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.

1. Select appropriate response - Protocol version
   24 JUL 2020

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

| 1. Consent Was: | OBTAINED  
| Date Written Consent Obtained  
| Aug/11/2020 |
**eCRF Audit Trail History**

### Demography

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

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<tr>
<td>2. Erroneous Visit</td>
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**Site No:** 1112  
**Site Name:** (1112) Clinical Research Atlanta
### Form Comments

#### Inclusion Criteria Not Met

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#### Exclusion Criteria Met

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### eCRF Audit Trail History

#### Disposition - Screening

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<td>1. Date of Completion/Discontinuation/Death</td>
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<td>4. Specify Status:</td>
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**[090177e196ae3dcf\Final\Final On: 01-Apr-2021 04:42 (GMT)](b) (4)**

**FDA-CBER-2021-5683-0791079**

---

**Header Text:** c4591001  
**Visit:** V1_DAY1_VAX1_L  
**Form:** DISPOSITION - SCREENING  
**Form Version:** 22-Apr-2020 21:03  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1112  
**Site Name:** (1112) Clinical Research Atlanta  
**Subject No:** 11121122  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:58
### Medical History Details

1.a  
**Line/MH Number:** [1]  
**Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:** Rosacea  
**Start Date:** Jan/1/2017  
**Ongoing:** YES

1.b  
**Line/MH Number:** [2]  
**Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:** Obesity  
**Start Date:** UNK/UNK/2018  
**Ongoing:** YES

1.c  
**Line/MH Number:** [3]  
**Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:** Intrauterine Device Placement  
**Start Date:** UNK/UNK/2017  
**Ongoing:** YES

1.d  
**Line/MH Number:** [4]  
**Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:** Intramural and Subserous Leiomyoma of Uterus  
**Start Date:** UNK/UNK/2016  
**Ongoing:** NO  
**End Date:** Nov/18/2020
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<td>Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:</td>
<td>[Abnormal Uterine bleeding]</td>
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<tr>
<td>Start Date:</td>
<td>UNK/UNK/2016</td>
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<tr>
<td>Ongoing: NO</td>
<td>End Date: Nov/18/2020</td>
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<tr>
<td>Vital Signs</td>
<td></td>
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<tr>
<td>-------------</td>
<td>--------</td>
</tr>
<tr>
<td>1. Date:</td>
<td>Aug/11/2020</td>
</tr>
<tr>
<td>2. Weight:</td>
<td>[192.0]</td>
</tr>
<tr>
<td>3. Unit:</td>
<td>LB</td>
</tr>
<tr>
<td>4. Height:</td>
<td>[67.0]</td>
</tr>
<tr>
<td>5. Unit:</td>
<td>in</td>
</tr>
<tr>
<td>6. Body Mass Index:</td>
<td>[30.1]</td>
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<table>
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<th>Vital Signs Details</th>
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<td>7.a Record Identifier:</td>
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<tr>
<td>Temperature:</td>
<td>[99.0]</td>
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<tr>
<td>Unit:</td>
<td>F</td>
</tr>
<tr>
<td>Temperature Location:</td>
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</table>
**eCRF Audit Trail History**

**Lab Urinalysis**

1. **Lab Panel:** URINALYSIS  
2. **Lab Sub-Panel:** PREGNANCY  
3. **Collection Date:** Aug/11/2020  
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

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<th>Details</th>
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<td>Aug/11/2020</td>
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<td>2. Randomization Number</td>
<td>[46901]</td>
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<td>3. Randomization Group</td>
<td>[ ]</td>
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### Electronic Sample Tracking

1. **Data Origin**: SITE
2. **Sample Type**: SERUM
3. **Sample Collected?**: YES  
   **Date of Collection**: Aug/11/2020
4. **If no sample was collected or sample was not collected according to protocol, please provide reason**: [ ]

### Aliquot

Please enter barcode for each aliquot.

5.a **Sample ID**: [BHX5WF]
5.b **Sample ID**: [BHX5WG]
5.c **Sample ID**: [BHX5WH]
5.d **Sample ID**: [BJ4P6Y]
5.e **Sample ID**: [BJ4P6Z]
### eCRF Audit Trail History

**Electronic Sample Tracking**

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<td>1.</td>
<td>Data Origin</td>
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<td>2.</td>
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<td>3.</td>
<td>Sample Collected?</td>
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<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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</tbody>
</table>

**Aliquot**

Please enter barcode for each aliquot.

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

   YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
### eCRF Audit Trail History

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

### Vaccination Symptoms Diary - Symptom Resolved Dates

1. Were medications to treat fever/pain given on the last day the Subject Diary was completed? NO

2.a Symptom: FEVER
   Were fever or systemic symptoms present on the last day the Subject Diary was completed? NO

2.b Symptom: FATIGUE
   Were fever or systemic symptoms present on the last day the Subject Diary was completed? NO

2.c Symptom: HEADACHE
   Were fever or systemic symptoms present on the last day the Subject Diary was completed? NO

2.d Symptom: CHILLS
   Were fever or systemic symptoms present on the last day the Subject Diary was completed? NO

2.e Symptom: VOMITING
   Were fever or systemic symptoms present on the last day the Subject Diary was completed? NO

2.f Symptom: DIARRHEA
   Were fever or systemic symptoms present on the last day the Subject Diary was completed? NO
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td><strong>2.g</strong></td>
<td><strong>Symptom:</strong> NEW OR WORSENED MUSCLE PAIN</td>
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<tr>
<td></td>
<td>Were fever or systemic symptoms present on the last day the Subject Diary was completed?</td>
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<tr>
<td><strong>2.h</strong></td>
<td><strong>Symptom:</strong> NEW OR WORSENED JOINT PAIN</td>
</tr>
<tr>
<td></td>
<td>Were fever or systemic symptoms present on the last day the Subject Diary was completed?</td>
</tr>
<tr>
<td><strong>3.</strong></td>
<td><strong>Injection Site Location:</strong> DELTOID MUSCLE</td>
</tr>
<tr>
<td><strong>4.</strong></td>
<td><strong>Injection Site Body Side:</strong> LEFT</td>
</tr>
<tr>
<td><strong>5.a</strong></td>
<td><strong>Injection Site Reaction:</strong> REDNESS</td>
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<tr>
<td></td>
<td>Were injection site reactions present on the last day the Subject Diary was completed?</td>
</tr>
<tr>
<td><strong>5.b</strong></td>
<td><strong>Injection Site Reaction:</strong> SWELLING</td>
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<tr>
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<td>Were injection site reactions present on the last day the Subject Diary was completed?</td>
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<tr>
<td><strong>5.c</strong></td>
<td><strong>Injection Site Reaction:</strong> PAIN AT INJECTION SITE</td>
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<td>Were injection site reactions present on the last day the Subject Diary was completed?</td>
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**eCRF Audit Trail History**

**Vital Signs**

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**Vital Signs Details**

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<td></td>
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<td></td>
<td>Temperature Location:</td>
<td>ORAL CAVITY</td>
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<td>eCRF Audit Trail History</td>
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<tr>
<td><strong>Lab Urinalysis</strong></td>
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<td>1. Lab Panel:</td>
<td>URINALYSIS</td>
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<td>2. Lab Sub-Panel:</td>
<td>PREGNANCY</td>
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<tr>
<td>3. Collection Date:</td>
<td>Sep/1/2020</td>
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</tr>
<tr>
<td>4. Laboratory Name and Address (Derived)</td>
<td>[STUDY SITE]</td>
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<tr>
<td>5. Specimen Type:</td>
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<td><strong>Lab Result</strong></td>
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<td>Result:</td>
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**eCRF Audit Trail History**

**Electronic Sample Tracking**

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**Aliquot**

Please enter barcode for each aliquot.

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## eCRF Audit Trail History

### Vaccination

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<td>1.</td>
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<td>Treatment Name</td>
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<td>6.</td>
<td>Body Side:</td>
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<td>Route:</td>
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**eCRF Audit Trail History**

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</table>
### eCRF Audit Trail History

**Vaccination Symptoms Diary - Symptom Resolved Dates**

1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?  
   - **NO**

2.a Symptom: **FEVER**  
   - Were fever or systemic symptoms present on the last day the Subject Diary was completed?  
   - **NO**

2.b Symptom: **FATIGUE**  
   - Were fever or systemic symptoms present on the last day the Subject Diary was completed?  
   - **NO**

2.c Symptom: **HEADACHE**  
   - Were fever or systemic symptoms present on the last day the Subject Diary was completed?  
   - **NO**

2.d Symptom: **CHILLS**  
   - Were fever or systemic symptoms present on the last day the Subject Diary was completed?  
   - **NO**

2.e Symptom: **VOMITING**  
   - Were fever or systemic symptoms present on the last day the Subject Diary was completed?  
   - **NO**

2.f Symptom: **DIARRHEA**  
   - Were fever or systemic symptoms present on the last day the Subject Diary was completed?  
   - **NO**
<table>
<thead>
<tr>
<th></th>
<th>Symptom:</th>
<th>NEW OR WORSENED MUSCLE PAIN</th>
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</thead>
<tbody>
<tr>
<td>2.g</td>
<td>Were fever or systemic symptoms present on the last day the Subject Diary was completed?</td>
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<tbody>
<tr>
<td>2.h</td>
<td>Were fever or systemic symptoms present on the last day the Subject Diary was completed?</td>
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<tr>
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<th>Injection Site Location:</th>
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<tbody>
<tr>
<td>3.</td>
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<table>
<thead>
<tr>
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<th>Injection Site Reaction:</th>
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<td>5.a</td>
<td>Were injection site reactions present on the last day the Subject Diary was completed?</td>
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<table>
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<tr>
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<tr>
<td>5.b</td>
<td>Were injection site reactions present on the last day the Subject Diary was completed?</td>
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</table>

<table>
<thead>
<tr>
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<th>Injection Site Reaction:</th>
<th>PAIN AT INJECTION SITE</th>
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<tbody>
<tr>
<td>5.c</td>
<td>Were injection site reactions present on the last day the Subject Diary was completed?</td>
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**eCRF Audit Trail History**

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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<tbody>
<tr>
<td>5.a</td>
<td>Sample ID</td>
</tr>
<tr>
<td>5.b</td>
<td>Sample ID</td>
</tr>
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<td>5.c</td>
<td>Sample ID</td>
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<td>5.d</td>
<td>Sample ID</td>
</tr>
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<td>5.e</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>
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**COVID-19 Illness Visit**

<table>
<thead>
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<th>3. COVID-19 Illness Visit</th>
<th></th>
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</thead>
</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**

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>
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<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>

**Header Text:**
c4591001

**Visit:** POT_COVID_ILL - New Unscheduled Visit

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

**Site No:** 1112

**Subject No:** 11121122

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

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

**Form Status:** Not Started

**Site Name:** (1112) Clinical Research Atlanta

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

---
### Health Care Utilization

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
</table>
| 1. | Physician or Healthcare Professional: [ ]
|   | Occurrence of Visits or Contacts: [ ]

### Health Care Utilization Other

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

### Health Care Utilization

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

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

1. Date of Visit //
2. Erroneous Visit

**COVID-19 Illness Visit**

3. COVID-19 Illness Visit:
<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>

---

**Header Text:** c4591001  
**Visit:** POT_COVID_CONVA - New Unscheduled Visit  
**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY  
**Form Version:** 22-Apr-2020 21:03  
**Form Status:** Not Started  
**Site No:** 1112  
**Site Name:** (1112) Clinical Research Atlanta  
**Subject No:** 11121122  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:58
**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>Unplanned Assessments</td>
<td></td>
</tr>
<tr>
<td>-----------------------</td>
<td></td>
</tr>
<tr>
<td>1. Assessments</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: Oct/1/2020</td>
</tr>
<tr>
<td>2.</td>
<td>Phase of Disposition: VACCINATION</td>
</tr>
<tr>
<td>3.</td>
<td>Status: COMPLETED</td>
</tr>
<tr>
<td>4.</td>
<td>Specify Status: [ ]</td>
</tr>
</tbody>
</table>

**eCRF Audit Trail History**

- Disposition - Treatment
  - Date of Completion/Discontinuation/Death: Oct/1/2020
  - Phase of Disposition: VACCINATION
  - Status: COMPLETED
  - Specify Status: [ ]
<table>
<thead>
<tr>
<th></th>
<th>Disposition - Follow-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Date of Completion/Discontinuation/Death:</td>
</tr>
<tr>
<td></td>
<td>//</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>

**Visit:** Follow-Up - Unscheduled  
**Site No:** 1112  
**Subject No:** 11121122  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:58
<table>
<thead>
<tr>
<th>Date of Visit</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Visit</td>
<td>//</td>
<td></td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>COVID-19 Repeat Swab</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. COVID-19 Repeat Swab:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Electronic Sample Tracking

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Data Origin</td>
</tr>
<tr>
<td>2.</td>
<td>Sample Type</td>
</tr>
</tbody>
</table>
| 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.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5.</td>
<td>Sample ID [ ]</td>
</tr>
<tr>
<td>#</td>
<td>Category</td>
</tr>
<tr>
<td>----</td>
<td>------------</td>
</tr>
<tr>
<td>1</td>
<td>ADVERSE EVENT</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>ADVERSE EVENT</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Sequence</td>
<td>Description</td>
</tr>
<tr>
<td>----------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>1.</td>
<td>Category:</td>
</tr>
<tr>
<td>2.</td>
<td>AE ID:</td>
</tr>
<tr>
<td>3.</td>
<td>Adverse Event: (If possible specify diagnosis, not individual symptoms)</td>
</tr>
<tr>
<td>4.</td>
<td>Start Date Time:</td>
</tr>
<tr>
<td>5.</td>
<td>Is the adverse event still ongoing?</td>
</tr>
<tr>
<td></td>
<td>End Date Time:</td>
</tr>
<tr>
<td>6.</td>
<td>Toxicity Grade:</td>
</tr>
<tr>
<td>7.</td>
<td>Is the adverse event serious?</td>
</tr>
<tr>
<td></td>
<td>If Yes, NOTIFY PFIZER IMMEDIATELY.</td>
</tr>
<tr>
<td></td>
<td>Fatal: Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).</td>
</tr>
<tr>
<td></td>
<td>Is this serious event associated with congenital anomaly or birth defect?</td>
</tr>
<tr>
<td></td>
<td>Did this serious event result in death?</td>
</tr>
<tr>
<td></td>
<td>Did this serious event require or prolong hospitalization?</td>
</tr>
<tr>
<td></td>
<td>Did this serious event result in persistent or significant disability/incapacity?</td>
</tr>
<tr>
<td></td>
<td>Is this serious event life threatening?</td>
</tr>
<tr>
<td></td>
<td>Other medically important serious event</td>
</tr>
<tr>
<td>8.</td>
<td>Is this adverse event the result of a study Medication Error?</td>
</tr>
<tr>
<td></td>
<td>If Yes, record the type of medication error on the Medication Error Log.</td>
</tr>
<tr>
<td>No.</td>
<td>Question</td>
</tr>
<tr>
<td>-----</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>9.</td>
<td>Is this event related to study treatment?</td>
</tr>
<tr>
<td></td>
<td>If Not Related to study treatment(s), this event is due to:</td>
</tr>
<tr>
<td></td>
<td>If Other, specify:</td>
</tr>
<tr>
<td>10.</td>
<td>Latest Action Taken with Study Treatment:</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>
</tbody>
</table>
## Adverse Event Report

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Category: ADVERSE EVENT</td>
</tr>
<tr>
<td>2.</td>
<td>AE ID: [2]</td>
</tr>
<tr>
<td>3.</td>
<td>Adverse Event: [Worsening of Abnormal Uterine Bleeding]</td>
</tr>
<tr>
<td>4.</td>
<td>Start Date Time: Sep/14/2020 UNK:UNK</td>
</tr>
<tr>
<td>5.</td>
<td>Is the adverse event still ongoing? NO</td>
</tr>
<tr>
<td>6.</td>
<td>Toxicity Grade: 3</td>
</tr>
<tr>
<td>7.</td>
<td>Is the adverse event serious? NO</td>
</tr>
</tbody>
</table>

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

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

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

| 9. | Is this event related to study treatment: NOT RELATED |

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

**OTHER**

If Other, specify:

- [history of uterine fibroids]
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>10.</strong> Latest Action Taken with Study Treatment:</td>
<td>NOT APPLICABLE</td>
</tr>
<tr>
<td><strong>11.</strong> Was a Concomitant Medication given?</td>
<td>NO</td>
</tr>
<tr>
<td><strong>12.</strong> Was a Non-Drug Treatment given?</td>
<td>YES</td>
</tr>
<tr>
<td><strong>13.</strong> What was the outcome of this adverse event?:</td>
<td>RECOVERED/RESOLVED</td>
</tr>
<tr>
<td><strong>14.</strong> Did the adverse event cause the subject to be discontinued from the study?</td>
<td>NO</td>
</tr>
<tr>
<td><strong>15.</strong> 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)

FDA-CBER-2021-5683-0791119
Medication Error

1. Category:

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

3. Start Date: //</p

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><strong>1.</strong></td>
<td>What is the medication identifier?</td>
</tr>
<tr>
<td><strong>2.</strong></td>
<td>Category:</td>
</tr>
<tr>
<td><strong>3.</strong></td>
<td>Concomitant Medications Pre-specified:</td>
</tr>
<tr>
<td><strong>4.</strong></td>
<td>Medication:</td>
</tr>
<tr>
<td></td>
<td>Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).</td>
</tr>
<tr>
<td><strong>5.</strong></td>
<td>Date:</td>
</tr>
<tr>
<td></td>
<td>//</td>
</tr>
<tr>
<td>#</td>
<td>Sponsor-Defined Identifier</td>
</tr>
<tr>
<td>----</td>
<td>---------------------------</td>
</tr>
<tr>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>
Concomitant Medications

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

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

**Form Status:** Not Started

**Site No:** 1112

**Site Name:** (1112) Clinical Research Atlanta

**Subject No:** 11121122

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:58
Vital Signs Details

2. Record Identifier:
   Temperature: [ ]
   Unit:
   Temperature Location:
**Lab Urinalysis**

1. Lab Panel: 
2. Lab Sub-Panel: 
3. Collection Date: //
4. Laboratory Name and Address (Derived) [ ]
5. Specimen Type: 

<table>
<thead>
<tr>
<th>Test</th>
<th>Result</th>
<th>Not Done</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

**Lab Result**

6. Sponsor ID: [ ]

**Form Details**
- **Header Text:** c4591001
- **Visit:** Unplanned Vaccination - Unscheduled
- **Form Version:** 20-Feb-2021 02:14
- **Site No:** 1112
- **Subject No:** 11121122
- **Generated By:** (b) (4)
- **Generated Time (GMT):** 29-Mar-2021 10:58
- **Site Name:** (1112) Clinical Research Atlanta
- **Subject Initials:** ---

**Form:** LAB URINALYSIS - PREGNANCY TEST
**Form Status:** Not Started

---

**Internal Reference:**
- FDA-CBER-2021-5683-0791131

---

**Page 58 of 200**
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Was there a temporary delay of vaccination?</td>
</tr>
<tr>
<td>2.</td>
<td>Treatment Name</td>
</tr>
<tr>
<td>3.</td>
<td>Formulation:</td>
</tr>
<tr>
<td>4.</td>
<td>Dose Date Time:</td>
</tr>
<tr>
<td>5.</td>
<td>Anatomical Location:</td>
</tr>
<tr>
<td>6.</td>
<td>Body Side:</td>
</tr>
<tr>
<td>7.</td>
<td>Route:</td>
</tr>
<tr>
<td>8.</td>
<td>Actual Dose:</td>
</tr>
<tr>
<td>9.</td>
<td>Unit:</td>
</tr>
<tr>
<td>10.</td>
<td>Timeframe Subject Was Observed</td>
</tr>
<tr>
<td>11.</td>
<td>Was the subject observed for at least the protocol specified observation period after investigational product administration?</td>
</tr>
<tr>
<td>Contact Outcome</td>
<td></td>
</tr>
<tr>
<td>-----------------</td>
<td>--</td>
</tr>
<tr>
<td>1. Contact Type:</td>
<td></td>
</tr>
<tr>
<td>2. Was contact made?</td>
<td></td>
</tr>
<tr>
<td>3. Comments:</td>
<td>[ ]</td>
</tr>
</tbody>
</table>
### Contact Outcome

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Contact Type:</td>
</tr>
<tr>
<td>2.</td>
<td>Was contact made?</td>
</tr>
<tr>
<td>3.</td>
<td>Comments: [ ]</td>
</tr>
<tr>
<td>Date of Visit</td>
<td>Jan/20/2021</td>
</tr>
<tr>
<td>---------------</td>
<td>-------------</td>
</tr>
<tr>
<td>1. Date of Visit</td>
<td>Jan/20/2021</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - Unscheduled

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

**Site No:** 1112

**Subject No:** 11121122

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

**Form:** DATE OF VISIT

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

**Site Name:** (1112) Clinical Research Atlanta

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:58

---

**eCRF Audit Trail History**

**Date of Visit**

1. Date of Visit  
   Jan/20/2021

2. Erroneous Visit
### eCRF Audit Trail History

**Further Vaccination Confirmation**

1. **Select appropriate response - Is participant willing to return for Vaccination 3?**
   - Participant is willing to return for Vaccination 3
     - Participant is: eligible per other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2
**Header Text:**  c4591001

**Visit:** Disposition - Unscheduled  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1112  
**Subject No:** 11121122  
**Generated By:** (b) (4)  

**Form:** TREATMENT UNBLINDED  
**Form Status:** Data Complete, Frozen, Verified  
**Site Name:** (1112) Clinical Research Atlanta  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:58

---

### eCRF Audit Trail History

**Treatment Unblinded**

1. Date Treatment Unblinded: Jan/20/2021
2. Primary Reason for Unblinding: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

---

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<table>
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<tr>
<th>Withdrawal Of Consent</th>
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**Header Text:** c4591001  
**Visit:** Disposition - Unscheduled  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1112  
**Subject No:** 11121122  
**Generated By:** (b) (4)  
**Site Name:** (1112) Clinical Research Atlanta  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:58  

Withdrawal Of Consent

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

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

### Cause of Death

| 2. Cause of Death Status: | 
| Cause of Death: | [ ] |
**eCRF Audit Trail History**

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

| Consent Was: | Obtained Date Written Consent Obtained Jan/22/2021 |
### 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
### eCRF Audit Trail History

**Disposition - Screening for Further Vaccination**

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<td>REPEAT SCREENING 1</td>
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<td>[ ]</td>
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</tr>
<tr>
<td>Lab Urinalysis</td>
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<tr>
<td>1. Lab Panel:</td>
<td>URINALYSIS</td>
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</tr>
<tr>
<td>2. Lab Sub-Panel:</td>
<td>PREGNANCY</td>
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</tr>
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<td>3. Collection Date:</td>
<td>Jan/22/2021</td>
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</tr>
<tr>
<td>4. Laboratory Name and Address</td>
<td>[STUDY SITE]</td>
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<tr>
<td>(Derived)</td>
<td></td>
<td></td>
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<td>5. Specimen Type:</td>
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<tr>
<td>Lab Result</td>
<td></td>
<td></td>
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<tr>
<td>6.a Sponsor ID:</td>
<td>[113]</td>
<td></td>
</tr>
<tr>
<td>Test:</td>
<td>Choriogonadotropin Beta_PX113</td>
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<tr>
<td>Result:</td>
<td></td>
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**Form Version:** 14-Jan-2021 02:21  
**Site No:** 1112  
**Subject No:** 11121122  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:58
**eCRF Audit Trail History**

**Electronic Sample Tracking**

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<td>3.</td>
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<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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<td>[BJ1JZW]</td>
<td></td>
</tr>
<tr>
<td>5.b</td>
<td>[BJ1JZX]</td>
<td></td>
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<td>5.c</td>
<td>[BRMY32]</td>
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## eCRF Audit Trail History

### Electronic Sample Tracking

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### Aliquot

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**Vaccination**

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<tr>
<td>2</td>
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<td>Formulation</td>
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<td>4</td>
<td>Dose Date Time</td>
</tr>
<tr>
<td>5</td>
<td>Anatomical Location</td>
</tr>
<tr>
<td>6</td>
<td>Body Side</td>
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<tr>
<td>7</td>
<td>Route</td>
</tr>
<tr>
<td>8</td>
<td>Actual Dose</td>
</tr>
<tr>
<td>9</td>
<td>Unit</td>
</tr>
<tr>
<td>10</td>
<td>Timeframe Subject Was Observed</td>
</tr>
<tr>
<td>11</td>
<td>Was the subject observed for at least the protocol specified observation period after investigational product administration?</td>
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**eCRF Audit Trail History**

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<tr>
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<tr>
<td>2. Erroneous Visit</td>
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<tr>
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<tr>
<td>2.</td>
<td>Lab Sub-Panel: Not Done</td>
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</tr>
<tr>
<td>3.</td>
<td>Collection Date: Not Done</td>
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<td>4.</td>
<td>Laboratory Name and Address (Derived): Not Done</td>
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### Lab Result

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<td>Test:</td>
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<tr>
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<td></td>
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<tr>
<td>Date of Collection:</td>
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<tr>
<td>If no sample was collected or sample was not collected according to protocol, please provide reason:</td>
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<tr>
<td>Sample ID</td>
<td>[BRMY6X]</td>
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eCRF Audit Trail History

**Vaccination**

1. Was there a temporary delay of vaccination? | NO
2. Treatment Name | [BNT162b2]
3. Formulation: | INJECTION
4. Dose Date Time: | Feb/11/2021 18:22
5. Anatomical Location: | DELTOID MUSCLE
6. Body Side: | LEFT
7. Route: | INTRAMUSCULAR
8. Actual Dose: | [30.0]
9. Unit: | ug
10. Timeframe Subject Was Observed | 30 MINUTES
11. Was the subject observed for at least the protocol specified observation period after investigational product administration? | YES
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<th>Date of Visit</th>
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</thead>
<tbody>
<tr>
<td>1. Date of Visit</td>
<td>Mar/11/2021</td>
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<tr>
<td>2. Erroneous Visit</td>
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### Contact Outcome

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<tr>
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<th>Contact Type:</th>
<th>TELEPHONE VISIT</th>
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| 2. | Was contact made? | YES  
|   | Date of Contact: | Mar/11/2021 |
| 3. | Comments: | [] |

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**Header Text:** c4591001  
**Visit:** V103_MONTH1  
**Form:** CONTACT OUTCOME  
**Form Version:** 22-Apr-2020 21:04  
**Form Status:** Data Complete, Verified  
**Site No:** 1112  
**Site Name:** (1112) Clinical Research Atlanta  
**Subject No:** 11121122  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:58
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</thead>
<tbody>
<tr>
<td>1. Date of Visit</td>
<td>//</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
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</tr>
<tr>
<td>Contact Outcome</td>
<td></td>
</tr>
<tr>
<td>-----------------</td>
<td></td>
</tr>
<tr>
<td>1. Contact Type:</td>
<td></td>
</tr>
<tr>
<td>2. Was contact made?</td>
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<tr>
<td>3. Comments: [ ]</td>
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## Date of Visit

<p>| | | |</p>
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<tr>
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</thead>
<tbody>
<tr>
<td>1.</td>
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<tr>
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<td>Erroneous Visit</td>
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<tr>
<td>Contact Outcome</td>
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<td>1. Contact Type:</td>
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<td>2. Was contact made?</td>
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<tr>
<td>3. Comments:</td>
<td>[ ]</td>
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**eCRF Audit Trail History**

**Disposition - Treatment**

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<tr>
<td>1.</td>
<td>Date of Completion/Discontinuation/Death : Mar/11/2021</td>
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<tr>
<td>2.</td>
<td>Phase of Disposition: OPEN LABEL TREATMENT</td>
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<td>3.</td>
<td>Status: COMPLETED</td>
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**eCRF Audit Trail History**

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**Audit Trail**

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

- CRF_Sign

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<th>Name</th>
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<th>Date</th>
<th>Type</th>
<th>Action</th>
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<tr>
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<td>Approved</td>
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<td>BOOK</td>
<td>Signed</td>
</tr>
</tbody>
</table>

**Affidavit:**

By my dated signature below, I, Nathan Segall, 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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**Back to Form**

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*(FDA-CBER-2021-5683-0791166)*
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**Confidential**

FDA-CBER-2021-5683-0791169
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This form requires signing by a member of each of the following signature groups:

- **CRF_Sign**

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<th>Signature Meaning</th>
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<th>Type</th>
<th>Action</th>
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<td>Approved</td>
<td>Mar-11-2021 18:56:31 (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, Nathan Segall, 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, Nathan Segall, 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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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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### 1.a Line/MH Number:

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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 Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

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**1.c Ongoing:**

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**1.d**

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<td>End Date</td>
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<td>NO</td>
<td>Nov/18/2020</td>
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<td>UNK/UNK/2016</td>
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Initial Entry: Auto calc (autocalc)
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<td>y Term: bleeding</td>
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### 1.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

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# Lab Panel

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# Lab Sub-Panel

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# Laboratory Name and Address (Derived)

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# Specimen Type

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**6.a**

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**6.a Result:**

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**Generated Time (GMT):** 29-Mar-2021 10:58
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<th>Reason</th>
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<td><strong>Data Entry:</strong> SERUM</td>
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### 3. Sample Collected?

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<td>'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.</td>
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Date of Collection: Aug/11/2020

### 5.a

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### 5.a Sample ID

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### 5.b

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### 5.b Sample ID

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

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

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- **Data Entry:** YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
### 1. Date of Visit

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1. **Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

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2.a

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2.a **Symptom:**

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2.a **Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

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**2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

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**2.c**

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2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

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Page 132 of 200
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**2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

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### 2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

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### 2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

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**Symptom:**

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

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3. Injection Site Location:

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### 5.a Injection Site Reaction:

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**Data Entry:**

Injection Site Reaction:: REDNESS

Were injection site reactions present on the last day the Subject Diary was completed?:

NO

**Initial Entry**

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### 5.a Were injection site reactions present on the last day the Subject Diary was completed?

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**Data Entry:**

NO

**Initial Entry**

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### 5.b

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**Data Entry:**

Injection Site Reaction:: SWELLING

Were injection site reactions present on the last day the Subject Diary was completed?:

NO

**Initial Entry**

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### 5.b Injection Site Reaction:

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### 5.b Were injection site reactions present on the last day the Subject Diary was completed?

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### 5.c Were injection site reactions present on the last day the Subject Diary was completed?

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### 2.a

#### 2.a Record Identifier:

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### 6.a

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### 2. Sample Type

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### 3. Sample Collected?

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### 5.a

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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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**FDA-CBER-2021-5683-0791218**
### 1. Date of Visit

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**Data Entry: Oct/1/2020**
1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

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<th>Reason</th>
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2.a

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<td>Symptom:: FEVER</td>
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<td>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</td>
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2.a Symptom:

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2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

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2.b

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Page 147 of 200
### 2.b Symptom:

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### 2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

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### 2.c

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Were fever or systemic symptoms present on the last day the Subject Diary was completed?:
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**Data Entry:**

- **2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

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**Data Entry:**

- **2.d Symptom:**

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**Data Entry:**

- **2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

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**Data Entry:**
- **Symptom:** VOMITING
- **Reason:** NO

### 2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

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**Data Entry:**
- **Value:** NO

### 2.f

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**Data Entry:**
- **Symptom:** DIARRHEA
- **Reason:** NO
2.5 Symptom:

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**Data Entry:** Injection Site Reaction: REDNESS

Were injection site reactions present on the last day the Subject Diary was completed?: NO

**Initial Entry**

### 5.a Were injection site reactions present on the last day the Subject Diary was completed?

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**Data Entry:** NO

### 5.b

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**Data Entry:** Injection Site Reaction: SWE LLI NG

Were injection site reactions present on the last day the Subject Diary was completed?: NO

**Initial Entry**
### 5.b Injection Site Reaction:

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### 5.5 Were injection site reactions present on the last day the Subject Diary was completed?

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### 5.c Injection Site Reaction:

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Were injection site reactions present on the last day the Subject Diary was completed?: NO

### 5.c Were injection site reactions present on the last day the Subject Diary was completed?

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### Sample Type

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### Sample Collected?

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<td>Oct-01-2020 16:40:44</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
<td>Data Entry: YES</td>
<td>Initial Entry</td>
</tr>
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<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
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<td>Date of Collection: Oct/1/2020</td>
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</tr>
</tbody>
</table>

### 5.a

<table>
<thead>
<tr>
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<th>Reason</th>
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<tbody>
<tr>
<td>Oct-01-2020 16:40:54</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
<td>Data Entry: Sample ID: BPXRY6</td>
<td>Initial Entry</td>
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<tr>
<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
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</table>
### 5.a Sample ID

<table>
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<th>Reason</th>
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<tbody>
<tr>
<td>Oct-01-2020 16:40:54 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
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<td>(b) (4), (b) (6)</td>
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<td>Initial Entry</td>
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### 5.b

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<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-01-2020 16:41:03 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Sample ID: BPXRY7</td>
<td>Initial Entry</td>
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</table>

### 5.b Sample ID

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Oct-01-2020 16:41:03 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: BPXRY7</td>
<td>Initial Entry</td>
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### 5.c

<table>
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<tbody>
<tr>
<td>Oct-01-2020 16:41:10 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Sample ID: BPXRY8</td>
<td>Initial Entry</td>
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### 5.c Sample ID

<table>
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<td>ACV0PFEINFP6000</td>
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### 5.d

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<th>Reason</th>
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<tbody>
<tr>
<td>Oct-01-2020 16:41:26 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Sample ID: BJ4PPK</td>
<td>Initial Entry</td>
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### 5.d Sample ID

<table>
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<tr>
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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
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<td>(b)</td>
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<td>Initial Entry</td>
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### 5.e

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<tr>
<td>Oct-01-2020 16:41:37</td>
<td>ACV0PFEINFP6000</td>
<td>(b)</td>
<td>Data Entry: Sample ID: BJ4PPL</td>
<td>Initial Entry</td>
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<td>(4), (6)</td>
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### 5.e Sample ID

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</thead>
<tbody>
<tr>
<td>Oct-01-2020 16:41:37</td>
<td>ACV0PFEINFP6000</td>
<td>(b)</td>
<td>Data Entry: BJ4PPL</td>
<td>Initial Entry</td>
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<tr>
<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td></td>
<td>(4), (6)</td>
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</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>Oct-01-2020 16:40:33</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4),</td>
<td>Data Entry: Oct/1/2020</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern</td>
<td></td>
<td>(b) (6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
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</table>

### 2. Phase of Disposition:

<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>Oct-01-2020 16:40:33</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td>Data Entry: VACCINATION</td>
<td>Initial Entry</td>
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<tr>
<td>(UTC-05:00) Eastern</td>
<td></td>
<td>(autocalc)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
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</table>

### 3. Status:

<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>Oct-01-2020 16:40:33</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4),</td>
<td>Data Entry: COMPLETED</td>
<td>Initial Entry</td>
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<tr>
<td>(UTC-05:00) Eastern</td>
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<td>(b) (6)</td>
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<td></td>
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<tr>
<td>Date</td>
<td>Location</td>
<td>User</td>
<td>Value</td>
<td>Reason</td>
</tr>
<tr>
<td>--------------------------</td>
<td>-----------------------------------------------</td>
<td>------------</td>
<td>---------------------</td>
<td>----------------</td>
</tr>
<tr>
<td>Jan-22-2021 17:34:22</td>
<td>ACV0PFEINFP6000 (UTC-05:00) Eastern Time</td>
<td>(b) (4)</td>
<td>Form Created</td>
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</tr>
<tr>
<td></td>
<td>(US &amp; Canada)</td>
<td>(b) (6)</td>
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</tr>
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</table>
### ADVERSE EVENT REPORT - Audit Trail

**Date:** Jan-22-2021 17:36:55  
**Location:** (UTC-05:00) Eastern Time (US & Canada)  
**User:** ACV0PFEINFP6000  
**Value:** 
- (b) (4) 
- (b) (6)  
**Reason:** Form Created
## 1. Category:

<table>
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<tr>
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<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-22-2021 17:34:22</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> ADVERSE EVENT</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

## 2. AE ID:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-22-2021 17:34:22</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> 1</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mar-09-2021 10:23:21</td>
<td>ACV0PFEINFP6000</td>
<td>Giselle Castillo</td>
<td><strong>Query 1:</strong> Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(b) (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mar-08-2021 13:48:57</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Query 1:</strong> Answered</td>
<td>per coordinator, sent today</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mar-04-2021 06:50:32</td>
<td>ACV0PFEINFP6000</td>
<td>Giselle Castillo</td>
<td><strong>Query 1:</strong> Reissued:Opened</td>
<td>Thank you for confirming. However, no FU with information from pathology report has been added. Thanks</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(b) (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feb-24-2021 14:21:22</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Query 1:</strong> Answered</td>
<td>per coordinator, follow up sent</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feb-23-2021 11:18:19</td>
<td>ACV0PFEINFP6000</td>
<td>Giselle Castillo</td>
<td><strong>Query 1:</strong> Reissued:Opened</td>
<td>Thanks for confirming. Please provide a future date for a FU so I can close the query.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(b) (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feb-15-2021 18:22:19</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4)</td>
<td><strong>Query 1:</strong> Answered</td>
<td>will send f/up</td>
</tr>
</tbody>
</table>
Visit: Logs - Unscheduled
Site No: 1112
Subject No: 11121122
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 10:58

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>Feb-01-2021 11:14:21 (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>Feb-01-2021 10:59:20 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Answered</td>
<td>New Information</td>
</tr>
<tr>
<td>Feb-01-2021 10:59:20 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Sep/14/2020 UNK:UNK</td>
<td>New Information</td>
</tr>
<tr>
<td>Feb-01-2021 09:37:41 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Opened</td>
<td>SAE RECON:AER#2021064931, the Onset Date was reported as 14SEP2020 in Safety database but in INFORM the Start date was unchanged</td>
</tr>
</tbody>
</table>
**Header Text:**
- **c4591001**
- **Visit:** Logs - Unscheduled
- **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History
- **Form Version:** 22-Apr-2020 21:02
- **Site No:** 1112
- **Site Name:** (1112) Clinical Research Atlanta
- **Subject No:** 11121122
- **Subject Initials:** ---
- **Generated By:** (b) (4)
- **Generated Time (GMT):** 29-Mar-2021 10:58

UNK/OCT/2020. Dates are to match therefore please update INFORM or submit a follow-up safety report to update Safety.

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Jan-22-2021 17:34:22 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Oct/UNK/2020 UNK:UNK</td>
<td>Initial Entry</td>
</tr>
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</table>

### 6. Toxicity Grade:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-22-2021 17:34:22 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: 3</td>
<td>Initial Entry</td>
</tr>
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</table>

### 7. Is the adverse event serious?

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-26-2021 09:40:25 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Jan-25-2021 10:22:53 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Answered</td>
<td>SAE has been submitted</td>
</tr>
<tr>
<td>Jan-25-2021 08:15:34 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Opened</td>
<td>SAE RECON: INTRAMURAL AND SUBSEROUS</td>
</tr>
<tr>
<td>Generated Time (GMT): 29-Mar-2021 10:58</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>-----------------------------------------</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AE CRF:</td>
<td><strong>leiomyoma of uterus</strong> is not reported to the 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>
<td></td>
<td></td>
<td></td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Query 1: Deleted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Query can be addressed internally</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Query 1: Candidate</th>
</tr>
</thead>
<tbody>
<tr>
<td>For AE intramural and subserous leiomyoma of uterus: Response to &quot;Is the adverse event serious?&quot; is 'Yes' but &quot;Serious Adverse Event Number&quot; is blank.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Data Entry: YES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is this serious event associated with congenital anomaly or birth defect?</td>
</tr>
<tr>
<td>NO</td>
</tr>
<tr>
<td>Did this serious event result in death?</td>
</tr>
<tr>
<td>NO</td>
</tr>
<tr>
<td>Did this serious event require or prolong hospitalization?</td>
</tr>
<tr>
<td>YES</td>
</tr>
<tr>
<td>Did this serious event result in persistent or significant disability/incapacity?</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>Jan-22-2021 17:34:22</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4),</td>
<td>Data Entry:</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>Jan-22-2021 17:34:22</td>
<td>(UTC-05:00) Eastern</td>
<td>(b) (6)</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>Location (US &amp; Canada)</td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

9. Is this event related to study treatment:

<table>
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<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-22-2021 17:34:22</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4),</td>
<td>Data Entry:</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>Jan-22-2021 17:34:22</td>
<td>(UTC-05:00) Eastern</td>
<td>(b) (6)</td>
<td>NOT RELATED</td>
<td></td>
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<tr>
<td>Location (US &amp; Canada)</td>
<td></td>
<td></td>
<td>If Not Related to study treatment (s), this event is due to:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>OTHER</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>If Other, specify:</td>
<td></td>
</tr>
<tr>
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<td>Unknown</td>
<td></td>
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</table>

10. Latest Action Taken with Study Treatment:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-22-2021 17:34:22</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4),</td>
<td>Data Entry:</td>
<td>Initial Entry</td>
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<tr>
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<td>(b) (6)</td>
<td>NOT APPLICABLE</td>
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11. Was a Concomitant Medication given?

<table>
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<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

***Confidential***
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>Jan-22-2021 17:34:22</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

13. What was the outcome of this adverse event?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-22-2021 17:34:22</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
<td>Data Entry: RECOVERED/RESOLVED</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-22-2021 17:34:22</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

15. Serious Adverse Event Number: For Pfizer Use Only

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-26-2021 09:40:15</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
<td>Data Entry: 2021064931</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>
### 1. Category:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-22-2021 17:36:55</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td><strong>Data Entry:</strong> ADVERSE EVENT</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern Time</td>
<td>(autocalc)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 2. AE ID:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-22-2021 17:36:55</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td>2</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern Time</td>
<td>(autocalc)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 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>Jan-28-2021 19:15:34</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
<td>Query 1: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern Time</td>
<td></td>
<td>(6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jan-26-2021 08:02:37</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
<td>Query 1: Answered</td>
<td>unlock med hx for update</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern Time</td>
<td></td>
<td>(b) (6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jan-25-2021 19:47:53</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
<td>Query 1: Opened</td>
<td>ClinQuery: Worsening of</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern Time</td>
<td></td>
<td>(6)</td>
<td></td>
<td>Abnormal Uterine Bleeding</td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td>Subject does not have a</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>medhx of uterine bleeding.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Please update the medhx or</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>verbatim term as appropriate.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Thanks</td>
</tr>
<tr>
<td>Jan-22-2021 17:36:55</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
<td><strong>Data Entry:</strong></td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern Time</td>
<td></td>
<td>(b) (6)</td>
<td>Worsening of Abnormal Uterine</td>
<td></td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
<td></td>
<td></td>
<td>Bleeding</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 5. Is the adverse event still ongoing?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-22-2021 17:36:55</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td>End Date Time: Nov/18/2020 UNK:UNK</td>
</tr>
</tbody>
</table>

### 6. Toxicity Grade:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-22-2021 17:36:55</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: 3</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 7. Is the adverse event serious?

*If Yes, NOTIFY PFIZER IMMEDIATELY.*

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-16-2021 03:00:12</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 3: Closed</td>
<td>Event no longer listed in SDB.</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feb-12-2021 10:56:04</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 3: Reissued:Candidate</td>
<td>Pending SDB update</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date:</td>
<td>Time:</td>
<td>Timezone:</td>
<td>Event:</td>
<td>Status:</td>
</tr>
<tr>
<td>-----------------</td>
<td>-------------</td>
<td>-------------------------</td>
<td>---------------------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>Feb-10-2021</td>
<td>08:02:02</td>
<td>Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000 (b) (4), (b) (6)</td>
<td>Query 3: Answered</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>update was submitted</td>
</tr>
<tr>
<td>Feb-10-2021</td>
<td>03:48:51</td>
<td>Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000 (b) (4), (b) (6)</td>
<td>Query 3: Opened</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>SAE RECON:AER#2021064931, abnormal uterine bleeding was reported as serious in Safety database while downgraded to non serious in inform. Please confirm event seriousness. If safety update is required, please submit a follow-up form.</td>
</tr>
<tr>
<td>Feb-09-2021</td>
<td>10:25:41</td>
<td>Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000 (b) (4), (b) (6)</td>
<td>Query 2: Deleted</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Changed Information</td>
</tr>
<tr>
<td>Feb-09-2021</td>
<td>10:25:41</td>
<td>Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000 (b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Changed Information</td>
</tr>
<tr>
<td>Jan-26-2021</td>
<td>09:41:20</td>
<td>Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000 (b) (4), (b) (6)</td>
<td>Query 2: Reissued: Candidate</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>pending SDB update</td>
</tr>
<tr>
<td>Jan-25-2021</td>
<td>10:23:13</td>
<td>Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000 (b) (4), (b) (6)</td>
<td>Query 2: Answered</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>SAE has been submitted</td>
</tr>
<tr>
<td>Jan-25-2021</td>
<td>08:16:35</td>
<td>Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000 (b) (4), (b) (6)</td>
<td>Query 2: Opened</td>
</tr>
</tbody>
</table>
|                 |             |                         |                                 | SAE RECON: Worsening of Abnormal Uterine Bleeding 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
<table>
<thead>
<tr>
<th>Date/Time</th>
<th>Time Zone</th>
<th>Event ID</th>
<th>Query Type</th>
<th>Serial No.</th>
<th>Data Entry</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-25-2021</td>
<td>08:15:56</td>
<td>ACV0PFEINFP6000</td>
<td>Query 1: Deleted</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jan-22-2021</td>
<td>17:36:55</td>
<td>ACV0PFEINFP6000</td>
<td>auto query</td>
<td>(autoquery)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jan-22-2021</td>
<td>17:36:55</td>
<td>ACV0PFEINFP6000</td>
<td>Data Entry: YES</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

For AE Worsening of Abnormal Uterine Bleeding: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
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>Jan-22-2021 17:36:55  (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
</tr>
</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>Jan-22-2021 17:36:55  (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NOT RELATED</td>
<td>Initial Entry</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>If Not Related to study treatment (s), this event is due to:</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>Jan-22-2021 17:36:55  (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NOT APPLICABLE</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

11. Was a Concomitant Medication given?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-22-2021 17:36:55  (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

12. Was a Non-Drug Treatment given?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-22-2021 17:36:55  (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: YES</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

---

***Confidential***
**Header Text:** c4591001  
**Visit:** Logs - Unscheduled  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1112  
**Subject No:** 11121122  
**Generated By:** (b) (4)  
**Date** | **Location** | **User** | **Value** | **Reason**  
--- | --- | --- | --- | ---  
Jan-22-2021 17:36:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | RECOVERED/RESOLVED | Initial Entry  

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

**Date** | **Location** | **User** | **Value** | **Reason**  
--- | --- | --- | --- | ---  
Jan-22-2021 17:36:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | NO | Initial Entry
### 1. Date of Visit

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-20-2021 14:06:59</td>
<td>ACV0PFEINFP6000</td>
<td>(b)</td>
<td>Jan/20/2021</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

**Data Entry:**

Jan/20/2021

**Reason:**

Initial Entry
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>
</table>
| Jan-20-2021 14:07:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (6) | **Data Entry:**
|                   |                   |               | Participant is willing to return for Vaccination 3
|                   |                   |               | Participant is: eligible per other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2 | Initial Entry           |
## 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>Mar-02-2021</td>
<td>ACV0PFEINFP6000</td>
<td>(b) 4, (b) 6</td>
<td>Data Entry §1 Jan/2021</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>13:21:36</td>
<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feb-26-2021</td>
<td>ACV0PFEINFP6000</td>
<td>(b) 4, (b) 6</td>
<td>Query 1: Closed</td>
<td>As per the confirmation from the site that they unblinded before contacting the subject to see if they were willing, CDS confirmed we can close these queries.</td>
</tr>
<tr>
<td>09:59:31</td>
<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feb-25-2021</td>
<td>ACV0PFEINFP6000</td>
<td>(b) 4, (b) 6</td>
<td>Query 1: Reissued: Opened</td>
<td>DM: Thank you. Please note that Date Treatment Unblinded (19/Jan/2021) should be equal to or after DOV in REVAX CONTACT (20/Jan/2021) visit when Reason is ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION. Please review and update as appropriate.</td>
</tr>
<tr>
<td>07:27:29</td>
<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feb-24-2021</td>
<td>ACV0PFEINFP6000</td>
<td>(b) 4, (b) 6</td>
<td>Query 1: Answered</td>
<td>subjects were unblinded before eligibility and/or willingness to continue was confirmed*.</td>
</tr>
<tr>
<td>14:19:41</td>
<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feb-23-2021</td>
<td>ACV0PFEINFP6000, InFormAdapter.Discrepancy</td>
<td>DMW QUERY (b) 4</td>
<td>Query 1: Opened</td>
<td>DMW7351615; Date Treatment Unblinded should be equal to or after DOV in REVAX CONTACT (20/Jan/2021) visit when Reason is ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION. Please review and update as appropriate.</td>
</tr>
<tr>
<td>04:36:58</td>
<td>(UTC-05:00) Eastern Time</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**2. Primary Reason for Unblinding:**

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-20-2021 14:06:49 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION</td>
<td>Initial Entry</td>
</tr>
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</table>
## Date of Visit

<table>
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<tr>
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<td>(b) 6</td>
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<td>(US &amp; Canada)</td>
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### Consent Was:

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

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**Data Entry: Jan/22/2021 Initial Entry**

### 2. Phase of Disposition:

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<td></td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: REPEAT SCREENING 1 Initial Entry</td>
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**Data Entry: REPEAT SCREENING 1 Initial Entry**

### 3. Status:

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<th>Reason</th>
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<td>Data Entry: COMPLETED Initial Entry</td>
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</table>

**Data Entry: COMPLETED Initial Entry**
**Back to Form**

### 1. Lab Panel:

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<td>Jan-22-2021 10:45:57 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
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### 2. Lab Sub-Panel:

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### 3. Collection Date:

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

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### 5. Specimen Type:

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### 6.a

<table>
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### 6.a Not Done:

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<td>(b) (4), (b) (6)</td>
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### 1. Data Origin

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<tr>
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<td>ACV0PFEINFP6000</td>
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<td>Initial Entry</td>
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### 2. Sample Type

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

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<th>Location</th>
<th>User</th>
<th>Value</th>
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<tbody>
<tr>
<td>Jan-22-2021 10:46:42</td>
<td>ACV0PFEINFP6000</td>
<td>auto query</td>
<td>Query 1: Deleted</td>
<td>Close Auto Query</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>auto query (autoquery)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Jan-22-2021 10:46:33</td>
<td>ACV0PFEINFP6000</td>
<td>auto query</td>
<td>Query 1: Candidate</td>
<td>'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>auto query (autoquery)</td>
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<tr>
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<td>(b) (4),</td>
<td><strong>Data Entry:</strong> YES</td>
<td>Initial Entry</td>
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<tr>
<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
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<td>Date of Collection: Jan/22/2021</td>
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### 5.a

<table>
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<th>Reason</th>
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<tbody>
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<td>Jan-22-2021 10:46:42</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4),</td>
<td><strong>Data Entry:</strong></td>
<td>Initial Entry</td>
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<tr>
<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>(b) (6)</td>
<td>Sample ID: BJ1JZW</td>
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### 5.a Sample ID

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<th>Reason</th>
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| Jan-22-2021 10:46:42  
(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b)      | Data Entry: BJ1JZW | Initial Entry   |

### 5.b

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| Jan-22-2021 10:46:51  
(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b)      | Data Entry: Sample ID: BJ1JZX | Initial Entry   |

### 5.b Sample ID

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| Jan-22-2021 10:46:51  
(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b)      | Data Entry: BJ1JZX | Initial Entry   |

### 5.c

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(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b)      | Data Entry: Sample ID: BRMY32 | Initial Entry   |

### 5.c Sample ID

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(UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b)      | Data Entry: BRMY32 | Initial Entry   |
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<td><strong>Data Entry:</strong> SITE</td>
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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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<td>auto query (autoquery)</td>
<td>Query 1: Candidate</td>
<td>'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.</td>
</tr>
<tr>
<td>Jan-22-2021 10:47:20 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
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<td>Initial Entry</td>
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### 5.a

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<th>Reason</th>
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<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Sample ID: BRMY2W</td>
<td>Initial Entry</td>
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</table>
### 5.a Sample ID

<table>
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<th>Value</th>
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## 1. Was there a temporary delay of vaccination?

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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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### 8. Actual Dose:

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### 9. Unit:

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<td>Jan-22-2021 10:46:22</td>
<td>ACV0PFEINFP6000</td>
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<td>ug</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. Lab Panel:

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### 3. Collection Date:

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<td>Mar-12-2021 15:44:08</td>
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<td>CLINQUERY-</td>
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<td></td>
<td>Please clarify why pregnancy tests were not performed at V3 &amp; V4. Subject is &lt;60 yrs old and has no MH of surgical sterilization. Test is required for WOCBP. Please review and record PDs, if applicable.</td>
</tr>
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</table>

<table>
<thead>
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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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6.a Sponsor ID:

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6.a Result:

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6.a Not Done:
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<td>(b) (4)</td>
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**Header Text:** c4591001
**Visit:** V102_VAX4
**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail
**History**
**Form Version:** 14-Jan-2021 02:21
**Site No:** 1112
**Site Name:** (1112) Clinical Research Atlanta
**Subject No:** 11121122
**Subject Initials:** ---
**Generated By:** (b) (4)
**Generated Time (GMT):** 29-Mar-2021 10:58
1. Data Origin

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<td>Feb-11-2021 21:53:18 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
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2. Sample Type

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3. Sample Collected?

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<td>Close Auto Query</td>
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<td>'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.</td>
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5.a

<table>
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<th>Reason</th>
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<td>(b), (4), (6)</td>
<td>Data Entry: Sample ID: BRMY6X</td>
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### 5.a Sample ID

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

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### 2. Treatment Name

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### 3. Formulation:

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### 5. Anatomical Location:

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### 6. Body Side:

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### 8. Actual Dose:

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### 9. Unit:

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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. Contact Type:

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### 2. Was contact made?

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| Mar-11-2021 17:57:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)   | **Data Entry:** YES | Date of Contact:  
Mar/11/2021   | Initial Entry |
### 1. Date of Completion/Discontinuation/Death:

<table>
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<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Mar-11-2021 17:57:32 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Mar/11/2021</td>
<td>Initial Entry</td>
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### 2. Phase of Disposition:

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<th>Reason</th>
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<td>Mar-11-2021 17:57:32 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: OPEN LABEL TREATMENT</td>
<td>Initial Entry</td>
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### 3. Status:

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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
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<td>Initial Entry</td>
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### 1. Subject Status

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<th>Value</th>
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<tbody>
<tr>
<td>Oct-01-2020 16:40:33</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> FOLLOW-UP</td>
<td>Initial Entry</td>
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<td>(US &amp; Canada)</td>
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<tr>
<td>Time (US &amp; Canada)</td>
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</tr>
<tr>
<td>Aug-11-2020 18:03:15</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> ENROLLED/RANDOMIZED</td>
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<td>(US &amp; Canada)</td>
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<td>Aug-11-2020 17:32:30</td>
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### 2. Subject Status Date

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<td><strong>Data Entry:</strong> Aug/11/2020</td>
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<td>Aug-11-2020 17:32:30</td>
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<td><strong>Data Entry:</strong> Aug/11/2020</td>
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### 1. Casebook Signature

<table>
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<th>Date</th>
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<tbody>
<tr>
<td>Sep-10-2020 10:06:20</td>
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<td>(b) (4) (6)</td>
<td>Data Entry: Click Here to Enable</td>
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**Form Version:** 22-Apr-2020 21:04  
**Site No:** 1112  
**Subject No:** 11121122  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:58

**Site Name:** (1112) Clinical Research Atlanta  
**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History  
**Form Status:** Data Complete, Signed, Verified

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**FDA-CBER-2021-5683-0791273**