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**

<table>
<thead>
<tr>
<th>1. Consent Was:</th>
<th>OBTAINED</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Date Written Consent Obtained Aug/11/2020</td>
</tr>
</tbody>
</table>
### Demography

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

**Date of Visit**

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>1</td>
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</tr>
<tr>
<td>2</td>
<td>Erroneous Visit</td>
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**Form Comments**

**Inclusion Criteria Not Met**

1. Description of Inclusion Criterion Not Met | Not Applicable

**Exclusion Criteria Met**

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

<table>
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<tr>
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<td>Phase of Disposition:</td>
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<td>3.</td>
<td>Status:</td>
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**Header Text:** c4591001  
**Visit:** V1_DAY1_VAX1_L  
**Form Version:** 22-Apr-2020 21:03  
**Form:** DISPOSITION - SCREENING  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1090  
**Site Name:** (1090) Wake Research Associates, LLC  
**Subject No:** 10901140  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:31
### Medical History Details

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<tr>
<th>Line/MH Number</th>
<th>Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies</th>
<th>Start Date</th>
<th>Ongoing</th>
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<tbody>
<tr>
<td>1.a</td>
<td>[Latex Allergy]</td>
<td>UNK/UNK/1990</td>
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<tr>
<td>1.b</td>
<td>[Allergy to Dust]</td>
<td>UNK/UNK/1990</td>
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<tr>
<td>1.c</td>
<td>[Allergy to Tomatoes]</td>
<td>UNK/UNK/1990</td>
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<tr>
<td>Line/MH Number</td>
<td>Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies</td>
<td>Start Date</td>
<td>Ongoing</td>
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<td>---------------</td>
<td>----------------------------------------------------------</td>
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<td>[8]</td>
<td>[Endometriosis]</td>
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<td>[9]</td>
<td>[polycystic ovarian syndrome]</td>
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<td>Line/MH Number:</td>
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<td>1.j</td>
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<td>[Type II Diabetes]</td>
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<td></td>
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<td>Jun/UNK/2020</td>
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<td>1.k</td>
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<td>Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:</td>
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<td></td>
<td>Start Date:</td>
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<td>[Meniscus Repair Surgery due to meniscus tear]</td>
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<td></td>
<td>Start Date:</td>
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<td>Ongoing: NO</td>
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<td></td>
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<td>Ongoing: NO</td>
<td>End Date:</td>
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</tr>
<tr>
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<tr>
<td>Line/MH Number:</td>
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<tr>
<td>Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:</td>
<td>[torn ACL]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Start Date:</td>
<td>UNK/UNK/2003</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ongoing:</td>
<td>NO</td>
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</tr>
<tr>
<td>End Date:</td>
<td>UNK/UNK/2003</td>
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<tr>
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</tr>
<tr>
<td>1.</td>
<td>Date</td>
<td>Aug/11/2020</td>
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</tr>
<tr>
<td>2.</td>
<td>Weight</td>
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<td>3.</td>
<td>Unit</td>
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<td>4.</td>
<td>Height</td>
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<td>5.</td>
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<td>cm</td>
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<td>6.</td>
<td>Body Mass Index</td>
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**Vital Signs Details**

<table>
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<th>Field</th>
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<td>Record Identifier</td>
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<td>Temperature</td>
<td>[98.4]</td>
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<td></td>
<td>Unit</td>
<td>F</td>
</tr>
<tr>
<td></td>
<td>Temperature Location</td>
<td>ORAL CAVITY</td>
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## eCRF Audit Trail History

### Lab Urinalysis

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>1.</td>
<td>Lab Panel: URINALYSIS</td>
</tr>
<tr>
<td>2.</td>
<td>Lab Sub-Panel: PREGNANCY</td>
</tr>
<tr>
<td>3.</td>
<td>Collection Date: Aug/11/2020</td>
</tr>
<tr>
<td>4.</td>
<td>Laboratory Name and Address (Derived): [STUDY SITE]</td>
</tr>
<tr>
<td>5.</td>
<td>Specimen Type: URINE</td>
</tr>
</tbody>
</table>

### Lab Result

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>6.a</td>
<td>Sponsor ID: [113]</td>
</tr>
<tr>
<td></td>
<td>Test: Choriogonadotropin Beta_PX113</td>
</tr>
<tr>
<td></td>
<td>Result: NEGATIVE</td>
</tr>
<tr>
<td></td>
<td>Not Done:</td>
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</table>
eCRF Audit Trail History

<table>
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<td>Aug/11/2020</td>
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<tr>
<td>2. Randomization Number</td>
<td>[46471]</td>
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<td>3. Randomization Group</td>
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**eCRF Audit Trail History**

### Electronic Sample Tracking

<p>| | | |</p>
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<tbody>
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<td>1.</td>
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<td>SITE</td>
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<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>
<td>[]</td>
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</tbody>
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### Aliquot

Please enter barcode for each aliquot.

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5.a</td>
<td>Sample ID</td>
<td>[BP3GCY]</td>
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<tr>
<td>5.b</td>
<td>Sample ID</td>
<td>[BP3GCX]</td>
</tr>
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<td>5.c</td>
<td>Sample ID</td>
<td>[BP3GCW]</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.

<table>
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<tr>
<th></th>
<th>Sample ID</th>
<th>[BP3GCN]</th>
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</table>
eCRF Audit Trail History

Vaccination

1. Was there a temporary delay of vaccination? NO
2. Treatment Name [BLINDED THERAPY]
3. Formulation: INJECTION
4. Dose Date Time: Aug/11/2020 16:20
5. Anatomical Location: DELTOID MUSCLE
6. Body Side: RIGHT
7. Route: INTRAMUSCULAR
8. Actual Dose: [ ]
9. Unit:
10. Timeframe Subject Was Observed THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11. Was the subject observed for at least the protocol specified observation period after investigational product administration? YES
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></th>
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</thead>
<tbody>
<tr>
<td>1. Date of Visit</td>
<td>Aug/31/2020</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>
### 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

2.g Symptom: NEW OR WORSENEP MUSCLE PAIN
   Were fever or systemic symptoms present on the last day
   the Subject Diary was completed? NO

2 h Symptom: NEW OR WORSENEP JOINT PAIN
   Were fever or systemic symptoms present on the last day
   the Subject Diary was completed? NO

3. Injection Site Location: DELTOID MUSCLE

4. Injection Site Body Side: RIGHT

5.a Injection Site Reaction: REDNESS
   Were injection site reactions present on the last day the
   Subject Diary was completed? NO

5.b Injection Site Reaction: SWELLING
   Were injection site reactions present on the last day the
   Subject Diary was completed? NO

5.c Injection Site Reaction: PAIN AT INJECTION SITE
   Were injection site reactions present on the last day the
   Subject Diary was completed? NO
### eCRF Audit Trail History

#### Vital Signs

<table>
<thead>
<tr>
<th></th>
<th>Date:</th>
<th>Aug/31/2020</th>
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</thead>
</table>

#### Vital Signs Details

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<tr>
<th></th>
<th>Record Identifier:</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Temperature:</td>
<td>[98.3]</td>
</tr>
<tr>
<td></td>
<td>Unit:</td>
<td>F</td>
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<td></td>
<td>Temperature Location:</td>
<td>ORAL CAVITY</td>
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</table>
**Lab Urinalysis**

<p>| | |</p>
<table>
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<tr>
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<tbody>
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</tr>
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<td>Lab Sub-Panel: PREGNANCY</td>
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<tr>
<td>3.</td>
<td>Collection Date: Aug/31/2020</td>
</tr>
<tr>
<td>4.</td>
<td>Laboratory Name and Address (Derived): [STUDY SITE]</td>
</tr>
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<td>Specimen Type: URINE</td>
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**Lab Result**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
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<td>Sponsor ID: [113]</td>
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<td></td>
<td>Test: Choriogonadotropin Beta_PX113</td>
</tr>
<tr>
<td></td>
<td>Result: NEGATIVE</td>
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<td>Not Done:</td>
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### eCRF Audit Trail History

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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<thead>
<tr>
<th>5.a</th>
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<tbody>
<tr>
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<td>[BN67X3]</td>
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<tr>
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</tr>
<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>
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<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>
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<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>
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<td>10.</td>
<td>Timeframe Subject Was Observed</td>
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<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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**Header Text**: c4591001  
**Visit**: V3_MONTH1_POSTVAX2_L  
**Form**: DATE OF VISIT  
**Form Version**: 22-Apr-2020 21:02  
**Site No**: 1090  
**Subject No**: 10901140  
**Generated By**: (b) (4)  
**Site Name**: (1090) Wake Research Associates, LLC  
**Subject Initials**: ---  
**Generated Time (GMT)**: 29-Mar-2021 10:31

### eCRF Audit Trail History

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**FDA-CBER-2021-5683-0920048**
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<td><strong>1.</strong></td>
<td>Were medications to treat fever/pain given on the last day the Subject Diary was completed?</td>
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<td><strong>2.a</strong></td>
<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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<tr>
<td></td>
<td>NO</td>
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<tr>
<td><strong>2.b</strong></td>
<td>Symptom: FATIGUE</td>
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<td>Were fever or systemic symptoms present on the last day the Subject Diary was completed?</td>
</tr>
<tr>
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<td>NO</td>
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<tr>
<td><strong>2.c</strong></td>
<td>Symptom: HEADACHE</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>
</tr>
<tr>
<td></td>
<td>NO</td>
</tr>
<tr>
<td><strong>2.d</strong></td>
<td>Symptom: CHILLS</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></td>
<td>NO</td>
</tr>
<tr>
<td><strong>2.e</strong></td>
<td>Symptom: VOMITING</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></td>
<td>NO</td>
</tr>
</tbody>
</table>
## Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

### Visit: V3_MONTH1_POSTVAX2_L

### Form Version: 30-Jul-2020 21:30

### Site No: 1090

### Subject No: 10901140

### Generated By: (b) (4)

### Subject Initials: ---

### Site Name: (1090) Wake Research Associates, LLC

### Generated Time (GMT): 29-Mar-2021 10:31

### Header Text: c4591001

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Were fever or systemic symptoms present on the last day the Subject Diary was completed?</td>
<td>NO</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Were fever or systemic symptoms present on the last day the Subject Diary was completed?</td>
<td>NO</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Were fever or systemic symptoms present on the last day the Subject Diary was completed?</td>
<td>NO</td>
</tr>
</tbody>
</table>

### Injection Site Location: DELTOID MUSCLE

### Injection Site Body Side: RIGHT

### Injection Site Reaction: REDNESS

### Injection Site Reaction: SWELLING

### Injection Site Reaction: PAIN AT INJECTION SITE

---

**Page 27 of 224**
### eCRF Audit Trail History

#### Electronic Sample Tracking

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

#### Aliquot

Please enter barcode for each aliquot.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5.a</td>
<td>Sample ID</td>
</tr>
<tr>
<td>5.b</td>
<td>Sample ID</td>
</tr>
<tr>
<td>5.c</td>
<td>Sample ID</td>
</tr>
</tbody>
</table>
**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>
</tbody>
</table>

**COVID-19 Illness Visit**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>3.</td>
<td>COVID-19 Illness Visit:</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td><strong>Date of Assessment:</strong></td>
<td>//</td>
</tr>
<tr>
<td><strong>Date of First Symptom Started:</strong></td>
<td>//</td>
</tr>
<tr>
<td><strong>Symptoms Ongoing?</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Symptoms:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Was symptom present?</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Symptoms - Other Text:</strong></td>
<td>[ ]</td>
</tr>
</tbody>
</table>

**Header Text:** c4591001
**Visit:** POT_COVID_ILL - New Unscheduled Visit
**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

**Form Version:** 20-Feb-2021 02:17
**Site No:** 1090
**Subject No:** 10901140
**Generated By:** (b) (4)

**Site Name:** (1090) Wake Research Associates, LLC
**Subject Initials:** ---
**Generated Time (GMT):** 29-Mar-2021 10:31
<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_ILL - New Unscheduled Visit
**Form Version:** 22-Apr-2020 21:03
**Site No:** 1090
**Subject No:** 10901140
**Generated By:** (b) (4)
**Generated Time (GMT):** 29-Mar-2021 10:31

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF
**Form Status:** Not Started
**Site Name:** (1090) Wake Research Associates, LLC
**Subject Initials:** ---
### Electronic Sample Tracking

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

### Aliquot

*Please enter barcode for each aliquot.*

5. **Sample ID**
   - [ ]
### Health Care Utilization

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

### Health Care Utilization Other

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

### Health Care Utilization

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

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

<table>
<thead>
<tr>
<th>COVID-19 Illness Visit</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>3. COVID-19 Illness Visit</td>
<td></td>
</tr>
<tr>
<td><strong>Electronic Sample Tracking</strong></td>
<td></td>
</tr>
<tr>
<td>-----------------------------</td>
<td></td>
</tr>
<tr>
<td>1. Data Origin</td>
<td></td>
</tr>
<tr>
<td>2. Sample Type</td>
<td></td>
</tr>
<tr>
<td>3. Sample Collected?</td>
<td></td>
</tr>
<tr>
<td>4. If no sample was collected or sample was not collected according to protocol, please provide reason: [ ]</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Aliquot</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Please enter barcode for each aliquot.</td>
</tr>
<tr>
<td>5. Sample ID [ ]</td>
</tr>
</tbody>
</table>
### Date of Visit

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

---

**Form:** DATE OF VISIT

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

**Site No:** 1090

**Subject No:** 10901140

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

**Site Name:** (1090) Wake Research Associates, LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31
### Unplanned Assessments

<table>
<thead>
<tr>
<th></th>
<th>Assessments</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>
**eCRF Audit Trail History**

### 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/2/2020</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>
### Disposition - Follow-Up

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

**Site No:** 1090  
**Site Name:** (1090) Wake Research Associates, LLC  
**Subject No:** 10901140  
**Subject Initials:** ---  
**Generated By:** [b] (4)  
**Generated Time (GMT):** 29-Mar-2021 10:31
<table>
<thead>
<tr>
<th>Date of Visit</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Visit</td>
<td>//</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>

### COVID-19 Repeat Swab

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

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

### Aliquot

Please enter barcode for each aliquot.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5.</td>
<td>Sample ID</td>
</tr>
<tr>
<td>#</td>
<td>Category</td>
</tr>
<tr>
<td>----</td>
<td>-----------------</td>
</tr>
<tr>
<td>1.</td>
<td>ADVERSE EVENT</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>ADVERSE EVENT</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>ADVERSE EVENT</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Adverse Event Report

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Category:</td>
<td>ADVERSE EVENT</td>
</tr>
<tr>
<td>AE ID:</td>
<td>[1]</td>
</tr>
<tr>
<td>Adverse Event:</td>
<td>acute appendicitis with perforation</td>
</tr>
<tr>
<td>Start Date Time:</td>
<td>Feb/4/2021 UNK:UNK</td>
</tr>
<tr>
<td>Is the adverse event still ongoing?</td>
<td>NO</td>
</tr>
<tr>
<td>Toxicity Grade:</td>
<td>4</td>
</tr>
<tr>
<td>Is the adverse event serious?</td>
<td>YES</td>
</tr>
<tr>
<td>Is this serious event associated with congenital anomaly or birth defect?</td>
<td>NO</td>
</tr>
<tr>
<td>Did this serious event result in death?</td>
<td>NO</td>
</tr>
<tr>
<td>Did this serious event require or prolong hospitalization?</td>
<td>YES</td>
</tr>
<tr>
<td>Did this serious event result in persistent or significant disability/incapacity?</td>
<td>NO</td>
</tr>
<tr>
<td>Is this serious event life threatening?</td>
<td>YES</td>
</tr>
<tr>
<td>Other medically important serious event</td>
<td>NO</td>
</tr>
<tr>
<td>Is this adverse event the result of a study Medication Error?</td>
<td>NO</td>
</tr>
</tbody>
</table>

---

### Notes
- **Is this adverse event still ongoing?** NO
- **End Date Time:** Feb/11/2021 UNK:UNK
- **Toxicity Grade:** 4
- **Is the adverse event serious?** YES
- **Is this serious event associated with congenital anomaly or birth defect?** NO
- **Did this serious event result in death?** NO
- **Did this serious event require or prolong hospitalization?** YES
- **Did this serious event result in persistent or significant disability/incapacity?** NO
- **Is this serious event life threatening?** YES
- **Other medically important serious event** NO
- **Is this adverse event the result of a study Medication Error?** NO
9. Is this event related to study treatment: | NOT RELATED  
If Not Related to study treatment(s), this event is due to: 
OTHER  
If Other, specify: 
[unknown]

10. Latest Action Taken with Study Treatment: | NOT APPLICABLE

11. Was a Concomitant Medication given? | YES

12. Was a Non-Drug Treatment given? | YES

13. What was the outcome of this adverse event?: | RECOVERED/RESOLVED

14. Did the adverse event cause the subject to be discontinued from the study? | NO

15. Serious Adverse Event Number: For Pfizer Use Only | [2021162151]
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.</strong> Category:</td>
<td>ADVERSE EVENT</td>
</tr>
<tr>
<td><strong>2.</strong> AE ID:</td>
<td>[2]</td>
</tr>
</tbody>
</table>
| **3.** Adverse Event:  
(If possible specify diagnosis, not individual symptoms) | [localized peritonitis] |
| **4.** Start Date Time: | Feb/4/2021 UNK:UNK |
| **5.** Is the adverse event still ongoing? | NO  
End Date Time:  
Feb/11/2021 UNK:UNK |
| **6.** Toxicity Grade: | 4 |
| **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). | YES  
Is this serious event associated with congenital anomaly or birth defect?  
NO  
Did this serious event result in death?  
NO  
Did this serious event require or prolong hospitalization?  
YES  
Did this serious event result in persistent or significant disability/incapacity?  
NO  
Is this serious event life threatening?  
YES  
Other medically important serious event  
NO |
| **8.** Is this adverse event the result of a study Medication Error?  
If Yes, record the type of medication error on the Medication Error Log. | NO |
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>9.</strong> Is this event related to study treatment:</td>
<td>NOT RELATED</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<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>YES</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>[2021162151]</td>
</tr>
</tbody>
</table>
### Adverse Event Report

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Category:</td>
<td>ADVERSE EVENT</td>
</tr>
<tr>
<td>2.</td>
<td>AE ID:</td>
<td>[3]</td>
</tr>
<tr>
<td>3.</td>
<td>Adverse Event:</td>
<td>(If possible specify diagnosis, not individual symptoms)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>[pelvic abscess]</td>
</tr>
<tr>
<td>4.</td>
<td>Start Date Time:</td>
<td>Feb/4/2021 UNK:UNK</td>
</tr>
<tr>
<td>5.</td>
<td>Is the adverse event still ongoing?</td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td>End Date Time:</td>
<td>Feb/11/2021 UNK:UNK</td>
</tr>
<tr>
<td>6.</td>
<td>Toxicity Grade:</td>
<td>4</td>
</tr>
<tr>
<td>7.</td>
<td>Is the adverse event serious?</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td>If Yes, NOTIFY PFIZER IMMEDIATELY.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Is this serious event associated with congenital anomaly or birth defect?</td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td>Did this serious event result in death?</td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td>Did this serious event require or prolong hospitalization?</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td>Did this serious event result in persistent or significant disability/incapacity?</td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td>Is this serious event life threatening?</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td>Other medically important serious event</td>
<td>NO</td>
</tr>
<tr>
<td>8.</td>
<td>Is this adverse event the result of a study Medication Error?</td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td>If Yes, record the type of medication error on the Medication Error Log.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td></td>
</tr>
</tbody>
</table>
| **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:  
   [appendicitis] |
<p>| <strong>10.</strong> Latest Action Taken with Study Treatment: | NOT APPLICABLE |
| <strong>11.</strong> Was a Concomitant Medication given? | YES |
| <strong>12.</strong> Was a Non-Drug Treatment given? | YES |
| <strong>13.</strong> What was the outcome of this adverse event?: | RECOVERED/RESOLVED |
| <strong>14.</strong> Did the adverse event cause the subject to be discontinued from the study? | NO |
| <strong>15.</strong> Serious Adverse Event Number: For Pfizer Use Only | [2021162151] |</p>
<table>
<thead>
<tr>
<th>#</th>
<th>Category</th>
<th>Medication Error</th>
<th>Start Date</th>
<th>Is the medication error Still Ongoing</th>
<th>Study Medication Errors Action</th>
<th>Form Instance</th>
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<tbody>
<tr>
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<td></td>
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<td></td>
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<td></td>
<td>Repeating Pages</td>
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</tbody>
</table>

FDA-CBER-2021-5683-0920073
<table>
<thead>
<tr>
<th>Medication Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Category:</td>
</tr>
<tr>
<td>2. Medication Error (Type of Medication Error): [ ]</td>
</tr>
<tr>
<td>3. Start Date:   //</td>
</tr>
<tr>
<td>4. Is the medication error still ongoing?</td>
</tr>
<tr>
<td>5. Latest Action Taken with Study Treatment:</td>
</tr>
<tr>
<td>6. Was a Concomitant Medication given?</td>
</tr>
<tr>
<td>7. Was a Non-Drug Treatment given?</td>
</tr>
<tr>
<td>8. Did the Medication Error cause the subject to be discontinued from the study?</td>
</tr>
<tr>
<td>9. Was this medication error associated with any adverse events?</td>
</tr>
<tr>
<td>10. Serious Adverse Event Number: For Pfizer Use Only [ ]</td>
</tr>
<tr>
<td>#</td>
</tr>
<tr>
<td>----</td>
</tr>
<tr>
<td>1.</td>
</tr>
<tr>
<td>Concomitant Medications</td>
</tr>
<tr>
<td>-------------------------------------------------------------</td>
</tr>
<tr>
<td>1. What is the medication identifier? [ ]</td>
</tr>
<tr>
<td>2. Category:</td>
</tr>
<tr>
<td>3. Concomitant Medications Pre-specified:</td>
</tr>
<tr>
<td>4. Medication:</td>
</tr>
<tr>
<td>Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation). [ ]</td>
</tr>
<tr>
<td>5. Date: //</td>
</tr>
<tr>
<td>#</td>
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<tr>
<td>----</td>
</tr>
<tr>
<td>1.</td>
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</tbody>
</table>

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED
## 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>
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<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>
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<tbody>
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<td>Repeating Pages</td>
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<td>Radiation Treatment</td>
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<td>4. Treatment:</td>
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<td>5. Start Date:</td>
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<td>6. Ongoing?</td>
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<td>Date of Transfusion</td>
<td>Form Instance</td>
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2. Date of Transfusion: //
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</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Visit //</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
</tr>
</tbody>
</table>
## Vital Signs

1. **Date:**  
   //

## Vital Signs Details

2. **Record Identifier:**

   **Temperature:** [ ]

   **Unit:** 

   **Temperature Location:**
## Lab Urinalysis

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

## Lab Result

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<tbody>
<tr>
<td>6.</td>
<td>Sponsor ID: [ ]</td>
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<tr>
<td></td>
<td>Test:</td>
</tr>
<tr>
<td></td>
<td>Result:</td>
</tr>
<tr>
<td></td>
<td>Not Done:</td>
</tr>
<tr>
<td>Vaccination</td>
<td></td>
</tr>
<tr>
<td>-----------------------------</td>
<td>---</td>
</tr>
<tr>
<td>1. Was there a temporary delay of vaccination?</td>
<td></td>
</tr>
<tr>
<td>2. Treatment Name</td>
<td>[ ]</td>
</tr>
<tr>
<td>3. Formulation:</td>
<td></td>
</tr>
<tr>
<td>4. Dose Date Time:</td>
<td>//</td>
</tr>
<tr>
<td>5. Anatomical Location:</td>
<td></td>
</tr>
<tr>
<td>6. Body Side:</td>
<td></td>
</tr>
<tr>
<td>7. Route:</td>
<td></td>
</tr>
<tr>
<td>8. Actual Dose:</td>
<td>[ ]</td>
</tr>
<tr>
<td>9. Unit:</td>
<td></td>
</tr>
<tr>
<td>10. Timeframe Subject Was Observed</td>
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</tr>
<tr>
<td>11. Was the subject observed for at least the protocol specified observation period after investigational product administration?</td>
<td></td>
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<tr>
<td>Contact Outcome</td>
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<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>
<tr>
<td>Contact Outcome</td>
<td></td>
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<td>----------------</td>
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</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>
**Header Text:** c4591001  
**Visit:** Potential ReVax Initial Contact - Unscheduled  
**Form:** DATE OF VISIT  
**Form Version:** 22-Apr-2020 21:02  
**Form Status:** Data Complete, Frozen, Verified  
**Site No:** 1090  
**Site Name:** (1090) Wake Research Associates, LLC  
**Subject No:** 10901140  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:31

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

#### Further Vaccination Confirmation

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<thead>
<tr>
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<tbody>
<tr>
<td>1.</td>
<td>Select appropriate response - Is participant willing to return for Vaccination 3?</td>
</tr>
<tr>
<td></td>
<td>Participant is willing to return for Vaccination 3</td>
</tr>
<tr>
<td></td>
<td>Participant is:</td>
</tr>
<tr>
<td></td>
<td>eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2</td>
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<tr>
<td>eCRF Audit Trail History</td>
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<tr>
<td>--------------------------</td>
<td></td>
</tr>
<tr>
<td><strong>Treatment Unblinded</strong></td>
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<tr>
<td>1. Date Treatment Unblinded :</td>
<td>Jan/25/2021</td>
</tr>
<tr>
<td>2. Primary Reason for Unblinding:</td>
<td>ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION</td>
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</table>
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

**Date of Visit**

<table>
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<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>1.</td>
<td>Jan/27/2021</td>
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<tr>
<td>2.</td>
<td>Erroneous Visit</td>
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</tr>
</tbody>
</table>
### Informed Consent - Further Vaccination

| 1. Consent Was: | OBTAINED  
| Date Written Consent Obtained | Jan/27/2021 |
### Form Comments

#### Inclusion Criteria Not Met

<table>
<thead>
<tr>
<th>1.</th>
<th>Description of Inclusion Criterion Not Met</th>
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#### Exclusion Criteria Met

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</tr>
<tr>
<td>---</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td><strong>Date of Completion/Discontinuation/Death:</strong> Jan/27/2021</td>
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<tr>
<td>2.</td>
<td><strong>Phase of Disposition:</strong> REPEAT SCREENING 1</td>
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</tr>
<tr>
<td>3.</td>
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</tr>
<tr>
<td>4.</td>
<td><strong>Specify Status:</strong> [ ]</td>
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</table>
### Lab Urinalysis

1. **Lab Panel:** URINALYSIS
2. **Lab Sub-Panel:** PREGNANCY
3. **Collection Date:** Jan/27/2021
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:**
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<thead>
<tr>
<th></th>
<th>Data Origin</th>
<th>SITE</th>
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<tbody>
<tr>
<td>2.</td>
<td>Sample Type</td>
<td>SERUM</td>
</tr>
<tr>
<td>3.</td>
<td>Sample Collected?</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td>Date of Collection:</td>
<td>Jan/27/2021</td>
</tr>
<tr>
<td>4.</td>
<td>If no sample was collected or sample was not collected according to protocol, please provide reason:</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

Aliquot

Please enter barcode for each aliquot.

| 5.a | Sample ID | [BMN9F6] |
| 5.b | Sample ID | [BMN9F5] |
| 5.c | Sample ID | [BP8G46] |
### eCRF Audit Trail History

**Electronic Sample Tracking**

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

<p>| | |</p>
<table>
<thead>
<tr>
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<tr>
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### Vaccination

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<td>NO</td>
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<td>2</td>
<td>Treatment Name</td>
<td>[BNT162b2]</td>
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<td>3</td>
<td>Formulation</td>
<td>INJECTION</td>
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<td>Dose Date Time</td>
<td>Jan/27/2021 13:32</td>
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<td>5</td>
<td>Anatomical Location</td>
<td>DELTOID MUSCLE</td>
</tr>
<tr>
<td>6</td>
<td>Body Side</td>
<td>LEFT</td>
</tr>
<tr>
<td>7</td>
<td>Route</td>
<td>INTRAMUSCULAR</td>
</tr>
<tr>
<td>8</td>
<td>Actual Dose</td>
<td>[30.0]</td>
</tr>
<tr>
<td>9</td>
<td>Unit</td>
<td>ug</td>
</tr>
<tr>
<td>10</td>
<td>Timeframe Subject Was Observed</td>
<td>30 MINUTES</td>
</tr>
<tr>
<td>11</td>
<td>Was the subject observed for at least the protocol specified observation period after investigational product administration?</td>
<td>YES</td>
</tr>
<tr>
<td>Date of Visit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>--------------</td>
<td>---</td>
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</tr>
<tr>
<td>1. Date of Visit</td>
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</tr>
<tr>
<td>2. Erroneous Visit</td>
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<td></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>3. Collection Date:</td>
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</tr>
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<td>4. Laboratory Name and Address (Derived):</td>
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<td>5. Specimen Type:</td>
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<td><strong>Lab Result</strong></td>
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<td>Sponsor ID: [113]</td>
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### Electronic Sample Tracking

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<td>4.</td>
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<td>[]</td>
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</table>

### Aliquot

Please enter barcode for each aliquot.

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</thead>
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</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>
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<td>5</td>
<td>Anatomical Location:</td>
</tr>
<tr>
<td>6</td>
<td>Body Side:</td>
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<td>7</td>
<td>Route:</td>
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<td>8</td>
<td>Actual Dose:</td>
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<td>Unit:</td>
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<td>Timeframe Subject Was Observed</td>
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<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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### Date of Visit

<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
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### Contact Outcome

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<tr>
<td>2.</td>
<td>Was contact made?</td>
<td></td>
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<td>3.</td>
<td>Comments:</td>
<td>[ ]</td>
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**Generated Time (GMT):** 29-Mar-2021 10:31

**Site Name:** (1090) Wake Research Associates, LLC

**Subject No:** 10901140

**Generated By:** (b) (4)
### Date of Visit

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<tr>
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<td>1. Contact Type:</td>
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<tr>
<td>2. Was contact made?</td>
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<td></td>
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<tr>
<td>3. Comments: [ ]</td>
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Date of Visit

1. Date of Visit
   //

2. Erroneous Visit
<table>
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<tr>
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<tbody>
<tr>
<td>1. Contact Type:</td>
</tr>
<tr>
<td>2. Was contact made?</td>
</tr>
<tr>
<td>3. Comments: [ ]</td>
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<tr>
<td>Disposition - Treatment</td>
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<tr>
<td>-------------------------------------------------------------</td>
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<tr>
<td>1. Date of Completion/Discontinuation/Death: //</td>
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<tr>
<td>2. Phase of Disposition:</td>
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<tr>
<td>3. Status:</td>
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Visit: FURTHER_VACCINATION_EOT - Unscheduled
Form: DISPOSITION - TREATMENT
Form Version: 20-Feb-2021 02:26
Site No: 1090
Subject No: 10901140
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 10:31
**Subject Audit Trail History**

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</tr>
<tr>
<td>Casebook Signature Form</td>
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</tr>
</tbody>
</table>

| 1. | Casebook Signature | Click Here to Enable |
Audit Trail

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

- CRF_Sign

<table>
<thead>
<tr>
<th>Name</th>
<th>Signature Meaning</th>
<th>Date</th>
<th>Type</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lisa Cohen</td>
<td>Approved</td>
<td>Mar-12-2021 08:43:25 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>BOOK</td>
<td>Signed</td>
</tr>
</tbody>
</table>

Affidavit:

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

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

To this I do attest by supplying my user name and password and clicking the button marked Submit below.
<table>
<thead>
<tr>
<th>Item</th>
<th>Date</th>
<th>User</th>
<th>Comment</th>
</tr>
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<tbody>
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<td>User</td>
<td>Comment</td>
</tr>
<tr>
<td>------</td>
<td>------</td>
<td>------</td>
<td>---------</td>
</tr>
<tr>
<td>Form</td>
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<td>(b) (4), (b) (6)</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>
This form requires signing by a member of each of the following signature groups:

- CRF_Sign

<table>
<thead>
<tr>
<th>Name</th>
<th>Signature Meaning</th>
<th>Date</th>
<th>Type</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Approved</td>
<td>Mar-12-2021 08:43:25 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>BOOK</td>
<td>Signed</td>
</tr>
</tbody>
</table>

Affidavit:

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

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

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

<table>
<thead>
<tr>
<th>Name</th>
<th>Signature Meaning</th>
<th>Date</th>
<th>Type</th>
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Affidavit:

N/A

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<tr>
<td>Lisa Cohen</td>
<td>Approved</td>
<td>Mar-11-2021 09:04:18 (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, Lisa Cohen, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

<table>
<thead>
<tr>
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<th>Signature Meaning</th>
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<th>Type</th>
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</tr>
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</table>

Affidavit:

N/A
### Affidavit

By my dated signature below, I, Matthew Hong, 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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<thead>
<tr>
<th>(b) (6)</th>
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<tr>
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<tr>
<td>Lisa Cohen</td>
<td>Approved</td>
<td>Mar-10-2021 09:01:09 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>BOOK</td>
</tr>
</tbody>
</table>

### Affidavit

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

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

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

<table>
<thead>
<tr>
<th>(b) (6)</th>
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<tr>
<td>Lisa Cohen</td>
<td>Approved</td>
<td>Mar-10-2021 07:55:13 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>BOOK</td>
</tr>
</tbody>
</table>
Affidavit:
By my dated signature below, I, Lisa Cohen, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

(b) (6)  N/A  Mar-09-2021 13:08:32 (UTC-05:00) Eastern Time (US & Canada)  Edit - All signatures invalidated

Affidavit:
N/A

Matthew Hong  Approved  Feb-19-2021 15:38:59 (UTC-05:00) Eastern Time (US & Canada)  BOOK  Signed

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

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

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

(b) (6)  N/A  Feb-19-2021 13:42:39 (UTC-05:00) Eastern Time (US & Canada)  Edit - All signatures invalidated

Affidavit:
N/A

Matthew Hong  Approved  Feb-19-2021 09:24:28 (UTC-05:00) Eastern Time (US & Canada)  BOOK  Signed
Affidavit:
By my dated signature below, I, Matthew Hong, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

<table>
<thead>
<tr>
<th>(b) (6)</th>
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<tr>
<td><strong>Affidavit:</strong></td>
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</tr>
<tr>
<td>Matthew Hong</td>
<td>Approved</td>
<td>Feb-18-2021 17:18:43 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
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<td><strong>Affidavit:</strong></td>
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</tr>
<tr>
<td>Matthew Hong</td>
<td>Approved</td>
<td>Feb-18-2021 16:22:47 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>Edit - All signatures invalidated</td>
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<td><strong>Affidavit:</strong></td>
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</tr>
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<td>Matthew Hong</td>
<td>Approved</td>
<td>Feb-18-2021 14:00:50 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>BOOK</td>
</tr>
</tbody>
</table>
**Affidavit:**

By my dated signature below, I, Matthew Hong, 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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<tr>
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</tr>
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Matthew Hong  | Approved | Feb-01-2021 12:05:19 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed

**Affidavit:**

By my dated signature below, I, Matthew Hong, 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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Matthew Hong  | Approved | Jan-29-2021 12:27:48 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed
**Affidavit:**
By my dated signature below, I, Matthew Hong, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

<table>
<thead>
<tr>
<th>Date/Time</th>
<th>Signature Approved</th>
<th>Time (Eastern Time)</th>
<th>Approved/Book/Signed</th>
<th>Edit - All signatures invalidated</th>
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</tr>
<tr>
<td>Matthew Hong</td>
<td>Approved</td>
<td>Jan-27-2021 14:35:47</td>
<td>BOOK Signed</td>
<td></td>
</tr>
<tr>
<td>Jan-27-2021 14:20:15</td>
<td>(b) (6)</td>
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<td></td>
<td></td>
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<tr>
<td>Wayne Harper</td>
<td>Approved</td>
<td>Oct-08-2020 15:45:00</td>
<td>BOOK Signed</td>
<td></td>
</tr>
</tbody>
</table>
Affidavit:
By my dated signature below, I, Wayne Harper, 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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</table>

Wayne Harper | Approved | Sep-11-2020 13:47:06 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |

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

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

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Aug-12-2020 14:54:23 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINF6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> 24 JUL 2020</td>
<td>Initial Entry</td>
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</table>

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

<table>
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<th>Date</th>
<th>Location</th>
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<th>Reason</th>
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<tbody>
<tr>
<td>Aug-12-2020 14:54:23 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINF6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> STAGE 3 COHORTS</td>
<td>Initial Entry</td>
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</table>
### 1. Consent Was:

<table>
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<tr>
<td>Aug-12-2020 14:54:36</td>
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<td>(b) (4), (b)</td>
<td><strong>Data Entry:</strong></td>
<td>Initial Entry</td>
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<tr>
<td>(UTC-05:00) Eastern</td>
<td></td>
<td>(b) (4), (b)</td>
<td><strong>OBTAINED</strong></td>
<td>Date Written Consent</td>
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<tr>
<td>Time (US &amp; Canada)</td>
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<td><strong>Obtained</strong></td>
<td>Obtained</td>
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<td><strong>Aug/11/2020</strong></td>
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</table>
### 1. Subject ID

<table>
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<tbody>
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<td>Item copied from previous form</td>
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<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
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### 2. Birth Date:

<table>
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<th>Reason</th>
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<tbody>
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<td>Aug-12-2020 14:53:54</td>
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<td>auto calc (autocalc)</td>
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<td>Enrollment Entry</td>
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### 3. Sex:

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<th>Reason</th>
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<tbody>
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<td>Aug-12-2020 14:54:57</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td></td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
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<td>(b) (4), (b) (6)</td>
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### 4. Ethnicity:

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<th>Reason</th>
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<td>(b) (4), (b) (6)</td>
<td>NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN</td>
<td>Initial Entry</td>
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### 5. Race: (Check X all that apply):

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<th>Reason</th>
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<tbody>
<tr>
<td>Aug-12-2020 14:54:57</td>
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<td>(b) (4), (b) (6)</td>
<td></td>
<td>Initial Entry</td>
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<tr>
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<td>(b) (4), (b) (6)</td>
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### 1. Date of Visit

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<th>Reason</th>
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<tbody>
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<td>Data Entry: Aug/11/2020</td>
<td>Initial Entry</td>
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**Location Description:**
ACV0PFEINF6000

**User Initials:**
(b) (4)
### 1. Date of Completion/Discontinuation/Death

<table>
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<tr>
<th>Date</th>
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<th>Reason</th>
</tr>
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<tbody>
<tr>
<td>Aug-12-2020 14:56:30 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: Aug/11/2020</td>
<td>Initial Entry</td>
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### 2. Phase of Disposition:

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<th>User</th>
<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Aug-12-2020 14:56:30 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: SCREENING</td>
<td>Initial Entry</td>
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</table>

### 3. Status:

<table>
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<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
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<tbody>
<tr>
<td>Aug-12-2020 14:56:30 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: COMPLETED</td>
<td>Initial Entry</td>
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### 1.a Medical History

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<th>Reason</th>
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<tbody>
<tr>
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<td>auto calc</td>
<td>Latex Allergy</td>
<td>Initial Entry</td>
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<td>(UTC-05:00) Eastern</td>
<td></td>
<td>(autocalc)</td>
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#### 1.a Line/MH Number:

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<td>(autocalc)</td>
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#### 1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

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

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**Term:** Asthmatic Bronchitis  
**Start Date:** UNK/UNK/1985  
**Ongoing:** YES

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

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**Start Date**

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Medical History
- Term: Kidney Stones
- Start Date: UNK/UNK/1996
- Ongoing: YES
### Medical History

**Term:** Endometriosis  
**Start Date:** UNK/UNK/2003  
**Ongoing:** YES

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**Start Date:** UNK/UNK/2003  
**Ongoing:** YES

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***Confidential***
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Term which may impact coding. Please review and remove any extra spaces.
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### 1.j Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

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- **Medical History Term:** Eczema
- **Start Date:** UNK/UNK/1985
- **Ongoing:** YES
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**Medical History Term:** Meniscus Repair Surgery due to meniscus tear
**Start Date:** UNK/UNK/2016
## GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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**Form Status:** Data Complete, Locked, Frozen, Verified  
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**Site Name:** (1090) Wake Research Associates, LLC  
**Subject No:** 10901140  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:31

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

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7.a

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**FDA-CBER-2021-5683-0920152**
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### 1. Data Origin

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### 2. Sample Type

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### 3. Sample Collected?

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Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03
Site No: 1090
Subject No: 10901140
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 10:31

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| Data Entry: NO | Initial Entry |

### 5.a

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**5.e Sample ID**
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### Sample Type

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### Sample Collected?

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***Confidential***
5.a

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5. Anatomical Location:

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Aug-12-2020 15:20:07</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (8)</td>
<td><strong>Data Entry:</strong> YES</td>
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</tr>
<tr>
<td>(UTC-05:00) Eastern Time</td>
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<tr>
<td>(US &amp; Canada)</td>
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### I. Select appropriate response - Reactogenicity diary collection

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<td>Aug-12-2020 15:20:16 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
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<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT</td>
<td>Initial Entry</td>
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</table>
**1. Date of Visit**

<table>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: Aug/31/2020</td>
<td>Initial Entry</td>
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</table>
1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

<table>
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<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Sep-01-2020 08:35:15</td>
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<td>Initial Entry</td>
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2.a

<table>
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<th>Reason</th>
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<tbody>
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<td>Data Entry: Symptom: FEVER Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO</td>
<td>Initial Entry</td>
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2.a Symptom:

<table>
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<th>Reason</th>
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<tbody>
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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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<th>Reason</th>
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<tbody>
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2.b

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<th>Reason</th>
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<tbody>
<tr>
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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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<td>Initial Entry</td>
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<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
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<td>FATIGUE</td>
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2.c

<table>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
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<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
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<td></td>
<td>HEADache</td>
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</table>

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

<table>
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<th>Reason</th>
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<tbody>
<tr>
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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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<tbody>
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<td>Initial Entry</td>
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### 2.d

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<td>(b) (4), (b) (6)</td>
<td>Data Entry: CHILLS</td>
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### 2.d Symptom:

<table>
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### 2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

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<td>Initial Entry</td>
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### 2.e

<table>
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### 2.e Symptom:

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

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<tbody>
<tr>
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<td>(b) (4), (b) (6)</td>
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<td>Reason</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>NO</td>
<td>Initial Entry</td>
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### 2.f

<table>
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<tbody>
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<td>Data Entry:</td>
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<td></td>
<td>DIA RR HE A</td>
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<tr>
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<td>Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO</td>
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</table>
### 2.f Symptom:

<table>
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<td><strong>Data Entry:</strong> DIARRHEA</td>
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### 2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

<table>
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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
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<td>(b) (4), (b) (6)</td>
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### 2.g

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**Data Entry:**

**Symptom:** NEW OR WORS ENED M USCLE PAIN

**Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO

Initial Entry
### 2.g Symptom:

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<th>Reason</th>
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### 2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

<table>
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<th>Reason</th>
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### 2.h

<table>
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Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO
### 2.h Symptom:

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<th>Reason</th>
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<td>(b) (4), (b) (6)</td>
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<td>Initial Entry</td>
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### 2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

<table>
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<th>Reason</th>
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<td>Initial Entry</td>
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### 3. Injection Site Location:

<table>
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<th>Reason</th>
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### 4. Injection Site Body Side:

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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
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### 5.a

<table>
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<th>Reason</th>
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<tbody>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: Injection Site Reaction: RE DN ES S NO</td>
<td>Initial Entry</td>
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</table>

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

---

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### 5.a Injection Site Reaction:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
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### 5.a Were injection site reactions present on the last day the Subject Diary was completed?

<table>
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<th>Value</th>
<th>Reason</th>
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<tbody>
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### 5.b Injection Site Reaction:

<table>
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<th>User</th>
<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
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<td>(b) (6)</td>
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<td>Initial Entry</td>
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<td>Time (US &amp; Canada)</td>
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### 5.b Were injection site reactions present on the last day the Subject Diary was completed?

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<th>Reason</th>
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<tbody>
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<td>(b) (4),</td>
<td>NO</td>
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<td>(UTC-05:00) Eastern</td>
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<td>Initial Entry</td>
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<tr>
<td>Time (US &amp; Canada)</td>
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### 5.c Injection Site Reaction:

<table>
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<th>Value</th>
<th>Reason</th>
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<td>Initial Entry</td>
</tr>
<tr>
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### 5.c Were injection site reactions present on the last day the Subject Diary was completed?

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<td>Reason</td>
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**2.a**

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<td>(b) (6)</td>
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**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History
**Form Version:** 21-Aug-2020 02:51
**Site No:** 1090
**Subject No:** 10901140
**Generated By:** (b) (4)
**Generated Time (GMT):** 29-Mar-2021 10:31

---

### Confidential

Page 153 of 224
### 1. Lab Panel:

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### 3. Collection Date:

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

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### 6.a

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<tr>
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### 2. Sample Type

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### 3. Sample Collected?

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<tbody>
<tr>
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<td>Close Auto Query</td>
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<td>Aug-31-2020 16:40:31</td>
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<td>Query 1: Candidate</td>
<td>'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.</td>
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### 5.a

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### Sample ID

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1. Was there a temporary delay of vaccination?

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3. Formulation

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5. Anatomical Location

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6. Body Side

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7. Route:

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10. Timeframe Subject Was Observed

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

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### Date of Visit

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**Back to Form**
### 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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<td>Data Entry: Symptom:: FEVER</td>
<td>Initial Entry</td>
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<td>Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO</td>
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### 2.a Symptom:

<table>
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<tr>
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<th>Value</th>
<th>Reason</th>
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<tbody>
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<td>(b) (4), (b) (6)</td>
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<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

<table>
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<th>Reason</th>
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### 2.b

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<td>(b) (4), (b) (6)</td>
<td>Data Entry: Symptom:: FA</td>
<td>Initial Entry</td>
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2. Symptom:

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<th>Value</th>
<th>Reason</th>
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Where fever or systemic symptoms present on the last day the Subject Diary was completed?: NO

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

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<th>Reason</th>
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<tbody>
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2.c

<table>
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<th>Reason</th>
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<td>HE AD AC HE</td>
<td>Initial Entry</td>
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Where fever or systemic symptoms present on the last day the Subject Diary was completed?: NO

Page 162 of 224
<table>
<thead>
<tr>
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<th>Reason</th>
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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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**2.d Symptom:**

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

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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

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### 2.f Symptom:

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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

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<td>ACV0PFEINFP6000</td>
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<td>Data Entry: Symptom:: NEW OR WORSE NED MUSCLE PA IN</td>
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Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO
### 2.g Symptom:

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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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### 2.h

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**Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO

### 2.h Symptom:

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

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<tbody>
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### 3. Injection Site Location:

<table>
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<tr>
<th>Date</th>
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<th>Reason</th>
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<tbody>
<tr>
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<td>(autocalc)</td>
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### 4. Injection Site Body Side:

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### 5.a Injection Site Reaction:

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**Injection Site Reaction:**

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

- **RE**
- **DN**
- **ESS**

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

<table>
<thead>
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<th>Value</th>
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<tbody>
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5.b

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<td>reactions present on the</td>
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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

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<td>Reaction: PAIN AT INJECTION SITE</td>
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### 5.c Injection Site Reaction:

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

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<th>Reason</th>
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### 1. Data Origin

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### 2. Sample Type

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

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<th>Reason</th>
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<tbody>
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<td>ACV0PFEINFP6000</td>
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<td>Query 1: Deleted</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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<tr>
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### 5.a

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### 5. a Sample ID

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<th>Reason</th>
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<tbody>
<tr>
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<td>Data Entry: BP8FX5</td>
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### 5. b Sample ID

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<td>Data Entry: Sample ID: BLB88J</td>
<td>Initial Entry</td>
</tr>
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### 5. c Sample ID

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

<table>
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<tr>
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<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: Oct/2/2020</td>
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</tbody>
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### 2. Phase of Disposition:

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<th>Value</th>
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<tbody>
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<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: VACCINATION</td>
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### 3. Status:

<table>
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<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
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<tbody>
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<td>Oct-05-2020 08:49:29</td>
<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: COMPLETED</td>
</tr>
<tr>
<td>Date</td>
<td>Location</td>
<td>User</td>
<td>Value</td>
<td>Reason</td>
</tr>
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</tr>
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<td>(b) (4), (b) (6)</td>
<td>Form Created</td>
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### Back to Form

<table>
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<th>Value</th>
<th>Reason</th>
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<tbody>
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<td>(b) (4), (b) (6)</td>
<td>Form Created</td>
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<tr>
<td>Date</td>
<td>Location</td>
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<td>Reason</td>
</tr>
<tr>
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1. **Category:**

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<th>Reason</th>
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<tbody>
<tr>
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<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> ADVERSE EVENT</td>
<td>Initial Entry</td>
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</table>

2. **AE ID:**

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-18-2021 13:15:53 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> 1</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mar-12-2021 13:33:02 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 6: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Mar-12-2021 07:47:44 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 6: Answered</td>
<td>faxed already. Subject does not take DM medication</td>
</tr>
<tr>
<td>Mar-11-2021 12:48:08 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 6: Opened</td>
<td>Clinical - please submit a SAE update with the subject's med Hx (including T2DM) and any concomitant medications subject was receiving for</td>
</tr>
<tr>
<td>Date</td>
<td>Time</td>
<td>Time Zone</td>
<td>Event Description</td>
<td></td>
</tr>
<tr>
<td>-------------------</td>
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<td>----------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Mar-11-2021</td>
<td>12:47:38</td>
<td>(UTC-05:00)</td>
<td>Clinical - please submit a SAE update with the subject's med Hx and all concomitant medications subject was receiving when SAE began.</td>
<td></td>
</tr>
<tr>
<td>Mar-11-2021</td>
<td>12:45:28</td>
<td>(UTC-05:00)</td>
<td>Clinical - please submit a SAE update with the subject's med Hx and all concomitant medications subject was receiving when SAE began.</td>
<td></td>
</tr>
<tr>
<td>Mar-10-2021</td>
<td>14:37:44</td>
<td>(UTC-05:00)</td>
<td>Response satisfies query.</td>
<td></td>
</tr>
<tr>
<td>Mar-10-2021</td>
<td>09:03:54</td>
<td>(UTC-05:00)</td>
<td>Discrepancy has been closed.</td>
<td></td>
</tr>
<tr>
<td>Mar-10-2021</td>
<td>08:17:33</td>
<td>(UTC-05:00)</td>
<td>per query</td>
<td></td>
</tr>
<tr>
<td>Mar-10-2021</td>
<td>08:17:33</td>
<td>(UTC-05:00)</td>
<td>per query</td>
<td></td>
</tr>
<tr>
<td>Date/Time</td>
<td>Event Details</td>
<td>Data Entry</td>
<td>Query Status</td>
<td>Notes</td>
</tr>
<tr>
<td>-----------</td>
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<tr>
<td>Mar-10-2021 08:17:33 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>SAE RECON: AER#2021162151, event term was recorded as 'acute appendicitis with perforation and localized peritonitis with pelvic abscess' for coding and reconciliation. Please consider to split the terms as 3 separate entries to match Safety database.</td>
<td>per query</td>
</tr>
<tr>
<td>Mar-10-2021 04:05:00 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 4: Opened</td>
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<td>Mar-09-2021 22:17:54 (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>
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<td>Mar-09-2021 14:37:28 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000.InFormAdapter.Discrepancy</td>
<td>PFETMS Oracle (b) (4), (b)</td>
<td>Query 3: Opened</td>
<td>Multiple concepts in the term ACUTE APPENDICITIS WITH PERFORATION AND LOCALIZED PERITONITIS WITH PELVIC ABSCESS. Split the term into ACUTE APPENDICITIS WITH</td>
</tr>
<tr>
<td>Date/Time</td>
<td>User/Event</td>
<td>Description</td>
<td></td>
<td></td>
</tr>
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<td>-----------------------------------</td>
<td>------------</td>
<td>-----------------------------------------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mar-09-2021 13:08:32 (UTC-05:00)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mar-09-2021 13:08:32 (UTC-05:00)</td>
<td>ACV0PFEINFP6000</td>
<td><strong>Data Entry:</strong> acute appendicitis with perforation and localized peritonitis, with pelvic abscess</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mar-09-2021 09:34:49 (UTC-05:00)</td>
<td>ACV0PFEINFP6000</td>
<td><strong>Query 2:</strong> Opened</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mar-05-2021 21:25:58 (UTC-05:00)</td>
<td>ACV0PFEINFP6000</td>
<td><strong>Query 1:</strong> Closed</td>
<td></td>
<td></td>
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</tbody>
</table>

PERFORATION and LOCALIZED PERITONITIS and PELVIC ABSCESS and report as 3 separate entries. Thank you.

Clinical - event term is 'ruptured appendix'; however, SAE report event term updated to 'Acute appendicitis with perforation and located peritonitis, with pelvic abscess'. Please harmonize event reporting, and update where appropriate.

Query closed; will follow for requested surgery date information.
<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
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<tr>
<td>Mar-03-2021 17:37:03</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Answered</td>
<td>surgery was on 08 Feb 2021, we will send in f/u report</td>
</tr>
<tr>
<td>Feb-22-2021 09:32:49</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Opened</td>
<td>Clinical - please update SAE report with the specific date that emergency surgery was performed</td>
</tr>
<tr>
<td>Feb-18-2021 13:15:53</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry:</td>
<td>Initial Entry</td>
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<tr>
<td></td>
<td></td>
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<td>Feb/4/2021 UNK:UNK</td>
<td>ruptured a appendix</td>
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</table>

4. Start Date Time:

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<td>Data Entry:</td>
<td>New Information</td>
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<td>Feb/4/2021 UNK:UNK</td>
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<td>(b) (4), (b) (6)</td>
<td>Query 1: Closed</td>
<td>onset date of 08Feb21 in both locations now</td>
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<tr>
<td>Mar-09-2021 05:25:40</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Opened</td>
<td>SAE RECON: AER#2021162151, onset date was recorded as 04Feb2021 in Safety database however, recorded as 08Feb2021 on AE CRF. Please confirm correct Onset Date. If safety update is</td>
</tr>
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</table>
5. Is the adverse event still ongoing?

<table>
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<th>Reason</th>
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<tbody>
<tr>
<td>Feb-18-2021 13:15:53</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4),</td>
<td>NO</td>
<td>End Date Time:</td>
</tr>
<tr>
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<td></td>
<td>(b) (b)</td>
<td></td>
<td>Feb/11/2021 UNK:UNK</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Initial Entry</td>
</tr>
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</table>

6. Toxicity Grade:

<table>
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<th>Value</th>
<th>Reason</th>
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<tbody>
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<td>Feb-18-2021 13:15:53</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4),</td>
<td>4</td>
<td>Initial Entry</td>
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<tr>
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<td></td>
<td>(b) (b)</td>
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<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>Mar-05-2021 21:25:08</td>
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<td>(b) (4),</td>
<td>Query 2: Closed</td>
<td>Query closed; will follow for requested COVID test information.</td>
</tr>
<tr>
<td></td>
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<td>(b) (b)</td>
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<tr>
<td>Mar-03-2021 17:37:43</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4),</td>
<td>Query 2: Answered</td>
<td>we will include that in f/u report</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(b) (6)</td>
<td></td>
<td></td>
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<tr>
<td>Mar-01-2021 10:55:17</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4),</td>
<td>Query 2: Reissued:Opened</td>
<td>Clinical - thank you; please include</td>
</tr>
<tr>
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<td>(b) (6)</td>
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**Header Text**: c4591001  
**Visit**: Logs - Unscheduled  
**Form Version**: 22-Apr-2020 21:02  
**Site No**: 1090  
**Subject No**: 10901140  
**Generated By**: (b) (4)  
**Generated Time (GMT)**: 29-Mar-2021 10:31

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<tbody>
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<td>ACV0PFEINFP6000</td>
<td>Query 2: Answered</td>
</tr>
<tr>
<td>Feb-22-2021 09:33:47 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Query 2: Opened</td>
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<tr>
<td>Feb-19-2021 03:23:10 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Query 1: Deleted</td>
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<td>ACV0PFEINFP6000</td>
<td>Query 1: Candidate</td>
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<tr>
<td>Feb-18-2021 13:15:53 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

For AE ruptured appendix: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse event Number" is blank.

Clinical COVID test status (yes/no) during Hosp was not reported in the SAE. Please submit a follow-up SAE form [#2021162151] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.

it was negative per pt, but we are awaiting medical records to confirm the COVID test date in the report.

**Data Entry**:  
**YES**  
Is this serious event associated with congenital anomaly or birth defect?  
NO  
Did this serious event result in death?
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>Feb-18-2021 13:15:53 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFE1NF6000</td>
<td>(b) (4), (b) (8)</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>Feb-18-2021 13:15:53 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFE1NF6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NOT RELATED</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

**OTHER**

If Other, specify:

unknown
### 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>Feb-18-2021 13:15:53</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NOT APPLICABLE</td>
<td>Initial Entry</td>
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### 11. Was a Concomitant Medication given?

<table>
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<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Mar-09-2021 22:18:22</td>
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<td>(b) (4), (b) (6)</td>
<td>Query 2: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Mar-09-2021 13:08:58</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 2: Answered</td>
<td>New Information</td>
</tr>
<tr>
<td>Mar-09-2021 13:08:58</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: YES</td>
<td>New Information</td>
</tr>
<tr>
<td>Mar-09-2021 09:33:21</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Opened</td>
<td>Clinical Con Med for event is NO; however SAE update states subject received amoxicillin/clavulanate antibiotic. Please review Con med for event, and update as applicable</td>
</tr>
<tr>
<td>Mar-01-2021 10:57:12</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Closed</td>
<td>Query closed; will follow for requested antibiotic usage information.</td>
</tr>
<tr>
<td>Feb-25-2021 17:21:46</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Answered</td>
<td>awaiting medical records for specific antibiotics</td>
</tr>
<tr>
<td>Feb-22-2021 09:30:23</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Opened</td>
<td>Clinical - Con Med for SAE is 'NO'; however, SAE report states subject received antibiotics. Please</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>Feb-18-2021 13:15:53</td>
<td>ACV0PFEINFP6000</td>
<td>(b)</td>
<td>(4), (6)</td>
<td>Data Entry: YES</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>Feb-18-2021 13:15:53</td>
<td>ACV0PFEINFP6000</td>
<td>(b)</td>
<td>(4), (6)</td>
<td>Data Entry: RECOVERED/RESOLVED</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>Feb-18-2021 13:15:53</td>
<td>ACV0PFEINFP6000</td>
<td>(b)</td>
<td>(4), (6)</td>
<td>Data Entry: NO</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>Feb-19-2021 03:23:10</td>
<td>ACV0PFEINFP6000</td>
<td>(b)</td>
<td>Data Entry:</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td></td>
<td>(4), (6)</td>
<td>2021162151</td>
<td></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>Mar-10-2021 08:20:25</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td>Data Entry:</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern Time</td>
<td>(autocalc)</td>
<td></td>
<td>ADVERSE EVENT</td>
<td></td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
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<td></td>
<td></td>
<td></td>
</tr>
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</table>

### 2. AE ID:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mar-10-2021 08:20:25</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td>Data Entry:</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern Time</td>
<td>(autocalc)</td>
<td></td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
<td></td>
<td></td>
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<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>Mar-10-2021 17:10:56</td>
<td>ACV0PFEINFP6000.InFormAdapter.Discrepancy</td>
<td>PFETMS Oracle</td>
<td>Query 1:</td>
<td>Discrepancy has been closed.</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern Time</td>
<td></td>
<td></td>
<td>Closed</td>
<td></td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mar-10-2021 14:34:39</td>
<td>ACV0PFEINFP6000</td>
<td>auto query</td>
<td>Query 1:</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern Time</td>
<td>(autoquery)</td>
<td></td>
<td>Answered</td>
<td></td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mar-10-2021 14:34:39</td>
<td>ACV0PFEINFP6000</td>
<td></td>
<td>Data Entry:</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern Time</td>
<td></td>
<td></td>
<td>localized peritonitis</td>
<td></td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mar-10-2021 09:11:15</td>
<td>ACV0PFEINFP6000.InFormAdapter.Discrepancy</td>
<td>PFETMS Oracle</td>
<td>Query 1:</td>
<td>Spacing:</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern Time</td>
<td></td>
<td></td>
<td>Oopened</td>
<td>Verbatim Term</td>
</tr>
<tr>
<td>(US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td>contains leading,</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>trailing or</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>more than one</td>
</tr>
</tbody>
</table>
4. Start Date Time:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mar-10-2021 08:20:25 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: localized peritonitis</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

| Mar-10-2021 08:22:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/10/2021 UNK:UNK | Transcription Error         |

SAE RECON: AER#2021162151 onset date was recorded as 04Feb2021 in Safety database however, recorded as 10Feb2021 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.
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>Mar-10-2021 08:20:25</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Mar/10/2021 UNK:UNK</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>
<tr>
<td>Mar-10-2021 08:22:21</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO End Date Time: Feb/10/2021 UNK:UNK</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mar-10-2021 08:20:25</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO End Date Time: Mar/10/2021 UNK:UNK</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>

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>Mar-10-2021 08:20:25</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: 4</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>Mar-10-2021 14:36:02</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Deleted</td>
<td>Close Auto Query</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 8. Is this adverse event the result of a study Medication Error?

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Time (UTC)</th>
<th>ID</th>
<th>Event Type</th>
<th>Data Entry</th>
<th>Initial Entry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mar-10-2021 08:20:25</td>
<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Auto query (autoquery)</td>
<td><strong>Data Entry:</strong> YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES Other medically important serious event NO</td>
<td>For AE localized peritonitis: Response to &quot;Is the adverse event serious?&quot; is 'Yes' but &quot;Serious Adverse Event Number&quot; is blank.</td>
</tr>
<tr>
<td>Date</td>
<td>Location</td>
<td>User</td>
<td>Value</td>
<td>Reason</td>
<td></td>
</tr>
<tr>
<td>---------------</td>
<td>-------------------</td>
<td>-----------------</td>
<td>-------------</td>
<td>-------------------------</td>
<td></td>
</tr>
<tr>
<td>Mar-10-2021 08:20:25 (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>
<td></td>
</tr>
</tbody>
</table>

9. Is this event related to study treatment:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mar-12-2021 13:27:56 (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>Mar-11-2021 15:44:57 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Answered</td>
<td>per query</td>
</tr>
<tr>
<td>Mar-11-2021 15:44:57 (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>per query</td>
</tr>
<tr>
<td></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>appendicitis</td>
</tr>
<tr>
<td>Mar-11-2021 12:37:36 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Opened</td>
<td>Clinical - other case for event is UNKNOWN; however, the event occurs in the setting of appendicitis. Please review for potential other cause, and update if appropriate</td>
</tr>
<tr>
<td>Mar-10-2021 08:20:25 (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>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>
</tbody>
</table>
10. Latest Action Taken with Study Treatment:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mar-10-2021 08:20:25 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> NOT APPLICABLE</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

11. Was a Concomitant Medication given?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mar-10-2021 08:20:25 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> YES</td>
<td>Initial Entry</td>
</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>Mar-11-2021 12:36:46 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Closed</td>
<td>answered</td>
</tr>
<tr>
<td>Mar-11-2021 09:01:38 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Answered</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Mar-11-2021 09:01:38 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> YES</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Mar-11-2021 06:07:53 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Opened</td>
<td>DM: The response for &quot;Was a Non-Drug Treatment given?&quot; is missing. Kindly review and update.</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>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mar-10-2021 08:20:25</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4)</td>
<td>NO</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
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<td>(b) (6)</td>
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</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>Mar-10-2021 14:36:02</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4)</td>
<td>2021162151</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td></td>
<td>(b) (6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td>Location</td>
<td>User</td>
<td>Value</td>
<td>Reason</td>
</tr>
<tr>
<td>----------------------</td>
<td>---------------------------------</td>
<td>--------------------</td>
<td>-------------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>Mar-10-2021 08:21:54 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> ADVERSE EVENT</td>
<td>Initial Entry</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td><strong>Reason</strong></td>
<td></td>
</tr>
</tbody>
</table>

1. **Category:**

2. **AE ID:**

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-10-2021 08:21:54 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> 3</td>
<td>Initial Entry</td>
</tr>
<tr>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>Reason</strong></td>
<td></td>
</tr>
</tbody>
</table>

4. **Start Date Time:**

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mar-12-2021 10:44:59 (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>Mar-11-2021 09:00:48 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Answered</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Mar-11-2021 09:00:48 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
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<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Feb/4/2021 UNK:UNK</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Mar-10-2021 14:40:32 (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#2021162151 onset date was recorded as</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>Mar-10-2021 08:21:54 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Feb/10/2021 UNK:UNK</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>Mar-11-2021 09:01:21 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> NO End Date Time: Feb/11/2021 UNK:UNK</td>
<td>to match safety dates</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>Mar-10-2021 08:21:54 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> 4</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).
**Date** | **Location** | **User** | **Value** | **Reason**
--- | --- | --- | --- | ---
Mar-10-2021 14:36:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query
Mar-10-2021 08:21:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | For AE pelvic abscess: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Mar-10-2021 08:21:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 (b) (4), (b) (6) | (b) (4), (b) (6) | Data Entry: YES
Is this serious event associated with congenital anomaly or birth defect?

NO
Did this serious event result in death?

NO
Did this serious event require or prolong hospitalization?

YES
Did this serious event result in persistent or significant disability/incapacity?

NO
Is this serious event life threatening?

YES
Other medically important serious event

Initial Entry
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>Mar-10-2021 08:21:54</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>Mar-12-2021 13:29:00</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Mar-11-2021 15:45:36</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Answered</td>
<td>per query</td>
</tr>
<tr>
<td>Mar-11-2021 15:45:36</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NOT RELATED</td>
<td>per query</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>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>OTHER</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>If Other, specify:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>appendicitis</td>
</tr>
<tr>
<td>Mar-11-2021 12:38:00</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Opened</td>
<td>Clinical - other case for event is UNKNOWN; however, the event occurs in the setting of appendicitis. Please review for potential other cause, and update if appropriate</td>
</tr>
<tr>
<td>Mar-10-2021 08:21:54</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry:</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>
### 10. Latest Action Taken with Study Treatment:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mar-10-2021 08:21:54</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
<td>Data Entry: Initial Entry</td>
<td></td>
</tr>
</tbody>
</table>

### 11. Was a Concomitant Medication given?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mar-10-2021 08:21:54</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
<td>Data Entry: Initial Entry</td>
<td></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>Mar-10-2021 08:21:54</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
<td>Data Entry: Initial Entry</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mar-10-2021 08:21:54</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
<td>Data Entry: Initial Entry</td>
<td></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>
</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>Mar-10-2021 14:36:13</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (6)</td>
<td>2021162151</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

Mar-10-2021 08:21:54
(UTC-05:00) Eastern Time (US & Canada)

Data Entry: 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-27-2021 14:20:15</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Jan/22/2021</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 1. Select appropriate response - Is participant willing to return for Vaccination 3?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-27-2021 14:20:44 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Deleted</td>
<td>Close Auto Query</td>
</tr>
<tr>
<td>Jan-27-2021 14:20:29 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Candidate</td>
<td>The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.</td>
</tr>
</tbody>
</table>
| Jan-27-2021 14:20:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | **Data Entry:** Participant is willing to return for Vaccination 3  
Participant is:  
eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2 | Initial Entry |

---

**FDA-CBER-2021-5683-0920224**

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***Confidential***
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>Jan-27-2021 14:20:44</td>
<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Jan/25/2021 Initial Entry</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-27-2021 14:20:44</td>
<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: ASSESS ELIGIBILITY FOR A DDITIONAL VACCINATION Initial Entry</td>
</tr>
</tbody>
</table>
### 1. Date of Visit

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-29-2021 16:56:21 (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>Jan-29-2021 12:10:09 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Answered</td>
<td>Changed data per query</td>
</tr>
<tr>
<td>Jan-29-2021 07:19:23 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Opened</td>
<td>DM: Kindly consider to update missing SWAB PFE and SAMP TRK forms or else clarify. Thank you.</td>
</tr>
<tr>
<td>Jan-27-2021 14:20:56 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Jan/27/2021</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>
### 1. Consent Was:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-27-2021 14:21:07</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: OBTAINED Date Written Consent Obtained Jan/27/2021</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td></td>
<td>(b) (4), (b) (6)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Data Entry:**
- OBTAINED
- Date Written Consent Obtained
- Jan/27/2021
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>Jan-27-2021 14:21:35</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Jan/27/2021</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
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<td>(b) (4), (b) (6)</td>
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</table>

2. Phase of Disposition:

<table>
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<tr>
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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-27-2021 14:21:35</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: REPEAT SCREENING 1</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>

3. Status:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-27-2021 14:21:35</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: COMPLETED</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td></td>
<td>(b) (4), (b) (6)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 1. Lab Panel:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-27-2021 14:21:58</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td>Data Entry: URINALYSIS</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

**Location**: (UTC-05:00) Eastern Time (US & Canada)

### 2. Lab Sub-Panel:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-27-2021 14:21:58</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td>Data Entry: PREGNANCY</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

**Location**: (UTC-05:00) Eastern Time (US & Canada)

### 3. Collection Date:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-27-2021 14:21:58</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Jan/27/2021</td>
<td>Initial Entry</td>
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</tbody>
</table>

**Location**: (UTC-05:00) Eastern Time (US & Canada)

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

<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>Jan-27-2021 14:21:58</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td>Data Entry: STUDY SITE</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

**Location**: (UTC-05:00) Eastern Time (US & Canada)

### 5. Specimen Type:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-27-2021 14:21:58</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td>Data Entry: URINE</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

**Location**: (UTC-05:00) Eastern Time (US & Canada)

### 6.a

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

**Location**: (b) (4)
<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-27-2021 14:21:58 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: 113</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>Jan-27-2021 14:21:58 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Choriogonadotropin Beta_PX113</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>Jan-27-2021 14:21:58 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NEGATIVE</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

6.a Test:

6.a Result:
### 1. Data Origin

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-29-2021 12:08:32 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: SITE</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

### 2. Sample Type

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-29-2021 12:08:32 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: SERUM</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

### 3. Sample Collected?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-29-2021 12:08:52 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Deleted</td>
<td>Close Auto Query</td>
</tr>
<tr>
<td>Jan-29-2021 12:08:32 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Candidate</td>
<td>'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.</td>
</tr>
<tr>
<td>Jan-29-2021 12:08:32 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: YES Date of Collection: Jan/27/2021</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

### 5.a

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
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## 5. a Sample ID

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## 5. b

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<td>Query</td>
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### 1. Data Origin

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### 2. Sample Type

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### 3. Sample Collected?

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

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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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4. Dose Date Time:

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5. Anatomical Location:

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6. Body Side:
7. **Route:**

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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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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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<tr>
<td>Time (US &amp; Canada)</td>
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6.a

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

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<tr>
<td>Feb-18-2021 16:23:06 (UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: 113</td>
<td>Initial Entry</td>
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### 6.a Test:

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<td>(b) (4), (b) (6)</td>
<td>Data Entry: Choriogonadotropin Beta_PX113</td>
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### 6.a Result:

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

<table>
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<tbody>
<tr>
<td>Feb-19-2021 13:42:39</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td>Data Entry: SITE</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern</td>
<td>(autocalc)</td>
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</tr>
<tr>
<td>Time (US &amp; Canada)</td>
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### 2. Sample Type

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<td>Feb-19-2021 13:42:39</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
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<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern</td>
<td>(autocalc)</td>
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<td>Time (US &amp; Canada)</td>
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### 3. Sample Collected?

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<tr>
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<td>ACV0PFEINFP6000</td>
<td>auto query</td>
<td>Query 1: Deleted</td>
<td>Close Auto Query</td>
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<td>(UTC-05:00) Eastern</td>
<td>(autoquery)</td>
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<td></td>
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<tr>
<td>Time (US &amp; Canada)</td>
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<td>Feb-19-2021 13:42:39</td>
<td>ACV0PFEINFP6000</td>
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<td>'Sample Collected?'</td>
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<td>is Yes, however no barcodes are entered. Please review and correct as appropriate.</td>
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<tr>
<td>Time (US &amp; Canada)</td>
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<td></td>
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<tr>
<td>Feb-19-2021 13:42:39</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: YES</td>
<td>Initial Entry</td>
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<tr>
<td>(UTC-05:00) Eastern</td>
<td>(b) (4), (b) (6)</td>
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### 5.a

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<td>Feb-19-2021 13:42:58</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Sample ID: BV0F6P</td>
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<td>(b) (4), (b) (6)</td>
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<tr>
<td>Time (US &amp; Canada)</td>
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### 5.a Sample ID

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<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> BV0F6P</td>
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**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB -

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

**Site Name:** (1090) Wake Research Associates, LLC

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

**Subject No:** 10901140

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:31
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### 2. Treatment Name

<table>
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<td>Feb-18-2021 16:23:30</td>
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### 3. Formulation:

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<td>auto calc (autocalc)</td>
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### 4. Dose Date Time:

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<td>(b) (4), (b) (6)</td>
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### 5. Anatomical Location:

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<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: DELTOID MUSCLE</td>
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### 6. Body Side:

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FDA-CBER-2021-5683-0920243
### 7. Route:

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<tbody>
<tr>
<td>Feb-18-2021 16:23:30</td>
<td>ACV0PFEB000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: INTRAMUSCULAR</td>
<td>Initial Entry</td>
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<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
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### 8. Actual Dose:

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<td>Feb-18-2021 16:23:30</td>
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<td>auto calc (autocalc)</td>
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<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
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### 9. Unit:

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<td>Feb-18-2021 16:23:30</td>
<td>ACV0PFEB000</td>
<td>auto calc (autocalc)</td>
<td>ug</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
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### 10. Timeframe Subject Was Observed

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<tbody>
<tr>
<td>Feb-18-2021 16:23:30</td>
<td>ACV0PFEB000</td>
<td>auto calc (autocalc)</td>
<td>30 MINUTES</td>
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### 11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

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<td>ACV0PFEB000</td>
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### 1. Subject Status

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<tr>
<td>Oct-05-2020 08:49:29</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: FOLLOW-UP</td>
<td>Initial Entry</td>
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<tr>
<td>Aug-12-2020 15:18:17</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: ENROLLED/RANDOMIZED</td>
<td>Initial Entry</td>
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<td>(UTC-05:00) Eastern</td>
<td>Time (US &amp; Canada)</td>
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<tr>
<td>Aug-12-2020 14:56:30</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: SCREENED</td>
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### 2. Subject Status Date

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<tr>
<td>Mar-09-2021 20:31:31</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Closed</td>
<td>Response satisfies query</td>
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<td>(UTC-05:00) Eastern</td>
<td>Time (US &amp; Canada)</td>
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<td>Mar-09-2021 13:10:26</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Answered</td>
<td>Changed data per query</td>
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<td>Time (US &amp; Canada)</td>
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<tr>
<td>Mar-09-2021 06:13:09</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Opened</td>
<td>SAE RECON:AER#2021162151 located peritonitis, with pelvic abscess (onset date:04Feb2021) was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.</td>
</tr>
<tr>
<td>(UTC-05:00) Eastern</td>
<td>Time (US &amp; Canada)</td>
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<td>Feb-19-2021 03:25:43</td>
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<td>Query 1: Closed</td>
<td>Response satisfies query</td>
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<td>(UTC-05:00) Eastern</td>
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<tr>
<td>Date/Time (Eastern Time (US &amp; Canada))</td>
<td>ACV0PFEINFP6000</td>
<td>Query Type</td>
<td>Data Entry</td>
<td>Initial Entry</td>
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<td>Feb-18-2021 13:16:11</td>
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<tr>
<td>Feb-18-2021 02:11:58</td>
<td>ACV0PFEINFP6000</td>
<td>Query: Opened</td>
<td></td>
<td>SAE RECON:AER#2021162151 ruptured appendix (onset date:08Feb2021) was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form</td>
</tr>
<tr>
<td></td>
<td>(b) (4), (b) (6)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Oct-05-2020 08:49:29</td>
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<td>Oct/2/2020</td>
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</tr>
<tr>
<td>Aug-12-2020 15:18:17</td>
<td>ACV0PFEINFP6000</td>
<td>Data Entry:</td>
<td>Initial Entry</td>
<td></td>
</tr>
<tr>
<td>(UTC-05:00) Eastern Time (US &amp; Canada)</td>
<td></td>
<td>Aug/11/2020</td>
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</tr>
<tr>
<td>Aug-12-2020 14:56:30</td>
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<td>Data Entry:</td>
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### 1. Casebook Signature

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<td>ACV0PFEINFP6000</td>
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<td><strong>Data Entry:</strong> Click Here to Enable</td>
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**Header Text:** c4591001  
**Visit:** Investigator Signature - Unscheduled  
**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History  
**Form Version:** 22-Apr-2020 21:04  
**Site No:** 1090  
**Subject No:** 10901140  
**Generated By:** (b) (4)  
**Site Name:** (1090) Wake Research Associates, LLC  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:31