**Cohort Selection**

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

<table>
<thead>
<tr>
<th></th>
<th>Select appropriate response</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Protocol version 24 JUL 2020</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>What cohort does the subject belong to? STAGE 3 COHORTS</td>
<td></td>
</tr>
</tbody>
</table>
Informed Consent

1. Consent Was: OBTAINED
   Date Written Consent Obtained
   Sep/18/2020
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>1.</td>
<td>Subject ID</td>
</tr>
<tr>
<td>2.</td>
<td>Birth Date:</td>
</tr>
<tr>
<td>3.</td>
<td>Sex:</td>
</tr>
<tr>
<td>4.</td>
<td>Ethnicity:</td>
</tr>
<tr>
<td>5.</td>
<td>Race: (Check X all that apply):</td>
</tr>
<tr>
<td>6.</td>
<td>Racial Designation:</td>
</tr>
</tbody>
</table>
**Header Text:** c4591001  
**Visit:** V1_DAY1_VAX1_L  
**Form:** DATE OF VISIT  
**Form Version:** 22-Apr-2020 21:02  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1088  
**Site Name:** (1088) PMG Research of Hickory LLC  
**Subject No:** 10881220  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:22

### eCRF Audit Trail History

**Date of Visit**

<table>
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<tr>
<th></th>
<th>Date of Visit</th>
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</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Date of Visit</td>
<td>Sep/18/2020</td>
</tr>
<tr>
<td>2</td>
<td>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

1. **Date of Completion/Discontinuation/Death**: Sep/18/2020
2. **Phase of Disposition**: SCREENING
3. **Status**: COMPLETED
4. **Specify Status**: [ ]
### Medical History Details

<table>
<thead>
<tr>
<th>Line/MH Number</th>
<th>Disease/Syndrome/Surgery/Non-Drug/Allergies/Drug Allergies</th>
<th>Start Date</th>
<th>Ongoing</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>allergic rhinitis</td>
<td>UNK/UNK/2015</td>
<td>YES</td>
</tr>
<tr>
<td>2</td>
<td>headaches</td>
<td>UNK/UNK/2009</td>
<td>YES</td>
</tr>
</tbody>
</table>
**Vital Signs**

1. Date: Sep/18/2020
2. Weight: [76.4]
3. Unit: kg
4. Height: [167.0]
5. Unit: cm
6. Body Mass Index: [27.4]

**Vital Signs Details**

7.a Record Identifier: 1
Temperature: [98.0]
Unit: F
Temperature Location: FOREHEAD
**eCRF Audit Trail History**

**Lab Urinalysis**

1. Lab Panel: URINALYSIS
2. Lab Sub-Panel: PREGNANCY
3. Collection Date: Sep/18/2020
4. Laboratory Name and Address (Derived): [STUDY SITE]
5. Specimen Type: URINE

**Lab Result**

6.a Sponsor ID: [113]
   Test: Choriogonadotropin Beta_PX113
   Result: NEGATIVE
   Not Done:
### eCRF Audit Trail History

<table>
<thead>
<tr>
<th>Disposition</th>
<th>Details</th>
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</thead>
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<tr>
<td>1. Randomization Date :</td>
<td>Sep/18/2020</td>
</tr>
<tr>
<td>2. Randomization Number:</td>
<td>[93296]</td>
</tr>
<tr>
<td>3. Randomization Group:</td>
<td>[ ]</td>
</tr>
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</table>
### eCRF Audit Trail History

#### Electronic Sample Tracking

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<th>Data Origin</th>
<th>SITE</th>
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<tbody>
<tr>
<td>2</td>
<td>Sample Type</td>
<td>SERUM</td>
</tr>
<tr>
<td>3</td>
<td>Sample Collected?</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Date of Collection: Sep/18/2020</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>
<th>[BN5VKC]</th>
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</thead>
<tbody>
<tr>
<td>5.a</td>
<td>Sample ID</td>
<td>[BN5VKD]</td>
</tr>
<tr>
<td>5.c</td>
<td>Sample ID</td>
<td>[BN5VKF]</td>
</tr>
<tr>
<td>5.d</td>
<td>Sample ID</td>
<td>[BRTN3M]</td>
</tr>
<tr>
<td>5.e</td>
<td>Sample ID</td>
<td>[BRTN3N]</td>
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## eCRF Audit Trail History

### Electronic Sample Tracking

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<td>1.</td>
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<td>SITE</td>
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<tr>
<td>2.</td>
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<tr>
<td>3.</td>
<td>Sample Collected?</td>
<td>YES</td>
</tr>
<tr>
<td>3.</td>
<td>Date of Collection</td>
<td>Sep/18/2020</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>
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### Aliquot

Please enter barcode for each aliquot.

| 5.a | Sample ID | [BP976M] |
**eCRF Audit Trail History**

### Vaccination

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<td>1</td>
<td>Was there a temporary delay of vaccination?</td>
</tr>
<tr>
<td></td>
<td>NO</td>
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<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/18/2020 10:08</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>
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<td></td>
<td>YES</td>
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</table>
### eCRF Audit Trail History

#### Reactogenicity Diary

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<td>1.</td>
<td>Select appropriate response - Reactogenicity diary collection</td>
<td>NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT</td>
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**eCRF Audit Trail History**

**Date of Visit**

<table>
<thead>
<tr>
<th></th>
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<tbody>
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<td>Date of Visit</td>
<td>Oct/9/2020</td>
</tr>
<tr>
<td>2</td>
<td>Erroneous Visit</td>
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</table>
**eCRF Audit Trail History**

**Vital Signs**

<table>
<thead>
<tr>
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**Vital Signs Details**

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<tr>
<td>2.a</td>
<td></td>
</tr>
<tr>
<td>Record Identifier:</td>
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</tr>
<tr>
<td>Temperature:</td>
<td>97.3</td>
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<tr>
<td>Unit:</td>
<td>F</td>
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<tr>
<td>Temperature Location:</td>
<td>FOREHEAD</td>
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<tr>
<td>eCRF Audit Trail History</td>
<td></td>
</tr>
<tr>
<td>--------------------------</td>
<td></td>
</tr>
<tr>
<td><strong>Lab Urinalysis</strong></td>
<td></td>
</tr>
<tr>
<td>1. Lab Panel:</td>
<td>URINALYSIS</td>
</tr>
<tr>
<td>2. Lab Sub-Panel:</td>
<td>PREGNANCY</td>
</tr>
<tr>
<td>3. Collection Date:</td>
<td>Oct/9/2020</td>
</tr>
<tr>
<td>4. Laboratory Name and Address (Derived)</td>
<td>[STUDY SITE]</td>
</tr>
<tr>
<td>5. Specimen Type:</td>
<td>URINE</td>
</tr>
<tr>
<td><strong>Lab Result</strong></td>
<td></td>
</tr>
<tr>
<td>6.a Sponsor ID:</td>
<td>[113]</td>
</tr>
<tr>
<td>Test:</td>
<td>Choriogonadotropin Beta_PX113</td>
</tr>
<tr>
<td>Result:</td>
<td>NEGATIVE</td>
</tr>
<tr>
<td>Not Done:</td>
<td></td>
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</table>
### eCRF Audit Trail History

#### 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></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>
<th></th>
</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>1.</td>
<td><strong>Was there a temporary delay of vaccination?</strong></td>
</tr>
<tr>
<td>2.</td>
<td><strong>Treatment Name</strong></td>
</tr>
<tr>
<td>3.</td>
<td><strong>Formulation:</strong></td>
</tr>
<tr>
<td>4.</td>
<td><strong>Dose Date Time:</strong></td>
</tr>
<tr>
<td>5.</td>
<td><strong>Anatomical Location:</strong></td>
</tr>
<tr>
<td>6.</td>
<td><strong>Body Side:</strong></td>
</tr>
<tr>
<td>7.</td>
<td><strong>Route:</strong></td>
</tr>
<tr>
<td>8.</td>
<td><strong>Actual Dose:</strong></td>
</tr>
<tr>
<td>9.</td>
<td><strong>Unit:</strong></td>
</tr>
<tr>
<td>10.</td>
<td><strong>Timeframe Subject Was Observed</strong></td>
</tr>
<tr>
<td>11.</td>
<td><strong>Was the subject observed for at least the protocol specified observation period after investigational product administration?</strong></td>
</tr>
<tr>
<td>Date of Visit</td>
<td>Nov/6/2020</td>
</tr>
<tr>
<td>---------------</td>
<td>------------</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>

---

**eCRF Audit Trail History**

**Date of Visit**

1. **Date of Visit**: Nov/6/2020
2. **Erroneous Visit**: 

---

- **FDA-CBER-2021-5683-0966857**
<table>
<thead>
<tr>
<th></th>
<th>Data Origin</th>
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<tbody>
<tr>
<td>2.</td>
<td>Sample Type</td>
<td>SERUM</td>
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<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/6/2020</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>
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</tr>
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</table>

### Aliquot

Please enter barcode for each aliquot.

<table>
<thead>
<tr>
<th></th>
<th>Sample ID</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5.a</td>
<td>[BRFFVD]</td>
<td></td>
</tr>
<tr>
<td>5.b</td>
<td>[BRFFVF]</td>
<td></td>
</tr>
<tr>
<td>5.c</td>
<td>[BRFFVG]</td>
<td></td>
</tr>
<tr>
<td>5.d</td>
<td>[BRZF9T]</td>
<td></td>
</tr>
<tr>
<td>5.e</td>
<td>[BRZF9V]</td>
<td></td>
</tr>
<tr>
<td>Date of Visit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td></td>
<td></td>
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<tr>
<td>1. Date of Visit</td>
<td></td>
<td></td>
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<tr>
<td>2. Erroneous Visit</td>
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</tbody>
</table>

Form: DATE OF VISIT
Form Version: 22-Apr-2020 21:02
Form Status: Not Started
Site No: 1088
Site Name: (1088) PMG Research of Hickory LLC
Subject No: 10881220
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 10:22
## 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**

<p>| | |</p>
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>1.</td>
<td>Date of Visit //</td>
</tr>
<tr>
<td>2.</td>
<td>Erroneous Visit</td>
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<tr>
<td>Electronic Sample Tracking</td>
<td></td>
</tr>
<tr>
<td>-----------------------------</td>
<td></td>
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<tr>
<td>1. Data Origin</td>
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<td>2. Sample Type</td>
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<td>3. Sample Collected?</td>
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<td>4. 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.

<table>
<thead>
<tr>
<th>5. Sample ID</th>
<th>[ ]</th>
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</table>
**Date of Visit**

1. Date of Visit  //

2. Erroneous Visit
### Electronic Sample Tracking

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

### Aliquot

Please enter barcode for each aliquot.

5. **Sample ID**
   - [ ]
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<thead>
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<td>2. Erroneous Visit</td>
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</table>

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

1. Date of Assessment: //

2. Date of First Symptom Started: //

3. Symptoms Ongoing?

### Symptoms

4. Symptoms:

   Was symptom present?

### Symptoms - Other

5. Symptoms - Other Text: [ ]
### Electronic Sample Tracking

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

Please enter barcode for each aliquot.

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</thead>
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<td>5.</td>
<td>Sample ID [ ]</td>
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</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?**
<table>
<thead>
<tr>
<th>Illness Details</th>
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<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>
</tbody>
</table>

<table>
<thead>
<tr>
<th>COVID-19 Illness Visit</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>3. COVID-19 Illness Visit:</td>
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<tr>
<td>Electronic Sample Tracking</td>
<td></td>
</tr>
<tr>
<td>----------------------------</td>
<td></td>
</tr>
<tr>
<td>1. Data Origin</td>
<td></td>
</tr>
<tr>
<td>2. Sample Type</td>
<td></td>
</tr>
<tr>
<td>3. Sample Collected?</td>
<td></td>
</tr>
<tr>
<td>4. If no sample was collected or sample was not collected according to protocol, please provide reason: [ ]</td>
<td></td>
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<thead>
<tr>
<th>Aliquot</th>
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<tbody>
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<td>Please enter barcode for each aliquot.</td>
</tr>
<tr>
<td>5. Sample ID [ ]</td>
</tr>
</tbody>
</table>
### Date of Visit

1. Date of Visit

2. Erroneous Visit

### COVID-19 Repeat Swab

3. COVID-19 Repeat Swab:
## Electronic Sample Tracking

1. **Data Origin**

2. **Sample Type**

3. **Sample Collected?**

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

   [ ]

## Aliquot

Please enter barcode for each aliquot.

5. **Sample ID**

   [ ]
<table>
<thead>
<tr>
<th>Date of Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Visit //</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
</tr>
</tbody>
</table>
**Unplanned Assessments**

| 1. | Assessments |

---

**Site No:** 1088  
**Site Name:** (1088) PMG Research of Hickory LLC  
**Subject No:** 10881220  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:22
<table>
<thead>
<tr>
<th>#</th>
<th>Category</th>
<th>AE Identifier</th>
<th>Adverse Event</th>
<th>Start Date</th>
<th>Is the Adverse Event Still Ongoing</th>
<th>Form Instance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>ADVERSE EVENT</td>
<td>1</td>
<td>right frontal meningioma</td>
<td>Sep/23/2020 UNK:UNK</td>
<td>YES</td>
<td>Repeating Pages</td>
</tr>
</tbody>
</table>
## Adverse Event Report

1. **Category:** ADVERSE EVENT

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

3. **Adverse Event:**
   (If possible specify diagnosis, not individual symptoms)
   [right frontal meningioma]

4. **Start Date Time:** Sep/23/2020 UNK:UNK

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

6. **Toxicity Grade:** 2
<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the adverse event serious?</td>
<td>YES</td>
</tr>
<tr>
<td>If Yes, NOTIFY PFIZER IMMEDIATELY.</td>
<td></td>
</tr>
<tr>
<td>Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).</td>
<td></td>
</tr>
<tr>
<td>Is this serious event associated with congenital anomaly or birth defect?</td>
<td>NO</td>
</tr>
<tr>
<td>Did this serious event result in death?</td>
<td>NO</td>
</tr>
<tr>
<td>Did this serious event require or prolong hospitalization?</td>
<td>NO</td>
</tr>
<tr>
<td>Did this serious event result in persistent or significant disability/incapacity?</td>
<td>NO</td>
</tr>
<tr>
<td>Is this serious event life threatening?</td>
<td>NO</td>
</tr>
<tr>
<td>Other medically important serious event</td>
<td>YES</td>
</tr>
<tr>
<td>Is this adverse event the result of a study Medication Error?</td>
<td>NO</td>
</tr>
<tr>
<td>If Yes, record the type of medication error on the Medication Error Log.</td>
<td></td>
</tr>
<tr>
<td>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>[unknown]</td>
</tr>
<tr>
<td>Latest Action Taken with Study Treatment:</td>
<td>NOT APPLICABLE</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>11.</td>
<td>Was a Concomitant Medication given?</td>
</tr>
<tr>
<td>12.</td>
<td>Was a Non-Drug Treatment given?</td>
</tr>
<tr>
<td>13.</td>
<td>What was the outcome of this adverse event?</td>
</tr>
<tr>
<td>14.</td>
<td>Did the adverse event cause the subject to be discontinued from the study?</td>
</tr>
<tr>
<td>15.</td>
<td>Serious Adverse Event Number: For Pfizer Use Only</td>
</tr>
<tr>
<td>#</td>
<td>Category</td>
</tr>
<tr>
<td>---</td>
<td>----------</td>
</tr>
<tr>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>
### Medication Error

1. Category: 

2. Medication Error (Type of Medication Error): [ ]

3. Start Date: //

4. Is the medication error still ongoing?

5. Latest Action Taken with Study Treatment:

6. Was a Concomitant Medication given?

7. Was a Non-Drug Treatment given?

8. Did the Medication Error cause the subject to be discontinued from the study?

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

10. Serious Adverse Event Number: For Pfizer Use Only [ ]
<table>
<thead>
<tr>
<th>#</th>
<th>Sponsor-Defined Identifier</th>
<th>Category for Medication</th>
<th>Concomitant Medications Pre-specified</th>
<th>Name of Medication</th>
<th>Start Date</th>
<th>Form Instance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Repeating Pages</td>
</tr>
</tbody>
</table>
## Concomitant Medications

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></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>
</tbody>
</table>

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).

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<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>

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Site No: 1088
Subject No: 10881220
Generated By: (b) (4)
<table>
<thead>
<tr>
<th>Concomitant Medications</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. <strong>What is the medication identifier?</strong></td>
</tr>
<tr>
<td>2. <strong>Category:</strong></td>
</tr>
<tr>
<td>3. <strong>Concomitant Medications Pre-specified:</strong></td>
</tr>
<tr>
<td>4. <strong>Medication:</strong></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>
</tr>
<tr>
<td>5. <strong>Dose:</strong></td>
</tr>
<tr>
<td>6. <strong>Dose Unit:</strong></td>
</tr>
<tr>
<td>7. <strong>Dose Frequency:</strong></td>
</tr>
<tr>
<td>8. <strong>Route:</strong></td>
</tr>
<tr>
<td>9. <strong>Start Date:</strong></td>
</tr>
<tr>
<td>10. <strong>Ongoing?</strong></td>
</tr>
<tr>
<td>#</td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>1.</td>
</tr>
</tbody>
</table>

**Header Text:** c4591001

**Visit:** Logs

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881220

Subject Initials: ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22
### 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>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>
### 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>
**Header Text:** c4591001  
**Visit:** Unplanned Vaccination - Unscheduled  
**Form:** DATE OF VISIT  
**Form Version:** 22-Apr-2020 21:02  
**Form Status:** Not Started  
**Site No:** 1088  
**Site Name:** (1088) PMG Research of Hickory LLC  
**Subject No:** 10881220  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:22

<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: 

---

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VITAL SIGNS - TEMP

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

**Form Status:** Not Started

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881220

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22
<table>
<thead>
<tr>
<th><strong>Lab Urinalysis</strong></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><strong>Lab Result</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>6. Sponsor ID: [ ]</td>
</tr>
<tr>
<td>Test:</td>
</tr>
<tr>
<td>Result:</td>
</tr>
<tr>
<td>Not Done:</td>
</tr>
<tr>
<td>Vaccination</td>
</tr>
<tr>
<td>-------------</td>
</tr>
<tr>
<td>1. Was there a temporary delay of vaccination?</td>
</tr>
<tr>
<td>2. Treatment Name</td>
</tr>
<tr>
<td>3. Formulation:</td>
</tr>
<tr>
<td>4. Dose Date Time:</td>
</tr>
<tr>
<td>5. Anatomical Location:</td>
</tr>
<tr>
<td>6. Body Side:</td>
</tr>
<tr>
<td>7. Route:</td>
</tr>
<tr>
<td>8. Actual Dose:</td>
</tr>
<tr>
<td>9. Unit:</td>
</tr>
<tr>
<td>10. Timeframe Subject Was Observed</td>
</tr>
<tr>
<td>11. Was the subject observed for at least the protocol specified observation period after investigational product administration?</td>
</tr>
<tr>
<td>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>
## Contact Outcome

1. **Contact Type:**

2. **Was contact made?**

3. **Comments:** [ ]
<table>
<thead>
<tr>
<th>Date of Visit</th>
<th>1. Date of Visit</th>
<th>//</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>
Informed Consent - Asymptomatic Surveillance

1. Consent Was:

No consent was obtained.
### Electronic Sample Tracking

1. Data Origin

2. Sample Type

3. Sample Collected?

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

   [ ]

#### Aliquot

Please enter barcode for each aliquot.

5. Sample ID

   [ ]
**Electronic Sample Tracking**

1. **Data Origin**

2. **Sample Type**

3. **Sample Collected?**

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

5. **Sample ID**

**Aliquot**

Please enter barcode for each aliquot.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Disposition - Follow-Up

1. **Date of Completion/Discontinuation/Death:** //

2. **Phase of Disposition:**

3. **Status:**

4. **Specify Status:** []

---

**FDA-CBER-2021-5683-0966902**
<table>
<thead>
<tr>
<th>Date of Visit</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Visit</td>
<td>Feb/18/2021</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>
### Further Vaccination Confirmation

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

### Treatment Unblinded

<table>
<thead>
<tr>
<th></th>
<th>Date Treatment Unblinded</th>
<th>Primary Reason for Unblinding</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Feb/18/2021</td>
<td>ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Withdrawal Of Consent

1. Withdrawal of Consent
   Date: //

- FDA-CBER-2021-5683-0966906
## Death Details

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

## Cause of Death

2. Cause of Death Status: 

| Cause of Death: | [ ] |
**eCRF Audit Trail History**

**Subject Status**

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Subject Status</td>
<td>FOLLOW-UP</td>
</tr>
<tr>
<td>2.</td>
<td>Subject Status Date</td>
<td>Nov/6/2020</td>
</tr>
<tr>
<td><strong>Header Text:</strong> c4591001</td>
<td><strong>Form:</strong> CASEBOOK SIGNATURE FORM</td>
<td></td>
</tr>
<tr>
<td>--------------------------</td>
<td>----------------------------------</td>
<td></td>
</tr>
<tr>
<td><strong>Visit:</strong> Investigator Signature - Unscheduled</td>
<td><strong>Form Status:</strong> Data Complete, Signed, Verified</td>
<td></td>
</tr>
<tr>
<td><strong>Form Version:</strong> 22-Apr-2020 21:04</td>
<td><strong>Site Name:</strong> (1088) PMG Research of Hickory LLC</td>
<td></td>
</tr>
<tr>
<td><strong>Site No:</strong> 1088</td>
<td><strong>Subject No:</strong> 10881220</td>
<td></td>
</tr>
<tr>
<td><strong>Subject Initials:</strong> ---</td>
<td><strong>Generated By:</strong> (b) (4)</td>
<td></td>
</tr>
<tr>
<td><strong>Generated Time (GMT):</strong> 29-Mar-2021 10:22</td>
<td><strong>Generated Time (GMT):</strong> 29-Mar-2021 10:22</td>
<td></td>
</tr>
</tbody>
</table>

**eCRF Audit Trail History**

**Casebook Signature Form**

1. Casebook Signature  | Click Here to Enable
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>(b) (6)</td>
<td>Approved</td>
<td>Feb-22-2021 15:09:25 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>BOOK</td>
<td>Signed</td>
</tr>
</tbody>
</table>

Affidavit:

By my dated signature below, I, (b) (6) 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.
**Header Text:** c4591001  
**Visit:** V1_DAY1_VAX1_L  
**Form:** INCLUSION/EXCLUSION CRITERIA -  
**Comments**  
**Form Version:** 15-Sep-2020 21:53  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1088  
**Site Name:** (1088) PMG Research of Hickory LLC  
**Subject No:** 10881220  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:22

<table>
<thead>
<tr>
<th>Item</th>
<th>Date</th>
<th>User</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form</td>
<td>Sep-18-2020 16:39:34 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>(b) (4), (b) (6)</td>
<td>Not Applicable</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>(b) (6)</td>
<td>Approved</td>
<td>Feb-22-2021 15:09:25 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>BOOK</td>
<td>Signed</td>
</tr>
</tbody>
</table>

Affidavit:

By my dated signature below, I, (b) (6), verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

| (b) (6) | N/A | Feb-18-2021 12:21:43 (UTC-05:00) Eastern Time (US & Canada) | Edit - All signatures invalidated |

Affidavit:

N/A

| (b) (6) | Approved | Nov-10-2020 15:13:07 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |
Affidavit:
By my dated signature below, I, (b) (6) 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-18-2020</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: 24 JUL 2020</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>16:38:00</td>
<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></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-18-2020</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: STAGE 3 COHORTS</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>16:38:00</td>
<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></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-18-2020 16:38:57 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> OBTAINED Date Written Consent Obtained Sep/18/2020</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-18-2020 16:37:25 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: 10881220</td>
<td>Item copied from previous form</td>
</tr>
</tbody>
</table>

2. **Birth Date:**

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
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<td>auto calc (autocalc)</td>
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<td>Enrollment Entry</td>
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3. **Sex:**

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<th>Reason</th>
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<tbody>
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<td>Sep-18-2020 16:39:05 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: FEMALE</td>
<td>Initial Entry</td>
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4. **Ethnicity:**

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<th>Reason</th>
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**Back to Form**
5. Race: (Check X all that apply):

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<th>Value</th>
<th>Reason</th>
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<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
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## 1. Date of Visit

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

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<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-18-2020</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry:</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>16:39:53 (UTC-05:00)</td>
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### 2. Phase of Disposition:

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<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry:</td>
<td>Initial Entry</td>
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<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Sep-18-2020</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry:</td>
<td>Initial Entry</td>
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<tr>
<td>16:39:53 (UTC-05:00)</td>
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### 1.a

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<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Sep-18-2020 16:40:19</td>
<td>ACV0PF6000</td>
<td>auto calc</td>
<td>allergic rhinitis</td>
<td>Initial Entry</td>
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**Data Entry:**

1. **Line/MH Number:**

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<tbody>
<tr>
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<td></td>
<td>Initial Entry</td>
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**Data Entry:** 1

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

<table>
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<th>Reason</th>
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### 1.a Start Date:

<table>
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<tbody>
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### 1.a Ongoing:

<table>
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### 1.b

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<th>Value</th>
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Medical History Term: headach
Start Date: UNK/UNK/2009
Ongoing: YES
### 1.b Line/MH Number:

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<th>Value</th>
<th>Reason</th>
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</table>
| Sep-18-2020
16:40:38
(UTC-05:00)
Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | **Data Entry:**
2                  | Initial Entry    |

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

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16:40:38
(UTC-05:00)
Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | **Data Entry:**
headaches      | Initial Entry    |

### 1.b Start Date:

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| Sep-18-2020
16:40:38
(UTC-05:00)
Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | **Data Entry:**
UNK/UNK/2009  | Initial Entry    |

### 1.b Ongoing:

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<th>Value</th>
<th>Reason</th>
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| Sep-18-2020
16:40:38       | ACV0PFEINFP6000   | (b) (4), (b) (6) | **Data Entry:**
YES            | Initial Entry    |
### 1. Date:

<table>
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### 2. Weight:

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### 3. Unit:

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### 4. Height:
### 5. Unit:

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### 6. Body Mass Index:

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<tbody>
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<td>Sep-18-2020</td>
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<tr>
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### 7.a

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### 7.a Record Identifier:

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### 7.a Temperature:

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### 7.a Unit:

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<tbody>
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### 2. Lab Sub-Panel:

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<td>auto calc (autocalc)</td>
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<tr>
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### 3. Collection Date:

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<td>Sep-18-2020</td>
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### 4. Laboratory Name and Address (Derived)

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5. Specimen Type:

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<td>auto calc (autocalc)</td>
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6.a

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<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> Sponsor-Defined Identifier:</td>
<td>Initial Entry</td>
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<td>Sponsor-Defined Identifier:</td>
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<td>Test:: Choriogon adiotropin Beta_PX11 3</td>
<td>Initial Entry</td>
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<td></td>
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<td>Result:: NEGATIVE</td>
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### 6.a Result:

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<th>Reason</th>
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<tbody>
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<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> NEGATIVE</td>
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1. Randomization Date:

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<tbody>
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<td>Data Entry: Sep/18/2020</td>
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2. Randomization Number:

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<th>Reason</th>
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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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**Data Entry:**

- YES
- Date of Collection: Sep/18/2020

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**5.a Sample ID**

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**Data Entry:**

- Initial Entry

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**5.b**

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**Form Version:** 22-Apr-2020 21:03  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1088  
**Site Name:** (1088) PMG Research of Hickory LLC  
**Subject No:** 10881220  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:22
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### 5.a Sample ID

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2. *Treatment Name*

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3. *Formulation:*

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4. *Dose Date Time:*

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### 5. Anatomical Location:

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### 6. Body Side:

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# 10. Timeframe Subject Was Observed

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

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**2.a**

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**2.a Record Identifier:**

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### 2.a Temperature Location:

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<th>Reason</th>
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<tbody>
<tr>
<td>Oct-09-2020 18:52:25 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: FOREHEAD</td>
<td>Initial Entry</td>
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### 1. Lab Panel:

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<tbody>
<tr>
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<td>18:52:41 (UTC-05:00)</td>
<td>Eastern Time (US &amp; Canada)</td>
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### 2. Lab Sub-Panel:

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<td>Initial Entry</td>
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### 3. Collection Date:

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<tbody>
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<td>Oct/9/2020</td>
<td>Initial Entry</td>
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### 4. Laboratory Name and Address (Derived)

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### 5. Specimen Type:

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<tbody>
<tr>
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<td>auto calc</td>
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<td>Initial Entry</td>
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<tr>
<td>18:52:41 (UTC-05:00)</td>
<td>Eastern Time (US &amp; Canada)</td>
<td>(autocalc)</td>
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### 6.a

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<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td><strong>Data Entry:</strong></td>
<td>Initial Entry</td>
</tr>
<tr>
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<td>Eastern Time (US &amp; Canada)</td>
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#### 6.a Sponsor ID:

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<tbody>
<tr>
<td>Oct-09-2020</td>
<td>ACV0PFEINFP6000</td>
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<td>Initial Entry</td>
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<td>Eastern Time (US &amp; Canada)</td>
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**6.a Test:**

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**6.a Result:**

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## 1. Data Origin

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<td>Oct-09-2020</td>
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## 2. Sample Type

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## 3. Sample Collected?

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<tbody>
<tr>
<td>Oct-09-2020</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
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<td>Close Auto Query</td>
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<table>
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<tr>
<td>Oct-09-2020</td>
<td>ACV0PFEINFP6000</td>
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<td>Query 1: Candidate</td>
<td>'Sample Collected?' is Yes, however</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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<tr>
<td>Oct-09-2020 18:53:42 (UTC-05:00)</td>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: Sample ID</td>
<td>BR2S4L K updated</td>
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### 5.a Sample ID

<table>
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<td>Date/Time</td>
<td>Code</td>
<td>Event</td>
<td>Data Entry</td>
<td>Remarks</td>
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1. Was there a temporary delay of vaccination?

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<tbody>
<tr>
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2. Treatment Name

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3. Formulation:

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<tbody>
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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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### 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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<td>ACV0PFEINFP6000 (b) (4), (b) (6)</td>
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<td>(UTC-05:00) Eastern Time (US &amp; Canada)</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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<th>Reason</th>
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<tbody>
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<tr>
<td>Nov-06-2020 15:24:11</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Candidate</td>
<td>'Sample Collected?' is Yes, however</td>
</tr>
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### 5.a

<table>
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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Nov-06-2020 15:24:21</td>
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<td>BRFFV D</td>
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**Data Entry: **
- Sample ID: BRFFV D

**Reason:** Initial Entry

### 5.a Sample ID

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</tbody>
</table>

**Data Entry: **
- Sample ID: BRFFVD

**Reason:** Initial Entry

### 5.b

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<th>Value</th>
<th>Reason</th>
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**Header Text:** c4591001  
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**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History  
**Form Version:** 22-Apr-2020 21:03  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1088  
**Site Name:** (1088) PMG Research of Hickory LLC  
**Subject No:** 10881220  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:22  

**Eastern Time (US & Canada):**  
**Nov-06-2020 15:24:11**  
**ACV0PFEINFP6000**  
**Data Entry:** YES  
**Date of Collection:** Nov/6/2020  

**no barcodes are entered. Please review and correct as appropriate.**
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**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

**Site No:** 1088

**Subject No:** 10881220

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

**Generated Time (GMT):** 29-Mar-2021 10:22
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<td>(b) (4), (b) (6)</td>
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<td>(UTC-05:00)</td>
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<td>Eastern Time (US &amp; Canada)</td>
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</table>
**1. Category:**

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<th>Reason</th>
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<tbody>
<tr>
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<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> ADVERSE EVENT</td>
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**2. AE ID:**

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<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
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<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>1</td>
<td>Initial Entry</td>
</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>
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<tbody>
<tr>
<td>Nov-02-2020 16:19:58 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Oct-21-2020 18:50:06 (UTC-05:00)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Answered</td>
<td>YES</td>
</tr>
<tr>
<td>Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Steven De Beukelaer</td>
<td>Query 1: Reissued: Opened</td>
<td>GPDCLIN: thank you. Yet the diagnosis was only made now recently, correct?</td>
</tr>
<tr>
<td>---------------------------</td>
<td>------------------</td>
<td>---------------------</td>
<td>--------------------------</td>
<td>----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Oct-14-2020 14:36:23 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oct-12-2020 04:07:59 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Steven De Beukelaer (b) (4)</td>
<td>Query 1: Opened</td>
<td>GPDCLIN: which symptoms let to this diagnosis? When did they start? Was it reported before? Thank you.</td>
</tr>
<tr>
<td>Oct-09-2020 15:08:56 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> right frontal menigioma</td>
<td>Initial Entry</td>
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4. Start Date Time:

<table>
<thead>
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<th>Value</th>
<th>Reason</th>
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<tr>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: Sep/23/2020 UNK:UNK</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>15:08:56 (UTC-05:00)</td>
<td>Eastern Time (US &amp; Canada)</td>
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5. Is the adverse event still ongoing?

<table>
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<th>Date</th>
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<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Oct-09-2020</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: YES</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>15:08:56 (UTC-05:00)</td>
<td>Eastern Time (US &amp; Canada)</td>
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</table>

6. Toxicity Grade:

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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Oct-09-2020</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: 2</td>
<td>Initial Entry</td>
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<tr>
<td>15:08:56 (UTC-05:00)</td>
<td>Eastern Time (US &amp; Canada)</td>
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</tr>
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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).

<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 11:14:46 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (5)</td>
<td>Query 4: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Nov-05-2020 09:07:23 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 4: Answered</td>
<td>Changed Information</td>
</tr>
</tbody>
</table>
| Nov-05-2020 09:07:23 (UTC-05:00) Eastern Time (US & Canada) | 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 | Changed Information |
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

YES

Nov-04-2020
02:10:36
(UTC-05:00)
Eastern Time
(US & Canada)

ACV0PFEINFP6000

(b) (4)

NO

(b) (4), (b)

Query 3: Closed

recorded in Safety
<table>
<thead>
<tr>
<th>Date/Time (UTC-05:00)</th>
<th>ACV0PFEINFP6000</th>
<th>Query</th>
<th>Clinical - SAE report only records 1 SAE category (Med Important); however, AE CRF shows 2 categories. Please review and update in the appropriate location, so the same category/categories are reported in both locations.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-03-2020 11:06:24</td>
<td>(b) (4), (b) (6)</td>
<td></td>
<td>SAE RECON: right frontal meningioma(Onset date: 18 Sep 2020) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF.</td>
</tr>
<tr>
<td>Nov-03-2020 08:26:00</td>
<td>(b) (4), (b) (6)</td>
<td></td>
<td>not yet reported in sdb</td>
</tr>
<tr>
<td>Date/Time</td>
<td>User/Query</td>
<td>Event Details</td>
<td></td>
</tr>
<tr>
<td>------------------------</td>
<td>------------</td>
<td>-------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Nov-03-2020 05:36:33</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6) Query 2: Opened For AE right frontal meningioma: Response to &quot;Is the adverse event serious?&quot; is 'Yes' but &quot;Serious Adverse Event Number&quot; is blank.</td>
<td></td>
</tr>
<tr>
<td>Nov-02-2020 12:43:27</td>
<td>ACV0PFEINFP6000</td>
<td>Samuel Dychter (b) (4) Query 1: Closed Response satisfies query</td>
<td></td>
</tr>
<tr>
<td>Nov-02-2020 12:37:56</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery) Query 2: Candidate For AE right frontal meningioma: Response to &quot;Is the adverse event serious?&quot; is 'Yes' but &quot;Serious Adverse Event Number&quot; is blank.</td>
<td></td>
</tr>
<tr>
<td>Nov-02-2020 12:37:56</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery) Query 1: Answered New Information</td>
<td></td>
</tr>
<tr>
<td>Data Entry:</td>
<td>New Information</td>
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<td></td>
</tr>
<tr>
<td>------------</td>
<td>-----------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>YES</td>
<td>Is this serious event associated with congenital anomaly or birth defect?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NO</td>
<td>Did this serious event result in death?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NO</td>
<td>Did this serious event require or prolong hospitalization?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>YES</td>
<td>Did this serious event result in persistent or significant disability/incapacity?</td>
<td></td>
<td></td>
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<tr>
<td>NO</td>
<td>Is this serious event associated with congenital anomaly or birth defect?</td>
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Additional information:
- **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail
- **Visit:** Logs - Unscheduled
- **Site No:** 1088
- **Subject No:** 10881220
- **Generated By:** (b) (4)
- **Generated Time (GMT):** 29-Mar-2021 10:22

**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?
  - YES
- Did this serious event result in persistent or significant disability/incapacity?
  - NO
- Is this serious event associated with congenital anomaly or birth defect?
  - NO
**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>
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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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<td>Initial Entry</td>
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Event life threatening?
- **NO**
- Other medically important serious event
  - **YES**

---

Query 1: Opened
GPD Clin: Since this AE could be considered as an important medical event, please consider reporting this event as an SAE. Thank you.
### 9. Is this event related to study treatment:

<table>
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<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: NOT RELATED</td>
<td>Initial Entry</td>
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<tr>
<td>15:08:56</td>
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<td></td>
<td>If Not Related to study treatment(s), this event is due to:</td>
<td></td>
</tr>
<tr>
<td>(UTC-05:00)</td>
<td></td>
<td></td>
<td>OTHER</td>
<td></td>
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<tr>
<td>Eastern Time (US &amp; Canada)</td>
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<td></td>
<td>If Other, specify:</td>
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<td>unknown</td>
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### 10. Latest Action Taken with Study Treatment:

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<td>Initial Entry</td>
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<td></td>
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<tr>
<td>(UTC-05:00)</td>
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<tr>
<td>Eastern Time (US &amp; Canada)</td>
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### 11. Was a Concomitant Medication given?

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<th>Reason</th>
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<td>Data Entry: NO</td>
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**Header Text:** c4591001
**Visit:** Logs - Unscheduled
**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History
**Form Version:** 22-Apr-2020 21:02
**Form Status:** Data Complete
**Site No:** 1088
**Site Name:** (1088) PMG Research of Hickory LLC
**Subject No:** 10881220
**Subject Initials:** ---
**Generated By:** (b) (4)
**Generated Time (GMT):** 29-Mar-2021 10:22

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**FDA-CBER-2021-5683-0966971**

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**Page 134 of 144**
### 12. Was a Non-Drug Treatment given?

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<th>User</th>
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<td><strong>Data Entry:</strong> NO</td>
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### 13. What was the outcome of this adverse event?:

<table>
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<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tr>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> NOT RECOVERED/NOT RESOLVED</td>
<td>Initial Entry</td>
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### 14. Did the adverse event cause the subject to be discontinued from the study?

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<th>Location</th>
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<th>Value</th>
<th>Reason</th>
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<td>(b) (4), (b) (6)</td>
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**Header Text:** c4591001  
**Visit:** Logs - Unscheduled  
**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1088  
**Subject No:** 10881220  
**Generated By:** (b) (4)  

**Visit Log - Unscheduled**

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**Site Name:** (1088) PMG Research of Hickory LLC  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:22

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**FDA-CBER-2021-5683-0966973**
### 1. Date of Completion/Discontinuation/Death:

<table>
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<th>Value</th>
<th>Reason</th>
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<tr>
<td>Nov-06-2020 15:25:10 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Nov/6/2020</td>
<td>Initial Entry</td>
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</tbody>
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### 2. Phase of Disposition:

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<tr>
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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Nov-06-2020 15:25:10 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: VACCINATION</td>
<td>Initial Entry</td>
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### 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>Nov-06-2020 15:25:10 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: COMPLETED</td>
<td>Initial Entry</td>
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</table>
### 1. Date of Visit

<table>
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<tr>
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<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-18-2021 12:21:43 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: Feb/18/2021</td>
<td>Initial Entry</td>
</tr>
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</table>
### 1. Select appropriate response - Is participant willing to return for Vaccination 3?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-18-2021</td>
<td>ACV0PFEINFP6000</td>
<td>auto query</td>
<td>Query 1: Deleted</td>
<td>Close Auto Query</td>
</tr>
<tr>
<td>12:22:09</td>
<td>(UTC-05:00)</td>
<td>(autoquery)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eastern Time</td>
<td>(US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feb-18-2021</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>
<td>12:21:53</td>
<td>(UTC-05:00)</td>
<td>(autoquery)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eastern Time</td>
<td>(US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feb-18-2021</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
<td>Data Entry:</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>12:21:53</td>
<td>(UTC-05:00)</td>
<td>(6)</td>
<td>Participant is willing</td>
<td></td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
<td></td>
<td></td>
<td>to return for Vaccination</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Participant is:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>eligible and NOT</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>confirmed to have</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>received only placebo</td>
<td></td>
</tr>
<tr>
<td></td>
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<td>at Vaccination 3</td>
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Header Text: c4591001
Visit: Potential ReVax Initial Contact - Unscheduled
Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History
Form Version: 10-Dec-2020 02:25
Site No: 1088
Subject No: 10881220
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 10:22
Site Name: (1088) PMG Research of Hickory LLC
Subject Initials: ---
### 1. Date Treatment Unblinded:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-18-2021</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>12:22:09 (UTC-05:00)</td>
<td></td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4),</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>Eastern Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td>(b) (6)</td>
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</table>

### 2. Primary Reason for Unblinding:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Feb-18-2021</td>
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</tr>
<tr>
<td>12:22:09 (UTC-05:00)</td>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4),</td>
<td>Initial Entry</td>
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<td>(b) (6)</td>
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<td>Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION</td>
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### 1. Subject Status

<table>
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<tr>
<th>Date</th>
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<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Nov-06-2020</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td><strong>Data Entry:</strong> FOLLOW-UP</td>
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<td>15:25:10</td>
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<td>Sep-18-2020</td>
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<td><strong>Data Entry:</strong> ENROLLED/RANDOMIZED</td>
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<td>16:42:20</td>
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### 2. Subject Status Date

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
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<th>Reason</th>
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<tbody>
<tr>
<td>Nov-06-2020</td>
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<td>auto calc</td>
<td><strong>Data Entry:</strong> Nov/6/2020</td>
<td>Initial Entry</td>
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<tr>
<td>15:25:10</td>
<td>Eastern Time (US &amp; Canada)</td>
<td>(autocalc)</td>
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<td>ACV0PFEINFP6000</td>
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<td>16:42:20</td>
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**Header Text:** c4591001  
**Visit:** Subject Status - Unscheduled  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1088  
**Subject No:** 10881220  
**Generated By:** (b) (4)  
**Form:** SUBJECT STATUS - eCRF Audit Trail History  
**Form Status:** Data Complete, Verified  
**Site Name:** (1088) PMG Research of Hickory LLC  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:22

<table>
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<th>Date/Time (UTC-05:00)</th>
<th>Value</th>
<th>Data Entry:</th>
<th>Initial Entry</th>
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</thead>
<tbody>
<tr>
<td>Sep-18-2020 16:39:53</td>
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<td>Sep/18/2020</td>
<td></td>
</tr>
<tr>
<td>(Eastern Time (US &amp; Canada))</td>
<td>auto calc (autocalc)</td>
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</table>
### 1. Casebook Signature

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-10-2020 15:12:55 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Click Here to Enable</td>
<td>Initial Entry</td>
</tr>
</tbody>
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