3: Closed</td>
<td>STAT, SPA confirmed it's OK to have more than 1 AE with DRUG WITHDRAWN</td>
</tr>
<tr>
<td>05:19:12 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nov-15-2020 08:42:19</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 3: Reissued:Opene d</td>
<td>Only 1 AE should have DRUG WITHDRAWN as Action Taken. Please have the PI decide which one would be the most appropriate.</td>
</tr>
<tr>
<td>08:42:19 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nov-11-2020 14:03:47</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 3: Reissued:Candid</td>
<td>DM: Do not issue query. Sending to</td>
</tr>
<tr>
<td>Date/Time</td>
<td>User</td>
<td>Query 3: Answered</td>
<td>Description</td>
<td></td>
</tr>
<tr>
<td>------------------------</td>
<td>---------------</td>
<td>-------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Nov-11-2020 08:44:45</td>
<td>Steven Choi</td>
<td></td>
<td>As written. Both AEs have the same start and stop date/time. Designating one AE to be DRUG WITHDRAWN as the LATEST ACTION TAKEN WITH STUDY DRUG and the other as NOT APPLICABLE would be arbitrary at best.</td>
<td></td>
</tr>
<tr>
<td>Nov-10-2020 19:14:11</td>
<td></td>
<td>Query 3: Opened</td>
<td>Only one primary Adverse Event should be chosen to have question 'LATEST ACTION TAKEN WITH STUDY DRUG' that would indicate DRUG WITHDRAWN. Multiple are selected at this time, please select ONLY Primary Adverse Event.</td>
<td></td>
</tr>
<tr>
<td>Nov-10-2020 19:13:44</td>
<td></td>
<td>Query 2: Closed</td>
<td>issued in error</td>
<td></td>
</tr>
<tr>
<td>Nov-10-2020 18:28:04</td>
<td></td>
<td>Query 2: Opened</td>
<td>Only one primary Adverse Event should be chosen to have question 'Did the adverse event cause the subject to be discontinued from the study?' answered as YES if</td>
<td></td>
</tr>
</tbody>
</table>
**11. Was a Concomitant Medication given?**

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-16-2020 16:03:54 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi</td>
<td>NO</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

**Data Entry:** DRUG WITHDRAWN

**Reason:** Initial Entry

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-16-2020 16:03:54 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi</td>
<td>NO</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

**Data Entry:** DRUG WITHDRAWN

**Reason:** Initial Entry
### 13. What was the outcome of this adverse event?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-16-2020 16:03:54 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi</td>
<td><strong>Data Entry:</strong> RECOVERED/RESOLVED</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-16-2020 16:03:54 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi</td>
<td><strong>Data Entry:</strong> NO</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>
## 1. Date of Completion/Discontinuation/Death:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-11-2020 10:02:14 (UTC-08:00) Pacific 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-11-2020 08:36:55 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Answered</td>
<td>Changed Information</td>
</tr>
<tr>
<td>Nov-11-2020 08:36:55 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi (b) (4)</td>
<td>Data Entry: Sep/23/2020</td>
<td>Changed Information</td>
</tr>
<tr>
<td>Nov-10-2020 18:29:23 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Opened</td>
<td>The discontinuation date of 14OCT2020 should be relative to the AE causing the withdrawal of the study vaccine, AE start 23SEP2020 and end 23SEP2020. Please adjust Discontinuation date.</td>
</tr>
<tr>
<td>Oct-19-2020 08:19:41 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi (b) (4)</td>
<td>Data Entry: Oct/14/2020</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-19-2020 08:19:41 (UTC-08:00) Pacific 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-21-2020 07:01:25 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Closed</td>
<td>Not required.</td>
</tr>
<tr>
<td>Oct-20-2020 08:32:01 (UTC-08:00) Pacific Time</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi (b) (4)</td>
<td>Query 2: Answered</td>
<td>As written. Pt is still in study, but refused</td>
</tr>
</tbody>
</table>
VAX2 and the NP swab. Moreover, saying that "the adverse event caused the pt to discontinue study treatment" would be more accurate.

Oct-20-2020 08:29:47 (UTC-08:00) Pacific Time
ACV0PFEINFP6000 auto query (autoquery) Query 1: Closed Close Auto Query

Oct-20-2020 08:29:34 (UTC-08:00) Pacific Time
ACV0PFEINFP6000 auto query (autoquery) Query 2: Opened Status is reported as Adverse Event, but there is no Adverse Event with 'Did the adverse event cause the subject to be discontinued from the study' reported as YES. Please check and correct the data.

Oct-20-2020 08:29:34 (UTC-08:00) Pacific Time
ACV0PFEINFP6000 Steven Choi (b) (4) Data Entry: ADVERSE EVENT Changed Information

Oct-19-2020 08:19:41 (UTC-08:00) Pacific Time
ACV0PFEINFP6000 Steven Choi (b) (4) Data Entry: OTHER Initial Entry

4. Specify Status:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-20-2020 08:29:47</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi</td>
<td>(b) (4)</td>
<td>Data Entry:</td>
</tr>
<tr>
<td>(UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Oct-19-2020 08:19:41</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi</td>
<td>(b) (4)</td>
<td>Data Entry:</td>
</tr>
<tr>
<td>(UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td>Pt refused the 2nd vaccine and NP swab, but is willing to come for future study visits.</td>
</tr>
</tbody>
</table>

Initial Entry
### 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-21-2020 08:14:20</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi</td>
<td>Data Entry:</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>(UTC-08:00) Pacific</td>
<td></td>
<td>(b) (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oct-16-2020 16:00:52</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi</td>
<td>Data Entry: Oct/14/2020</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-08:00) Pacific</td>
<td></td>
<td>(b) (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</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-21-2020 08:14:20</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td>Data Entry:</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>(UTC-08:00) Pacific</td>
<td></td>
<td>(autocalc)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oct-16-2020 16:00:52</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td>Data Entry: FOLLOW-UP</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-08:00) Pacific</td>
<td></td>
<td>(autocalc)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time (US &amp; Canada)</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>Oct-21-2020 12:53:18</td>
<td>ACV0PFEINFP6000</td>
<td>Hayley Wyper</td>
<td>Query 2: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>(UTC-08:00) Pacific</td>
<td></td>
<td>(b) (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oct-21-2020 08:14:31</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi</td>
<td>Query 2: Answered</td>
<td>Changed data per query</td>
</tr>
<tr>
<td>(UTC-08:00) Pacific</td>
<td></td>
<td>(b) (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oct-21-2020 03:22:44</td>
<td>ACV0PFEINFP6000</td>
<td>Hayley Wyper</td>
<td>Query 2: Reissued:Opened</td>
<td>CLINQUERY: Thanks for the update - to 'remove' the date on this field: if you cannot remove the date, consider applying a 'not applicable' comment to that field for now</td>
</tr>
<tr>
<td>(UTC-08:00) Pacific</td>
<td></td>
<td>(b) (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oct-20-2020 13:42:23</td>
<td>ACV0PFEINFP6000</td>
<td>auto query</td>
<td>Query 3: Closed</td>
<td>Close Auto Query</td>
</tr>
<tr>
<td>(UTC-08:00) Pacific</td>
<td></td>
<td>(autoquery)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>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>Oct-20-2020 13:42:23 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 2: Answered</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Oct-20-2020 13:42:23 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi (b) (4)</td>
<td>Data Entry:</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Oct-20-2020 13:42:12 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 3: Opened</td>
<td>Response to &quot;Status&quot; is OTHER but &quot;Specify Status&quot; is missing.</td>
</tr>
<tr>
<td>Oct-20-2020 10:03:12 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Hayley Wyper (b) (4)</td>
<td>Query 2: Opened</td>
<td>CLINQUERY: Per information provided, subject will continue on in study (just discontinued from treatment). if that is correct, please leave this FUP tab blank to indicate subject will continue with follow up</td>
</tr>
<tr>
<td>Oct-19-2020 08:18:16 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi (b) (4)</td>
<td>Data Entry: OTHER</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Oct-16-2020 16:01:40 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Closed</td>
<td>Close Auto Query</td>
</tr>
<tr>
<td>Oct-16-2020 16:00:52 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Opened</td>
<td>Response to &quot;Status&quot; is WITHDRAWAL BY SUBJECT but &quot;Specify Status&quot; is missing.</td>
</tr>
<tr>
<td>Oct-16-2020 16:00:52 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi (b) (4)</td>
<td>Data Entry: WITHDRAWAL BY SUBJECT</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

### 4. Specify Status:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-20-2020 13:42:12 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi (b) (4)</td>
<td>Data Entry:</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Oct-19-2020 08:18:46 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi (b) (4)</td>
<td>Data Entry: Pt refused the 2nd vaccine and NP sw ab, but is willing to come for future st</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Data Entry:</td>
<td>Initial Entry</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>------------</td>
<td>---------------</td>
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<tr>
<td>Pt withdrew consent for personal reasons.</td>
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<tr>
<th>Oct-16-2020 16:01:40 (UTC-08:00) Pacific Time (US &amp; Canada)</th>
<th>ACV0PFEINFP6000</th>
<th>Steven Choi (b) (4)</th>
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<tbody>
<tr>
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<td>Data Entry:</td>
</tr>
<tr>
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<td>Initial Entry</td>
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<tr>
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<td>Pt withdrew consent for personal reasons.</td>
</tr>
<tr>
<td>Date</td>
<td>Location</td>
<td>User</td>
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<td>Feb-22-2021 09:03:52 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi</td>
</tr>
</tbody>
</table>
### 1. Select appropriate response - Is participant willing to return for Vaccination 3?

<table>
<thead>
<tr>
<th>Date</th>
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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Feb-22-2021 10:00:03</td>
<td>ACV0PFEINFP6000</td>
<td>auto query</td>
<td>Query 1: Deleted</td>
<td>Close Auto Query</td>
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<td></td>
<td>(UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>(autoquery)</td>
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<tr>
<td>Feb-22-2021 09:03:59</td>
<td>ACV0PFEINFP6000</td>
<td>auto query</td>
<td>Query 1: Candidate</td>
<td>The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.</td>
</tr>
<tr>
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<td>(UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>(autoquery)</td>
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</tbody>
</table>
| Feb-22-2021 09:03:59  | ACV0PFEINFP6000 | Steven Choi | **Data Entry:** Participant is willing to return for Vaccination 3  
Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2 | Initial Entry |
|                       | (UTC-08:00) Pacific Time (US & Canada) | (b) (4)       |                               |                                             |
### 1. Date Treatment Unblinded:

<table>
<thead>
<tr>
<th>Date &amp; Time (UTC)</th>
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<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Feb-22-2021 10:00:03 (UTC-08:00)</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi</td>
<td>DM: Kindly consider to update this form if require else mark as Not applicable by selecting form level comment. Thank you.</td>
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</tr>
<tr>
<td>Feb-22-2021 09:59:48 (UTC-08:00)</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi</td>
<td>Data Entry: Not Applicable</td>
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<td>Oct-23-2020 17:34:18 (UTC-08:00)</td>
<td>ACV0PFEINFP6000</td>
<td>Erica Weaver</td>
<td>Query 1: Closed</td>
<td></td>
</tr>
<tr>
<td>Oct-23-2020 08:32:43 (UTC-08:00)</td>
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<td>Steven Choi</td>
<td>Query 1: Answered</td>
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</tr>
<tr>
<td>Oct-23-2020 08:32:32 (UTC-08:00)</td>
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<td>Steven Choi</td>
<td>Data Entry: Not Applicable</td>
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</tr>
<tr>
<td>Oct-21-2020 23:36:42 (UTC-08:00)</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi</td>
<td>Data Entry: Initial Entry</td>
<td></td>
</tr>
<tr>
<td>Oct-20-2020 13:41:33 (UTC-08:00)</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi</td>
<td>Data Entry: Initial Entry</td>
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</tr>
<tr>
<td>Oct-20-2020 13:41:21 (UTC-08:00)</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi</td>
<td>Data Entry: Initial Entry</td>
<td></td>
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</tbody>
</table>

### 2. Primary Reason for Unblinding:

<table>
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<tr>
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<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Feb-22-2021 10:00:03 (UTC-08:00)</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi</td>
<td>Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION</td>
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</tr>
<tr>
<td>Feb-22-2021 09:59:48 (UTC-08:00)</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi</td>
<td>Data Entry: Initial Entry</td>
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</tr>
<tr>
<td>Date/Time</td>
<td>User ID</td>
<td>Data Entry</td>
<td>Action</td>
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</tr>
<tr>
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</tr>
<tr>
<td>Oct-23-2020 08:32:32 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi (b) (4)</td>
<td>Not Applicable</td>
<td></td>
</tr>
<tr>
<td>Oct-20-2020 13:41:33 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi (b) (4)</td>
<td>Not Done</td>
<td></td>
</tr>
<tr>
<td>Oct-20-2020 13:41:21 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi (b) (4)</td>
<td>Initial Entry</td>
<td></td>
</tr>
</tbody>
</table>
**Back to Form**

### 1. Withdrawal of Consent Date :

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Oct-23-2020 17:34:03 UTC-08:00 Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Erica Weaver</td>
<td>(b) (4) Query 2: Closed</td>
<td>Response satisfies query</td>
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<td>Oct-23-2020 08:32:57 UTC-08:00 Pacific Time (US &amp; Canada)</td>
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<td>Steven Choi</td>
<td>(b) (4) Query 2: Answered</td>
<td>Changed data per query</td>
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<tr>
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<td>ACV0PFEINFP6000</td>
<td>Steven Choi</td>
<td>(b) (4) Data Entry:</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>Oct-21-2020 23:47:52 UTC-08:00 Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4); (b) (6)</td>
<td>Query 2: Opened</td>
<td>DM: Kindly consider to update this form if require else mark as Not applicable by selecting form level comment. Thank you.</td>
</tr>
<tr>
<td>Oct-20-2020 14:16:16 UTC-08:00 Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Hayley Wyper</td>
<td>(b) (4) Query 1: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Oct-20-2020 13:41:06 UTC-08:00 Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Answered</td>
<td>Transcription Error</td>
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<tr>
<td>Oct-20-2020 13:41:06 UTC-08:00 Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi</td>
<td>(b) (4) Data Entry:</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Oct-20-2020 10:05:19 UTC-08:00 Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Hayley Wyper</td>
<td>(b) (4) Query 1: Opened</td>
<td>CLINQUERY: WOC is reported as 14Oct20 yet information suggests subject will remain in study for follow up (discontinued from treatment). Please review since this WOC matches to withdrawal of consent to participate in the study overall</td>
</tr>
<tr>
<td>Oct-16-2020 15:59:45</td>
<td>ACV0PFEINFP6000</td>
<td>Steven Choi</td>
<td>Data Entry:</td>
<td>Initial Entry</td>
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<td>(b) (4)</td>
<td>Oct/14/2020</td>
<td>(UTC-08:00) Pacific Time (US &amp; Canada)</td>
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Header Text: c4591001
Visit: Disposition - Unscheduled
Form Version: 22-Apr-2020 21:03
Site No: 1054
Subject No: 10541186
Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT - eCRF Audit Trail History
Form Status: Data Complete, Frozen, Verified
Site Name: (1054) Collaborative Neuroscience Network, LLC.
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 04:44

(b) (4)
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<td>Transcription Error</td>
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<td>(UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Data Entry: DISCONTINUED</td>
<td>Changed Information</td>
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<td>Sep-24-2020 08:14:34</td>
<td>(UTC-08:00) Pacific Time (US &amp; Canada)</td>
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<td>Sep-24-2020 08:05:14</td>
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<td>ACV0PFEINFP6000</td>
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### 2. Subject Status Date

<table>
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<td>Oct-20-2020 13:42:23</td>
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<td>Transcription Error</td>
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<td>ACV0PFEINFP6000</td>
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**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1054  
**Subject No:** 10541186  
**Generated By:** (b) (4)  

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<td>Initial Entry</td>
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<td>Data Entry: Sep/23/2020</td>
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### 1. Casebook Signature

<table>
<thead>
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<th>Date</th>
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<th>Reason</th>
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<tbody>
<tr>
<td>Oct-05-2020 12:02:49</td>
<td>ACV0PF60000</td>
<td>Steven Choi</td>
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<td>(UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>(b) (4)</td>
<td>Data Entry: Click Here to Enable</td>
<td>Data Entry: Click Here to Enable</td>
<td>Initial Entry</td>
</tr>
</tbody>
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