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

<p>| | |</p>
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>1.</td>
<td>Select appropriate response - Protocol version</td>
</tr>
<tr>
<td></td>
<td>24 JUL 2020</td>
</tr>
<tr>
<td>2.</td>
<td>Select appropriate response - What cohort does the subject belong to?</td>
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<tr>
<td></td>
<td>STAGE 3 COHORTS</td>
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### eCRF Audit Trail History

<table>
<thead>
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<th>Informed Consent</th>
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</thead>
<tbody>
<tr>
<td>1. Consent Was: OBTAINED</td>
</tr>
<tr>
<td>Date Written Consent Obtained Aug/24/2020</td>
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**eCRF Audit Trail History**

<table>
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<tr>
<th>Demography</th>
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<tbody>
<tr>
<td>1. Subject ID</td>
<td>[10221053]</td>
</tr>
<tr>
<td>2. Birth Date:</td>
<td>(b) (6) 1956</td>
</tr>
<tr>
<td>3. Sex:</td>
<td>FEMALE</td>
</tr>
<tr>
<td>4. Ethnicity:</td>
<td>NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN</td>
</tr>
<tr>
<td>5. Race: (Check X all that apply):</td>
<td>WHITE</td>
</tr>
<tr>
<td>6. Racial Designation:</td>
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**Header Text:** c4591001
**Visit:** V1_DAY1_VAX1_L  **Form:** DATE OF VISIT
**Form Version:** 22-Apr-2020 21:02  **Form Status:** Data Complete, Locked, Frozen, Verified
**Site No:** 1022  **Site Name:** (1022) Wenatchee Valley Hospital Clinics
**Subject No:** 10221053  **Subject Initials:** ---
**Generated By:** (b) (4)  **Generated Time (GMT):** 29-Mar-2021 04:44

### eCRF Audit Trail History

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<thead>
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<tbody>
<tr>
<td>1. Date of Visit</td>
<td>Aug/24/2020</td>
<td></td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
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</table>
## Form Comments

### Inclusion Criteria Not Met

<table>
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<tr>
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### Exclusion Criteria Met

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</thead>
</table>
**eCRF Audit Trail History**

## Disposition - Screening

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<tbody>
<tr>
<td>1.</td>
<td>Date of Completion/Discontinuation/Death</td>
<td>Aug/24/2020</td>
</tr>
<tr>
<td>2.</td>
<td>Phase of Disposition:</td>
<td>SCREENING</td>
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<tr>
<td>3.</td>
<td>Status:</td>
<td>COMPLETED</td>
</tr>
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<td>4.</td>
<td>Specify Status:</td>
<td>[ ]</td>
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### Medical History Details

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<thead>
<tr>
<th>Line/MH Number</th>
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<th>1.b</th>
<th>1.c</th>
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<tbody>
<tr>
<td>Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:</td>
<td>[Osteoarthrosis right lower leg]</td>
<td>[Seasonal Allergies]</td>
<td>[Menopausal]</td>
</tr>
<tr>
<td>Start Date:</td>
<td>Nov/16/2007</td>
<td>Jul/17/2007</td>
<td>Dec/4/2018</td>
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<tr>
<td>Ongoing:</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Vital Signs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-------------</td>
<td>---</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date:</td>
<td>Aug/24/2020</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weight:</td>
<td>[182.6]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unit:</td>
<td>LB</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Height:</td>
<td>[65.5]</td>
<td></td>
<td></td>
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<tr>
<td>Unit:</td>
<td>in</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Body Mass Index:</td>
<td>[29.9]</td>
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</table>

<table>
<thead>
<tr>
<th>Vital Signs Details</th>
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<tbody>
<tr>
<td>Record Identifier:</td>
<td>1</td>
</tr>
<tr>
<td>Temperature:</td>
<td>[98.2]</td>
</tr>
<tr>
<td>Unit:</td>
<td>F</td>
</tr>
<tr>
<td>Temperature Location:</td>
<td>ORAL CAVITY</td>
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</table>
### Lab Urinalysis

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<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/24/2020</td>
</tr>
<tr>
<td>4</td>
<td>Laboratory Name and Address (Derived)</td>
</tr>
<tr>
<td></td>
<td>[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>
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</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>
</tr>
</tbody>
</table>

**eCRF Audit Trail History**

**Lab Urinalysis**

1. Lab Panel: URINALYSIS
2. Lab Sub-Panel: PREGNANCY
3. Collection Date: Aug/24/2020
4. Laboratory Name and Address (Derived): [STUDY SITE]
5. Specimen Type: URINE

6.a Sponsor ID: [113]
Test: Choriogonadotropin Beta PX113
Result: NEGATIVE
Not Done:
## eCRF Audit Trail History

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<th>Disposition</th>
<th>Description</th>
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<td>Randomization Date:</td>
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<td>2.</td>
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<td>3.</td>
<td>Randomization Group:</td>
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### eCRF Audit Trail History

#### Electronic Sample Tracking

<p>| | | |</p>
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<tr>
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<tbody>
<tr>
<td>1.</td>
<td>Data Origin</td>
<td>SITE</td>
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<td>2.</td>
<td>Sample Type</td>
<td>SERUM</td>
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<td>3.</td>
<td>Sample Collected?</td>
<td>YES</td>
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<td></td>
<td>Date of Collection:</td>
<td>Aug/24/2020</td>
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<tr>
<td>4.</td>
<td>If no sample was collected or sample was not collected according to protocol, please provide reason:</td>
<td>[]</td>
</tr>
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#### Aliquot

Please enter barcode for each aliquot.

<table>
<thead>
<tr>
<th></th>
<th>Sample ID</th>
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</thead>
<tbody>
<tr>
<td>5.a</td>
<td>[BPHDKP]</td>
</tr>
<tr>
<td>5.b</td>
<td>[BPHDKR]</td>
</tr>
<tr>
<td>5.c</td>
<td>[BP1C7C]</td>
</tr>
<tr>
<td>5.d</td>
<td>[BP1C7D]</td>
</tr>
<tr>
<td>5.e</td>
<td>[BP1C7F]</td>
</tr>
</tbody>
</table>
**eCRF Audit Trail History**

### Electronic Sample Tracking

<p>| | |</p>
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>1.</td>
<td>Data Origin</td>
</tr>
<tr>
<td></td>
<td>SITE</td>
</tr>
<tr>
<td>2.</td>
<td>Sample Type</td>
</tr>
<tr>
<td></td>
<td>NASAL_SWAB</td>
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<tr>
<td>3.</td>
<td>Sample Collected?</td>
</tr>
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<td></td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td>Date of Collection: Aug/24/2020</td>
</tr>
<tr>
<td>4.</td>
<td>If no sample was collected or sample was not collected according to protocol, please provide reason:</td>
</tr>
<tr>
<td></td>
<td>[ ]</td>
</tr>
</tbody>
</table>

### Aliquot

Please enter barcode for each aliquot.

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<table>
<thead>
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</thead>
<tbody>
<tr>
<td>5.a</td>
<td>Sample ID</td>
</tr>
<tr>
<td></td>
<td>[BP1C2P]</td>
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</table>
eCRF Audit Trail History

<table>
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<tr>
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</thead>
<tbody>
<tr>
<td>1. Was there a temporary delay of vaccination?</td>
<td>NO</td>
</tr>
<tr>
<td>2. Treatment Name</td>
<td>[BLINDED THERAPY]</td>
</tr>
<tr>
<td>3. Formulation:</td>
<td>INJECTION</td>
</tr>
<tr>
<td>4. Dose Date Time:</td>
<td>Aug/24/2020 11:09</td>
</tr>
<tr>
<td>5. Anatomical Location:</td>
<td>DELTOID MUSCLE</td>
</tr>
<tr>
<td>6. Body Side:</td>
<td>LEFT</td>
</tr>
<tr>
<td>7. Route:</td>
<td>INTRAMUSCULAR</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>
<td>THE PROTOCOL SPECIFIED OBSERVATION PERIOD</td>
</tr>
<tr>
<td>11. Was the subject observed for at least the protocol specified observation period after investigational product administration?</td>
<td>YES</td>
</tr>
</tbody>
</table>
1. Select appropriate response - Reactogenicity diary collection

NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
### eCRF Audit Trail History

<table>
<thead>
<tr>
<th>Date of Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Visit</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
</tr>
</tbody>
</table>
### Vital Signs Details

2.a  | Record Identifier: I  
| Temperature: [97.6]  
| Unit: F  
| Temperature Location: ORAL CAVITY

**eCRF Audit Trail History**

**Vital Signs**

| Date | Sep/14/2020 |

| Vital Signs Details |

| 2.a  | Record Identifier: 1  
| Temperature: [97.6]  
| Unit: F  
| Temperature Location: ORAL CAVITY |

---

**Visit:** V2_VAX2_L  
**Form:** VITAL SIGNS - TEMP  
**Form Version:** 21-Aug-2020 02:51  
**Site No:** 1022  
**Site Name:** (1022) Wenatchee Valley Hospital Clinics  
**Subject No:** 10221053  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Generated Time (GMT):** 29-Mar-2021 04:44
### eCRF Audit Trail History

#### Lab Urinalysis

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<table>
<thead>
<tr>
<th></th>
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</tr>
</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: Not Done</td>
</tr>
<tr>
<td>4.</td>
<td>Laboratory Name and Address (Derived) [ ]</td>
</tr>
<tr>
<td>5.</td>
<td>Specimen Type:</td>
</tr>
</tbody>
</table>

**Comments**

#### Lab Result

<p>| | |</p>
<table>
<thead>
<tr>
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<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:</td>
</tr>
<tr>
<td></td>
<td>Not Done: NOT DONE</td>
</tr>
</tbody>
</table>
**Electronic Sample Tracking**

1. **Data Origin**: SITE
2. **Sample Type**: NASAL_SWAB
3. **Sample Collected?**: YES  
   **Date of Collection**: Sep/14/2020
4. **If no sample was collected or sample was not collected according to protocol, please provide reason**: 

**Aliquot**

Please enter barcode for each aliquot.

5.a **Sample ID**: [BP1BMF]

---

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1. **Data Origin**: SITE
2. **Sample Type**: NASAL_SWAB
3. **Sample Collected?**: YES  
   **Date of Collection**: Sep/14/2020
4. **If no sample was collected or sample was not collected according to protocol, please provide reason**: 

**Aliquot**

Please enter barcode for each aliquot.

5.a **Sample ID**: [BP1BMF]
### eCRF Audit Trail History

**Vaccination**

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

<table>
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<th>Note</th>
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<td>2. Erroneous Visit</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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</tr>
<tr>
<td>4.</td>
<td>If no sample was collected or sample was not collected according to protocol, please provide reason:</td>
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</table>

### Aliquot

Please enter barcode for each aliquot.

<p>| 5.a | Sample ID | [BP1BXH] |
| 5.b | Sample ID | [BPHF1R] |
| 5.c | Sample ID | [BPHF1Y] |</p>
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<thead>
<tr>
<th>Date of Visit</th>
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</thead>
<tbody>
<tr>
<td>Erroneous Visit</td>
<td></td>
</tr>
<tr>
<td>COVID-19 Illness Visit</td>
<td>COVID_A</td>
</tr>
</tbody>
</table>

**eCRF Audit Trail History**

**Date of Visit**

1. Date of Visit: Jan/4/2021
2. Erroneous Visit
3. COVID-19 Illness Visit: COVID_A
## Signs and Symptoms

1. **Date of Assessment:** Jan/4/2021
2. **Date of First Symptom Started:** Jan/3/2021
3. **Symptoms Ongoing?** NO
   - **Date of Last Symptom Resolved:** Jan/10/2021

### Symptoms

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<tbody>
<tr>
<td>4.a</td>
<td>FEVER</td>
<td>NO</td>
</tr>
<tr>
<td>4.b</td>
<td>NEW OR INCREASED COUGH</td>
<td>NO</td>
</tr>
<tr>
<td>4.c</td>
<td>NEW OR INCREASED SHORTNESS OF BREATH</td>
<td>NO</td>
</tr>
<tr>
<td>4.d</td>
<td>CHILLS</td>
<td>YES</td>
</tr>
<tr>
<td>4.e</td>
<td>NEW OR INCREASED MUSCLE PAIN</td>
<td>YES</td>
</tr>
<tr>
<td>4.f</td>
<td>NEW LOSS OF TASTE OR SMELL</td>
<td>NO</td>
</tr>
<tr>
<td>4.g</td>
<td>NEW OR INCREASED SORE THROAT</td>
<td>NO</td>
</tr>
<tr>
<td>4.h</td>
<td>DIARRHEA</td>
<td>NO</td>
</tr>
<tr>
<td>4.i</td>
<td>VOMITING</td>
<td>YES</td>
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</table>
### Symptoms - Other

<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>5.a</td>
<td>[Fatigue]</td>
</tr>
<tr>
<td>5.b</td>
<td>[Nausea]</td>
</tr>
<tr>
<td>#</td>
<td>Date of Collection</td>
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<td>----</td>
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<tr>
<td>1.</td>
<td>Jan/4/2021</td>
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</tbody>
</table>
### Microbiology Specimen

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<tbody>
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<td>1.</td>
<td><strong>Actual Date of Collection:</strong> Jan/4/2021</td>
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<tr>
<td>2.</td>
<td><strong>Specimen Type:</strong> SWABBED MATERIAL</td>
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<td>3.</td>
<td><strong>Specimen Collection Location:</strong> NASOPHARYNX</td>
</tr>
<tr>
<td>4.</td>
<td><strong>Assay Code and Description:</strong> SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2</td>
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<td>5.</td>
<td><strong>Device Type:</strong> SARS-COV-2 DIAGNOSTIC TEST</td>
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<td>6.</td>
<td><strong>Trade Name:</strong> OTHER</td>
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<td>7.</td>
<td><strong>Test Result:</strong> POSITIVE</td>
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<tr>
<td>8.</td>
<td><strong>Comments/Findings/Details:</strong> [ ]</td>
</tr>
<tr>
<td>9.</td>
<td><strong>Trade Name Other, Specify:</strong> [Sofia 2 SARS CoV-2 Antigen FIA POC-CLIA-certified]</td>
</tr>
</tbody>
</table>
**Header Text:** c4591001  
**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/04/2021  
**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1022  
**Site Name:** (1022) Wenatchee Valley Hospital Clinics  
**Subject No:** 10221053  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 04:44  

### eCRF Audit Trail History

<table>
<thead>
<tr>
<th>Electronic Sample Tracking</th>
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<tbody>
<tr>
<td><strong>1.</strong> Data Origin</td>
</tr>
<tr>
<td><strong>2.</strong> Sample Type</td>
</tr>
<tr>
<td><strong>3.</strong> Sample Collected?</td>
</tr>
<tr>
<td><strong>4.</strong> Date of Collection:</td>
</tr>
</tbody>
</table>

If no sample was collected or sample was not collected according to protocol, please provide reason: [ ]

### Aliquot

Please enter barcode for each aliquot.

<table>
<thead>
<tr>
<th>Sample ID</th>
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FDA-CBER-2021-5683-0899641
**eCRF Audit Trail History**

**Electronic Sample Tracking**

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**Aliquot**

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Health Care Utilization

1.a | Physician or Healthcare Professional: | SPECIALIST
   | Occurrence of Visits or Contacts: | NO

1.b | Physician or Healthcare Professional: | EMERGENCY ROOM
   | Occurrence of Visits or Contacts: | NO

1.c | Physician or Healthcare Professional: | PRIMARY CARE PHYSICIAN
   | Occurrence of Visits or Contacts: | NO

1.d | Physician or Healthcare Professional: | URGENT CARE
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1.e | Physician or Healthcare Professional: | TELEPHONE CONSULTATION
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1.f | Physician or Healthcare Professional: | OTHER
   | Occurrence of Visits or Contacts: | NO

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? NO
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**Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY**

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Subject No: 10221053
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 04:44
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**Form Instance**

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<td>Erythrocytes_PX3</td>
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Not Done: Not Done Comments

LNMT Not Done

Low

High

Unit

### 5.g

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Not Done: Not Done Comments

LNMT Not Done

Low

High

Unit
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**Comments**

Not Done

[ ]

Low
[ ]

High
[ ]

Unit
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<th>Diastolic:</th>
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<table>
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<th>Heart Rate in beats/minute:</th>
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<tbody>
<tr>
<td></td>
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<td></td>
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<tr>
<td>#</td>
<td>Date:</td>
<td>Vital Signs Details</td>
<td>Form Instance</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
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</tbody>
</table>
| 1. | Not Done | Record Identifier: Oxygen Saturation  
Not Done Not Done | Repeating Pages |
| Vital Signs |  
|-------------|---|
| **1.** Date: | Not Done |
| | // |

| Vital Signs Details |  
|---------------------|---|
| **2.a** Record Identifier: | Not Done |
| | 1 |

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<tr>
<td>#</td>
<td>Date Time of Assessment</td>
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### Oxygenation Parameters

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<td>Arterial Blood Gases PaO2 (mmHg):</td>
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<td>[ ]</td>
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<td></td>
<td>FiO2 (Fraction of Inhaled Oxygen):</td>
<td>Not Done</td>
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**Comments**
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<th>Category for Medication</th>
<th>Concomitant Medications Pre-specified</th>
<th>Name of Medication</th>
<th>Start Date</th>
<th>Form Instance</th>
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</thead>
<tbody>
<tr>
<td>1.</td>
<td>Not Done</td>
<td>Not Done</td>
<td>Not Done</td>
<td>Not Done</td>
<td>Not Done</td>
<td>Repeating Pages</td>
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</table>

(b) (4)
### Concomitant Medications

1. **What is the medication identifier?**
   - Not Done
   - 
   - [ ]
   - **Comments**

2. **Category:**
   - Not Done
   - 
   - **Comments**

3. **Concomitant Medications Pre-specified:**
   - Not Done
   - 
   - **Comments**

4. **Medication:**
   - Not Done
   - 
   - [ ]
   - **Comments**

5. **Start Date:**
   - Not Done
   - 
   - //
   - **Comments**

6. **Ongoing?**
   - Not Done
   - 
   - **Comments**
<table>
<thead>
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<th>Date of Assessment</th>
<th>Location of Assessment</th>
<th>Imaging Method</th>
<th>Overall Assessment</th>
<th>Form Instance</th>
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### Imaging

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<tr>
<td>2</td>
<td>Type of Imaging Exam:</td>
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<tr>
<td>3</td>
<td>Assessment:</td>
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**Header Text:** c4591001  
**Visit:** POT_COVID_CONV A 1 - Unscheduled Visit on Feb/01/2021  
**Form:** DATE OF VISIT - ILLNESS CONVALESCENT  
**Form Version:** 22-Apr-2020 21:04  
**Site No:** 1022  
**Subject No:** 10221053  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 04:44

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**eCRF Audit Trail History**

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<td>Feb/1/2021</td>
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<tr>
<td>2. Erroneous Visit</td>
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**COVID-19 Illness Visit**

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**Header Text:** c4591001  
**Visit:** POT_COVID_CONV A 1 - Unscheduled Visit on Feb/01/2021  
**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY  
**Form Version:** 22-Apr-2020 21:03  
**Form Status:** Data Complete, Frozen, Verified  
**Site No:** 1022  
**Site Name:** (1022) Wenatchee Valley Hospital Clinics  
**Subject No:** 10221053  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 04:44

### eCRF Audit Trail History

**Electronic Sample Tracking**

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<td>Feb/1/2021</td>
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<th>If no sample was collected or sample was not collected according to protocol, please provide reason:</th>
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<td>4.</td>
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### Aliquot

Please enter barcode for each aliquot.

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<td>[BS7DVB]</td>
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<tr>
<td>5.b</td>
<td>[BS7DVC]</td>
</tr>
<tr>
<td>5.c</td>
<td>[BRDY0B]</td>
</tr>
<tr>
<td>Date of Visit</td>
<td></td>
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<td>--------------</td>
<td></td>
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**Header Text:** e4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1022

**Site Name:** (1022) Wenatchee Valley Hospital Clinics

**Subject No:** 10221053

**Subject Initials:** ---

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

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

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Header Text: c4591001
Visit: Unplanned - New Unscheduled Visit
Form Version: 22-Apr-2020 21:04
Site No: 1022
Subject No: 10221053
Generated By: (b) (4)

Form: UNPLANNED VISIT
Form Status: Not Started
Site Name: (1022) Wenatchee Valley Hospital Clinics
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 04:44

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FDA-CBER-2021-5683-0899674

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<tr>
<td>Disposition - Follow-Up</td>
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<td>----------------------------------------</td>
<td></td>
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<tr>
<td>1. Date of Completion/Discontinuation/Death: //</td>
<td></td>
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<tr>
<td>2. Phase of Disposition:</td>
<td></td>
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<tr>
<td>3. Status:</td>
<td></td>
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<td>4. Specify Status: [ ]</td>
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Visitor: Follow-Up - Unscheduled  
Form: DISPOSITION - FOLLOW-UP  
Form Status: Not Started  
Site No: 1022  
Site Name: (1022) Wenatchee Valley Hospital Clinics  
Subject Initials: ---  
Subject No: 10221053  
Generated By: (b) (4)  
Generated Time (GMT): 29-Mar-2021 04:44
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<td>2. Erroneous Visit</td>
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**COVID-19 Repeat Swab**

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

1. **Data Origin**

2. **Sample Type**

3. **Sample Collected?**

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

### Aliquot

Please enter barcode for each aliquot.

5. **Sample ID**
   
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**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 04:44
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<th>Start Date</th>
<th>Is the Adverse Event Still On going</th>
<th>Form Instance</th>
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<tbody>
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<td>Moderate Chills</td>
<td>Feb/1/2021 19:00</td>
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</tr>
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<td>2.</td>
<td>ADVERSE EVENT</td>
<td>2</td>
<td>Moderate Headache</td>
<td>Feb/1/2021 19:00</td>
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<td>Repeating Pages</td>
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<tr>
<td>3.</td>
<td>ADVERSE EVENT</td>
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<td>Generalized Myalgias</td>
<td>Feb/1/2021 19:00</td>
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<td>Repeating Pages</td>
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<td>4.</td>
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<td>Injection Site Pain</td>
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<td>Moderate Diarrhea</td>
<td>Feb/4/2021 08:00</td>
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<tr>
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<td></td>
<td>(If possible specify diagnosis, not individual symptoms)</td>
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<td>4.</td>
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<td>NO</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>End Date Time:</td>
<td>Feb/3/2021 19:00</td>
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<tr>
<td>6.</td>
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<td>2</td>
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</tr>
<tr>
<td>7.</td>
<td>Is the adverse event serious?</td>
<td>NO</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>If Yes, NOTIFY PFIZER IMMEDIATELY.</td>
<td></td>
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<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>
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<tr>
<td>8.</td>
<td>Is this adverse event the result of a study Medication Error?</td>
<td>NO</td>
<td></td>
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<tr>
<td></td>
<td>If Yes, record the type of medication error on the Medication Error Log.</td>
<td></td>
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<tr>
<td>9.</td>
<td>Is this event related to study treatment:</td>
<td>RELATED</td>
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<tr>
<td>10.</td>
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<td>11.</td>
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<td></td>
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<td>NO</td>
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<td>13.</td>
<td>What was the outcome of this adverse event?:</td>
<td>RECOVERED/RESOLVED</td>
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<td>14.</td>
<td>Did the adverse event cause the subject to be discontinued from the study?</td>
<td>NO</td>
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<td></td>
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<tr>
<td><strong>Adverse Event:</strong></td>
<td>[Moderate Headache]</td>
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<td></td>
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<tr>
<td><strong>Start Date Time:</strong></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Is the adverse event still ongoing?</strong></td>
<td>NO</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>End Date Time:</strong></td>
<td>Feb/3/2021 19:00</td>
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<tr>
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<td></td>
<td></td>
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<td></td>
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<tr>
<td><strong>Is the adverse event serious?</strong></td>
<td>NO</td>
<td></td>
<td></td>
<td></td>
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<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>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>Is this adverse event the result of a study Medication Error?</strong></td>
<td>NO</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>If Yes, record the type of medication error on the Medication Error Log.</td>
<td></td>
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<tr>
<td><strong>Is this event related to study treatment:</strong></td>
<td>RELATED</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Latest Action Taken with Study Treatment:</strong></td>
<td>DRUG WITHDRAWN</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>Was a Concomitant Medication given?</strong></td>
<td>NO</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Question</td>
<td>Answer</td>
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</tr>
<tr>
<td>12. Was a Non-Drug Treatment given?</td>
<td>NO</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>13. What was the outcome of this adverse event?</td>
<td>RECOVERED/RESOLVED</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. Did the adverse event cause the subject to be discontinued from the study?</td>
<td>NO</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15. Serious Adverse Event Number: For Pfizer Use Only</td>
<td>[ ]</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
Adverse Event Report

1. Category: ADVERSE EVENT

2. AE ID: [3]

3. Adverse Event: [Generalized Myalgias]
   (If possible specify diagnosis, not individual symptoms)

4. Start Date Time: Feb/1/2021 19:00

5. Is the adverse event still ongoing? NO
   End Date Time: Feb/3/2021 19:00

6. Toxicity Grade: 2

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).
   NO

8. Is this adverse event the result of a study Medication Error? NO
   If Yes, record the type of medication error on the Medication Error Log.

9. Is this event related to study treatment: RELATED

10. Latest Action Taken with Study Treatment: DRUG WITHDRAWN

11. Was a Concomitant Medication given? NO
| 12. | Was a Non-Drug Treatment given? | NO |
| 13. | What was the outcome of this adverse event? | RECOVERED/RESOLVED |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO |
| 15. | Serious Adverse Event Number: For Pfizer Use Only | [ ] |
### Adverse Event Report

<table>
<thead>
<tr>
<th></th>
<th>ADVERSE EVENT REPORT</th>
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</thead>
<tbody>
<tr>
<td>1.</td>
<td>Category: ADVERSE EVENT</td>
</tr>
<tr>
<td>2.</td>
<td>AE ID: [4]</td>
</tr>
<tr>
<td>3.</td>
<td>Adverse Event: (If possible specify diagnosis, not individual symptoms) [Injection Site Pain]</td>
</tr>
<tr>
<td>4.</td>
<td>Start Date Time: Feb/1/2021 19:00</td>
</tr>
<tr>
<td>5.</td>
<td>Is the adverse event still ongoing? NO</td>
</tr>
<tr>
<td></td>
<td>End Date Time: Feb/4/2021 19:00</td>
</tr>
<tr>
<td>6.</td>
<td>Toxicity Grade: 3</td>
</tr>
<tr>
<td>7.</td>
<td>Is the adverse event serious? NO</td>
</tr>
<tr>
<td></td>
<td>If Yes, NOTIFY PFIZER IMMEDIATELY.</td>
</tr>
<tr>
<td></td>
<td>Fatal: Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).</td>
</tr>
<tr>
<td>8.</td>
<td>Is this adverse event the result of a study Medication Error? NO</td>
</tr>
<tr>
<td></td>
<td>If Yes, record the type of medication error on the Medication Error Log.</td>
</tr>
<tr>
<td>9.</td>
<td>Is this event related to study treatment: RELATED</td>
</tr>
<tr>
<td>10.</td>
<td>Latest Action Taken with Study Treatment: DRUG WITHDRAWN</td>
</tr>
<tr>
<td>11.</td>
<td>Was a Concomitant Medication given? NO</td>
</tr>
<tr>
<td>Question</td>
<td>Answer</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>---------------------------------</td>
</tr>
<tr>
<td>12. Was a Non-Drug Treatment given?</td>
<td>NO</td>
</tr>
<tr>
<td>13. What was the outcome of this adverse event?</td>
<td>RECOVERED/RESOLVED</td>
</tr>
<tr>
<td>14. Did the adverse event cause the subject to be discontinued from the study?</td>
<td>NO</td>
</tr>
<tr>
<td>15. Serious Adverse Event Number: For Pfizer Use Only</td>
<td>[ ]</td>
</tr>
</tbody>
</table>
# Adverse Event Report

1. **Category:** ADVERSE EVENT

2. **AE ID:** [5]

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

4. **Start Date Time:** Feb/4/2021 08:00

5. **Is the adverse event still ongoing?**
   **NO**
   **End Date Time:**
   Feb/7/2021 08:00

6. **Toxicity Grade:** 2

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).
   **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**

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

10. **Latest Action Taken with Study Treatment:**
    DRUG WITHDRAWN

11. **Was a Concomitant Medication given?**
    **NO**

---

**Header Text:** c4591001  
**Visit:** Logs - Unscheduled  
**Form:** ADVERSE EVENT REPORT  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1022  
**Site Name:** (1022) Wenatchee Valley Hospital Clinics  
**Subject No:** 10221053  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 04:44
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<tr>
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<td>Was a Non-Drug Treatment given?</td>
</tr>
<tr>
<td>13.</td>
<td>What was the outcome of this adverse event?</td>
</tr>
<tr>
<td>14.</td>
<td>Did the adverse event cause the subject to be discontinued from the study?</td>
</tr>
<tr>
<td>15.</td>
<td>Serious Adverse Event Number: For Pfizer Use Only</td>
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<p>| | |</p>
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<tbody>
<tr>
<td></td>
<td>NO</td>
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<tr>
<td></td>
<td>RECOVERED/RESOLVED</td>
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<tr>
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<td>NO</td>
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<td>Category</td>
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</table>
Medication Error

1. Category:

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

3. Start Date:
   //

4. Is the medication error still ongoing?

5. Latest Action Taken with Study Treatment:

6. Was a Concomitant Medication given?

7. Was a Non-Drug Treatment given?

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

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

10. Serious Adverse Event Number:
    For Pfizer Use Only
    [ ]
<table>
<thead>
<tr>
<th>#</th>
<th>Sponsor-Defined Identifier</th>
<th>Category for Medication</th>
<th>Concomitant Medications Pre-specified</th>
<th>Name of Medication</th>
<th>Start Date</th>
<th>Form Instance</th>
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<tbody>
<tr>
<td>1.</td>
<td></td>
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<td>Repeating Pages</td>
</tr>
<tr>
<td>Concomitant Medications</td>
<td></td>
<td></td>
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<tr>
<td>-------------------------</td>
<td></td>
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<tr>
<td>1. What is the medication identifier?</td>
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<td>2. Category:</td>
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<tr>
<td>3. Concomitant Medications Pre-specified:</td>
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</table>
| 4. Medication: | ...
<p>| 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. Date: | // |</p>
<table>
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<th>Sponsor-Defined Identifier</th>
<th>Category for Medication</th>
<th>Concomitant Medications Pre-specified</th>
<th>Name of Medication</th>
<th>Dose Description</th>
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</table>
## Concomitant Medications

1. **What is the medication identifier?**
   - 

2. **Category:**
   - 

3. **Concomitant Medications Pre-specified:**
   - 

4. **Medication:**
   - Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).
   - 

5. **Dose:**
   - 

6. **Dose Unit:**
   - 

7. **Dose Frequency:**
   - 

8. **Route:**
   - 

9. **Start Date:**
   - //

10. **Ongoing?**
    - (b) (4)

---

**FDA-CBER-2021-5683-0899695**
<table>
<thead>
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<th>Start Date</th>
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## Radiation Treatment

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<tr>
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<tr>
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<td>What is the treatment Identifier?</td>
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<tr>
<td>3.</td>
<td>Concomitant Non-drug Treatment Pre-specified:</td>
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<tr>
<td>4.</td>
<td>Treatment:</td>
</tr>
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<td>5.</td>
<td>Start Date:</td>
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<tr>
<td>6.</td>
<td>Ongoing?</td>
</tr>
<tr>
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<td>Transfusion Type</td>
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1. Transfusion Type:  
2. Date of Transfusion: //
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<tr>
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<td>2. Erroneous Visit</td>
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### Vital Signs

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### Vital Signs Details

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<td>Temperature: [ ]</td>
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<td>Unit:</td>
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<td>Temperature Location:</td>
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**Form: VITAL SIGNS - TEMP**
**Form Version: 20-Feb-2021 02:16**
**Site No: 1022**
**Site Name: (1022) Wenatchee Valley Hospital Clinics**
**Subject No: 10221053**
**Generated By: (b) (4)**
**Generated Time (GMT): 29-Mar-2021 04:44**
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<th><strong>Lab Urinalysis</strong></th>
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<td>2. Lab Sub-Panel:</td>
</tr>
<tr>
<td>3. Collection Date: //</td>
</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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<th><strong>Lab Result</strong></th>
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<td>Result:</td>
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<tr>
<td>Not Done:</td>
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<td>Vaccination</td>
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<tr>
<td>1. Was there a temporary delay of vaccination?</td>
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<tr>
<td>2. Treatment Name</td>
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<td>3. Formulation:</td>
</tr>
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<td>4. Dose Date Time:</td>
</tr>
<tr>
<td>5. Anatomical Location:</td>
</tr>
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<td>6. Body Side:</td>
</tr>
<tr>
<td>7. Route:</td>
</tr>
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<td>8. Actual Dose:</td>
</tr>
<tr>
<td>9. Unit:</td>
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<tr>
<td>10. Timeframe Subject Was Observed</td>
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<tr>
<td>11. Was the subject observed for at least the protocol specified observation period after investigational product administration?</td>
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### Contact Outcome

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<table>
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<tbody>
<tr>
<td>1.</td>
<td>Contact Type:</td>
</tr>
<tr>
<td>2.</td>
<td>Was contact made?</td>
</tr>
<tr>
<td>3.</td>
<td>Comments: [ ]</td>
</tr>
</tbody>
</table>
### Contact Outcome

1. **Contact Type:**

2. **Was contact made?**

3. **Comments:** [ ]
Header Text: e4591001
Visit: Potential ReVax Initial Contact - Unscheduled
Form Version: 22-Apr-2020 21:02
Site No: 1022
Subject No: 10221053
Generated By: (b) (4)

Form: DATE OF VISIT
Form Status: Data Complete, Frozen, Verified
Site Name: (1022) Wenatchee Valley Hospital Clinics
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

<table>
<thead>
<tr>
<th>Date of Visit</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Visit</td>
<td>Jan/5/2021</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
<tr>
<td></td>
<td>eCRF Audit Trail History</td>
</tr>
<tr>
<td>---</td>
<td>-------------------------</td>
</tr>
<tr>
<td></td>
<td>Further Vaccination Confirmation</td>
</tr>
<tr>
<td><strong>1.</strong></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: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2</td>
</tr>
</tbody>
</table>
**eCRF Audit Trail History**

<table>
<thead>
<tr>
<th>Treatment Unblinded</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date Treatment Unblinded: Jan/15/2021</td>
</tr>
<tr>
<td>2. Primary Reason for Unblinding: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION</td>
</tr>
</tbody>
</table>

---

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1022

**Subject No:** 10221053

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

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

| 1. Withdrawal of Consent Date | // |

**Form:** WITHDRAWAL OF CONSENT

**Visit:** Disposition - Unscheduled

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

**Site No:** 1022

**Subject No:** 10221053

**Generated By:**

**Site Name:** (1022) Wenatchee Valley Hospital Clinics

**Subject Initials:** ---

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

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Date of Collection / Notification of Death: //</td>
</tr>
</tbody>
</table>

### Cause of Death

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2.</td>
<td>Cause of Death Status:</td>
</tr>
<tr>
<td></td>
<td>Cause of Death: [ ]</td>
</tr>
</tbody>
</table>
Header Text: c4591001
Visit: V101_VAX3
Form Version: 22-Apr-2020 21:02
Site No: 1022
Subject No: 10221053
Generated By: (b) (4)
Form: DATE OF VISIT
Form Status: Data Complete, Frozen, Verified
Site Name: (1022) Wenatchee Valley Hospital Clinics
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History
Date of Visit

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

1. Consent Was: OBTAINED
   Date Written Consent Obtained
   Feb/1/2021
### Form Comments

#### Inclusion Criteria Not Met

1. Description of Inclusion Criterion Not Met
   - Not Applicable

#### Exclusion Criteria Met

2. Description of Exclusion Criterion Met
   - Not Applicable
**Disposition - Screening for Further Vaccination**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Date of Completion/Discontinuation/Death:</strong></td>
<td>Feb/1/2021</td>
</tr>
<tr>
<td><strong>2. Phase of Disposition:</strong></td>
<td>REPEAT SCREENING 1</td>
</tr>
<tr>
<td><strong>3. Status:</strong></td>
<td>COMPLETED</td>
</tr>
<tr>
<td><strong>4. Specify Status:</strong></td>
<td>[ ]</td>
</tr>
</tbody>
</table>

---

FDA-CBER-2021-5683-0899714
### Lab Urinalysis

1. **Lab Panel:**

2. **Lab Sub-Panel:**

3. **Collection Date:** Not Done

   //

4. **Laboratory Name and Address (Derived)**: [ ]

5. **Specimen Type:**

### Lab Result

6.a  | Sponsor ID: [113]
--- | ---
**Test:** Choriogonadotropin Beta_PX113
**Result:**
**Not Done:** NOT DONE
### eCRF Audit Trail History

#### Electronic Sample Tracking

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>1.</td>
<td>Data Origin</td>
<td>SITE</td>
</tr>
<tr>
<td>2.</td>
<td>Sample Type</td>
<td>SERUM</td>
</tr>
<tr>
<td>3.</td>
<td>Sample Collected?</td>
<td>NO</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>[Patient lab samples were scanned into her COVID convalescent visit.]</td>
</tr>
</tbody>
</table>

#### Aliquot

Please enter barcode for each aliquot.

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

#### Electronic Sample Tracking

<table>
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<th>Data Origin</th>
<th>Sample Type</th>
<th>Sample Collected?</th>
<th>Date of Collection</th>
<th>If no sample was collected or sample was not collected according to protocol, please provide reason:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>SITE</td>
<td>NASAL_SWAB</td>
<td>YES</td>
<td>Feb/1/2021</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

**Aliquot**

Please enter barcode for each aliquot.

<table>
<thead>
<tr>
<th></th>
<th>Sample ID</th>
<th>[BRDXYX]</th>
</tr>
</thead>
</table>
### eCRF Audit Trail History

**Vaccination**

1. Was there a temporary delay of vaccination? | NO  
2. Treatment Name | [BNT162b2]  
3. Formulation: | INJECTION  
4. Dose Date Time: | Feb/1/2021 11:25  
5. Anatomical Location: | DELTOID MUSCLE  
6. Body Side: | LEFT  
7. Route: | INTRAMUSCULAR  
8. Actual Dose: | [30.0]  
9. Unit: | ug  
10. Timeframe Subject Was Observed | 30 MINUTES  
11. Was the subject observed for at least the protocol specified observation period after investigational product administration? | YES
Date of Visit

1. Date of Visit Feb/19/2021
2. Erroneous Visit
<table>
<thead>
<tr>
<th><strong>Lab Urinalysis</strong></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>1. Lab Panel:</td>
<td></td>
</tr>
<tr>
<td>2. Lab Sub-Panel:</td>
<td></td>
</tr>
<tr>
<td>3. Collection Date:</td>
<td>Not Done</td>
</tr>
<tr>
<td></td>
<td>//</td>
</tr>
<tr>
<td>4. Laboratory Name and Address (Derived)</td>
<td>[]</td>
</tr>
<tr>
<td>5. Specimen Type:</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th><strong>Lab Result</strong></th>
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</tr>
</thead>
<tbody>
<tr>
<td>6.a Sponsor ID:</td>
<td>[113]</td>
</tr>
<tr>
<td>Test:</td>
<td>Choriogonadotropin Beta_PX113</td>
</tr>
<tr>
<td>Result:</td>
<td></td>
</tr>
<tr>
<td>Not Done:</td>
<td>NOT DONE</td>
</tr>
</tbody>
</table>
**eCRF Audit Trail History**

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

<table>
<thead>
<tr>
<th>5.a</th>
<th>Sample ID</th>
<th>BM94VG</th>
</tr>
</thead>
</table>

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**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1022  
**Subject No:** 10221053  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 04:44
<table>
<thead>
<tr>
<th>Vaccination</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>1. Was there a temporary delay of vaccination?</td>
<td>Not Done</td>
</tr>
<tr>
<td>2. Treatment Name</td>
<td>Not Done</td>
</tr>
<tr>
<td></td>
<td>[ ]</td>
</tr>
<tr>
<td>3. Formulation:</td>
<td>Not Done</td>
</tr>
<tr>
<td>4. Dose Date Time:</td>
<td>Not Done</td>
</tr>
<tr>
<td></td>
<td>//</td>
</tr>
<tr>
<td>5. Anatomical Location:</td>
<td>Not Done</td>
</tr>
<tr>
<td>6. Body Side:</td>
<td>Not Done</td>
</tr>
<tr>
<td>7. Route:</td>
<td>Not Done</td>
</tr>
<tr>
<td>8. Actual Dose:</td>
<td>Not Done</td>
</tr>
<tr>
<td></td>
<td>[ ]</td>
</tr>
<tr>
<td>9. Unit:</td>
<td>Not Done</td>
</tr>
<tr>
<td>10. Timeframe Subject Was Observed</td>
<td>Not Done</td>
</tr>
<tr>
<td>11. Was the subject observed for at least the protocol specified observation period after investigational product administration?</td>
<td>Not Done</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>
<tr>
<td>Contact Outcome</td>
<td></td>
</tr>
<tr>
<td>-----------------</td>
<td></td>
</tr>
<tr>
<td>1. Contact Type:</td>
<td></td>
</tr>
<tr>
<td>2. Was contact made?</td>
<td></td>
</tr>
<tr>
<td>3. Comments: [ ]</td>
<td></td>
</tr>
</tbody>
</table>
**Date of Visit**

1. Date of Visit  //
2. Erroneous Visit

---

**Form**: DATE OF VISIT
**Form Status**: Not Started
**Site Name**: (1022) Wenatchee Valley Hospital Clinics
**Subject Initials**: ---
**Generated Time (GMT)**: 29-Mar-2021 04:44
<table>
<thead>
<tr>
<th>Contact Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Contact Type:</td>
</tr>
<tr>
<td>2. Was contact made?</td>
</tr>
<tr>
<td>3. Comments: [ ]</td>
</tr>
<tr>
<td>Date of Visit</td>
</tr>
<tr>
<td>---------------</td>
</tr>
<tr>
<td>1. Date of Visit //</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
</tr>
</tbody>
</table>
### Contact Outcome

1. **Contact Type:**

2. **Was contact made?**

3. **Comments:** [ ]
**Disposition - Treatment**

1. Date of Completion/Discontinuation/Death: Feb/19/2021
2. Phase of Disposition: OPEN LABEL TREATMENT
3. Status: ADVERSE EVENT
4. Specify Status: [ ]
## eCRF Audit Trail History

<table>
<thead>
<tr>
<th>Subject Status</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject Status</td>
<td>FOLLOW-UP</td>
</tr>
<tr>
<td>Subject Status Date</td>
<td>Oct/16/2020</td>
</tr>
</tbody>
</table>
### Casebook Signature Form

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Casebook Signature</td>
</tr>
</tbody>
</table>
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>(b) (6)</td>
<td>Approved</td>
<td>Mar-09-2021 09:15:09 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>BOOK</td>
<td>Signed</td>
</tr>
</tbody>
</table>

Affidavit:

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

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

To this I do attest by supplying my user name and password and clicking the button marked Submit below.
<table>
<thead>
<tr>
<th>Item</th>
<th>Date</th>
<th>User</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form</td>
<td>Aug-24-2020 11:01:56 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>(b) (4), (b) (6)</td>
<td>Not Applicable</td>
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</tbody>
</table>

Back to Form
<table>
<thead>
<tr>
<th>Item</th>
<th>Date Details</th>
<th>User</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>Sep-14-2020  13:02:01 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
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<tr>
<td>Item</td>
<td>Date</td>
<td>User</td>
<td>Comment</td>
</tr>
<tr>
<td>------</td>
<td>-----------------------------</td>
<td>---------------</td>
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</tr>
<tr>
<td>Form</td>
<td>Jan-04-2021 13:19:09 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>(b) (4), (b) (6)</td>
<td>Not Done</td>
</tr>
<tr>
<td>Item</td>
<td>Date</td>
<td>User</td>
<td>Comment</td>
</tr>
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<td>------</td>
<td>------</td>
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</tr>
<tr>
<td>1</td>
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<td>(b) (4), (b) (6)</td>
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</tbody>
</table>
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/04/2021

Form: RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Site No: 1022

Subject No: 10221053

Generated By: [b] (4)

Site Name: (1022) Wenatchee Valley Hospital Clinics

Subject Initials: ---

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

Item | Date | User | Comment
--- | --- | --- | ---
2 | Jan-04-2021 13:19:09 (UTC-08:00) Pacific Time (US & Canada) | [b] (4), [b] (6) | Not Done
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/04/2021
Form: RESPIRATORY TREATMENT - Comments
Form Version: 06-Jul-2020 21:53
Site No: 1022
Site Name: (1022) Wenatchee Valley Hospital Clinics
Subject No: 10221053
Subject Initials: ---
Generated By: [b] (4)
Generated Time (GMT): 29-Mar-2021 04:44

<table>
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<tr>
<th>Item</th>
<th>Date</th>
<th>User</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>Jan-04-2021 13:19:09 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>(b) (4), (b) (6)</td>
<td>Not Done</td>
</tr>
<tr>
<td>Item</td>
<td>Date</td>
<td>User</td>
<td>Comment</td>
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<tr>
<td>------</td>
<td>-------------------------------------------</td>
<td>------------</td>
<td>----------------</td>
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<tr>
<td>4</td>
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<tr>
<td>Item</td>
<td>Date</td>
<td>User</td>
<td>Comment</td>
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<td>-------------------------------------------</td>
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</tr>
<tr>
<td>5</td>
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<td>(b) (4), (b) (6)</td>
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</tr>
</tbody>
</table>

**Header Text:** c4591001

**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/04/2021

**Form:** RESPIRATORY TREATMENT - Comments

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1022

**Site Name:** (1022) Wenatchee Valley Hospital Clinics

**Subject No:** 10221053

**Subject Initials:** ---

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

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

**Form Status:** Data Complete, Frozen

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FDA-CBER-2021-5683-0899740

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Page 126 of 397
Id: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/04/2021
Form: RESPIRATORY TREATMENT - Comments
Form Version: 06-Jul-2020 21:53
Form Status: Data Complete, Frozen
Site No: 1022
Site Name: (1022) Wenatchee Valley Hospital Clinics
Subject No: 10221053
Subject Initials: ---
Generated By: [b] (4)
Generated Time (GMT): 29-Mar-2021 04:44

<table>
<thead>
<tr>
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<tbody>
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</tr>
<tr>
<td>Item</td>
<td>Date</td>
<td>User</td>
<td>Comment</td>
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</tr>
<tr>
<td>Form</td>
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<td>(b) (4), (b) (6)</td>
<td>Not Done</td>
</tr>
<tr>
<td>Item</td>
<td>Date</td>
<td>User</td>
<td>Comment</td>
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<tr>
<td>------</td>
<td>------</td>
<td>------</td>
<td>---------</td>
</tr>
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<td>1</td>
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<td>(b) (4), (b) (6)</td>
<td>Not Done</td>
</tr>
<tr>
<td>Item</td>
<td>Date</td>
<td>User</td>
<td>Comment</td>
</tr>
<tr>
<td>------</td>
<td>-------------------------------------------</td>
<td>---------------</td>
<td>-----------</td>
</tr>
<tr>
<td>2</td>
<td>Jan-04-2021 13:20:05 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>(b) (4), (b) (6)</td>
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</table>

**Header Text:** c4591001  
**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/04/2021  
**Form:** ILLNESS DETAILS - SEVERE - Comments  
**Form Version:** 17-Jul-2020 21:55  
**Site No:** 1022  
**Subject No:** 10221053  
**Generated By:** (b) (4)  
**Site Name:** (1022) Wenatchee Valley Hospital Clinics  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 04:44  
**Form Status:** Data Complete, Frozen  

**Back to Form**
<table>
<thead>
<tr>
<th>Item</th>
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<th>User</th>
<th>Comment</th>
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<tbody>
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<td>3</td>
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<td>(b) (4), (b) (6)</td>
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<tr>
<td>Item</td>
<td>Date</td>
<td>User</td>
<td>Comment</td>
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<tr>
<td>------</td>
<td>------</td>
<td>------</td>
<td>---------</td>
</tr>
<tr>
<td>4</td>
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Form Status: Data Complete, Frozen

Site Name: (1022) Wenatchee Valley Hospital Clinics

Subject Initials: ---

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

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**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/04/2021

**Site No:** 1022

**Subject No:** 10221053

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

**Site Name:** Wenatchee Valley Hospital Clinics

**Subject Initials:** ---

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

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Form Status: Data Complete, Frozen
Site Name: (1022) Wenatchee Valley Hospital Clinics
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 04:44

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Site Name: (1022) Wenatchee Valley Hospital Clinics
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**FDA-CBER-2021-5683-0899774**

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Form Status: Data Complete, Frozen
Site Name: (1022) Wenatchee Valley Hospital Clinics
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**Form:** VITAL SIGNS - COVID - Comments

**Form Version:** 21-Aug-2020 02:50

**Site No:** 1022

**Site Name:** (1022) Wenatchee Valley Hospital Clinics

**Subject No:** 10221053

**Subject Initials:** ---

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

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

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Form: VITAL SIGNS - PULSE OX ROOM AIR - Comments
Form Version: 21-Aug-2020 02:51
Form Status: Data Complete, Frozen
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Site Name: (1022) Wenatchee Valley Hospital Clinics
Subject No: 10221053
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 04:44

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**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/04/2021

**Form Version:** 06-Jul-2020 21:52

**Site No:** 1022

**Site Name:** (1022) Wenatchee Valley Hospital Clinics

**Subject No:** 10221053

**Subject Initials:** ---

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

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

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## Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/04/2021

### Form: IMAGING - Comments

- **Form Version:** 06-Jul-2020 21:53
- **Form Status:** Data Complete, Frozen
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- **Subject No:** 10221053
  - **Subject Initials:** ---
- **Generated By:** [b] (4)
  - **Generated Time (GMT):** 29-Mar-2021 04:44

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

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

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

To this I do attest by supplying my user name and password and clicking the button marked Submit below.
Affidavit:
By my dated signature below, I declare, 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

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

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

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**3. Status:**

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

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

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- **Medical History Term:** Menopausal
- **Start Date:** Dec/4/2018
- **Ongoing:** YES

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

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7.a Temperature:

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### 6.a

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**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1022  
**Subject No:** 10221053  
**Generated By:** (b) (4)  
**Form:** RANDOMIZATION - eCRF Audit Trail History  
**Site Name:** (1022) Wenatchee Valley Hospital Clinics  
**Generated Time (GMT):** 29-Mar-2021 04:44

### Back to Form

#### 1. Randomization Date:

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#### Date of Collection:
Aug/24/2020

### 5.a

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### 3. Sample Collected?

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*Note: (UTC-08:00) Pacific Time (US & Canada)*
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: LEFT</td>
<td>Initial Entry</td>
</tr>
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</table>
7. Route:

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10. Timeframe Subject Was Observed

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

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

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1. Date of Visit

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<td>Sep/14/2020</td>
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### 2.a

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### 2.a Record Identifier:

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### 2.a Temperature:

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

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6.a

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<td>(b) (4),</td>
<td>Data Entry:</td>
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<td>in Beta_PX113</td>
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6.a Not Done:

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### 1. Data Origin

<table>
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<tbody>
<tr>
<td>Sep-14-2020 13:03:37 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: SITE</td>
<td>Initial Entry</td>
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### 2. Sample Type

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<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: NASAL_SWAB</td>
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### 3. Sample Collected?

<table>
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<th>Reason</th>
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<tbody>
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<td>auto query (autoquery)</td>
<td>Query 1: Deleted</td>
<td>Close Auto Query</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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<tr>
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<td>Initial Entry</td>
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### 5.a

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<th>Reason</th>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: Sample ID: BP1BMF</td>
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### 5.a Sample ID

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**Data Entry:**
- BP1BMF

**Reason:**
- Initial Entry

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### Audit Trail History
- **Form Version:** 22-Apr-2020 21:03
- **Form Status:** Data Complete, Locked, Frozen, Verified
- **Site No:** 1022
- **Site Name:** (1022) Wenatchee Valley Hospital Clinics
- **Subject Initials:** ---
- **Generated Time (GMT):** 29-Mar-2021 04:44
## 1. Was there a temporary delay of vaccination?

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<th>Reason</th>
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## 2. Treatment Name

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## 3. Formulation:

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## 4. Dose Date Time:

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## 5. Anatomical Location:

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## 6. Body Side:

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7. Route:

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<th>Reason</th>
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10. Timeframe Subject Was Observed

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<th>Value</th>
<th>Reason</th>
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<tbody>
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<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> THE PROTOCOL SPECIFIED OBSERVATION PERIOD</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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### 1. Date of Visit

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### 1. Data Origin

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### 2. Sample Type

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### 3. Sample Collected?

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<th>Reason</th>
</tr>
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<tbody>
<tr>
<td>Oct-16-2020 12:36:45 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Deleted</td>
<td>Close Auto Query</td>
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<tr>
<td>Oct-16-2020 12:36:37 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Candidate</td>
<td>'Sample Collected&quot; is Yes, however no barcodes are entered. Please review and correct as appropriate.</td>
</tr>
<tr>
<td>Oct-16-2020 12:36:37 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: YES</td>
<td>Date of Collection: Oct/16/2020</td>
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### 5.a

<table>
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<th>Reason</th>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: Sample ID: BP1BXH</td>
<td>Initial Entry</td>
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### 5.a Sample ID

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### 5.b Sample ID

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<td>(b) (4), (b) (6)</td>
<td>Data Entry: Sample ID: BPHF1R</td>
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### 5.c Sample ID

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<td>Data Entry: Sample ID: BPHF1Y</td>
<td>Initial Entry</td>
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### 5.c Sample ID

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<th>Reason</th>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: Sample ID: BPHF1Y</td>
<td>Initial Entry</td>
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### 1. Date of Visit

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<tr>
<td>Jan-04-2021 13:31:44 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
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<td>auto query (autoquery)</td>
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<tr>
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<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 2: Deleted</td>
<td>Close Auto Query</td>
</tr>
<tr>
<td>Jan-04-2021 13:16:10 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 2: Candidate</td>
<td>Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.</td>
</tr>
<tr>
<td>Jan-04-2021 13:16:10 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Candidate</td>
<td>Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.</td>
</tr>
<tr>
<td>Jan-04-2021 13:16:10 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: Jan/4/2021</td>
<td>Initial Entry</td>
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### 3. COVID-19 Illness Visit

<table>
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<th>Reason</th>
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<tbody>
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<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: COVID_A</td>
<td>Initial Entry</td>
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**1. Date of Assessment:**

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<th>Reason</th>
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<tbody>
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<td>(b) (4), (b)</td>
<td>Data Entry: Jan/4/2021</td>
<td>Initial Entry</td>
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<tr>
<td>(UTC-08:00) Pacific</td>
<td>Time (US &amp; Canada)</td>
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**2. Date of First Symptom Started:**

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<tbody>
<tr>
<td>Jan-04-2021 13:16:58</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
<td>Data Entry: Jan/3/2021</td>
<td>Initial Entry</td>
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<tr>
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<td>Time (US &amp; Canada)</td>
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**3. Symptoms Ongoing?**

<table>
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<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-03-2021 09:44:00</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
<td>Query 1: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>(UTC-08:00) Pacific</td>
<td>Time (US &amp; Canada)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Feb-02-2021 13:29:20</td>
<td>ACV0PFEINFP6000</td>
<td>auto query</td>
<td>Query 1: Answered</td>
<td>New Information</td>
</tr>
<tr>
<td>(UTC-08:00) Pacific</td>
<td>(autoquery)</td>
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<tr>
<td>Feb-02-2021 13:29:20</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
<td>Data Entry: NO</td>
<td>New Information</td>
</tr>
<tr>
<td>(UTC-08:00) Pacific</td>
<td>Time (US &amp; Canada)</td>
<td></td>
<td>Date of Last Symptom Resolved: Jan/10/2021</td>
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<tr>
<td>Feb-02-2021 11:56:40</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
<td>Query 1:Opened</td>
<td>CLINQUERY: Please clarify whether the reported symptoms are still ongoing? If symptoms have ended, please update ‘Symptoms Ongoing’ on to ‘NO’ and add Date of Last</td>
</tr>
</tbody>
</table>
### 4.a

**Date** | **Location** | **User** | **Value** | **Reason**
--- | --- | --- | --- | ---
Jan-04-2021 13:16:58 (UTC-08:00) Pacific Time (US & Canada) | ACV0PF0EINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry

**Data Entry:**
Symptoms: **FEVER**
Symptom Present: NO

### 4.a Symptoms:

**Date** | **Location** | **User** | **Value** | **Reason**
--- | --- | --- | --- | ---
Jan-04-2021 13:16:58 (UTC-08:00) Pacific Time (US & Canada) | ACV0PF0EINFP6000 | (b) (4), (b) (6) | Data Entry: FEVER | Initial Entry

### 4.a Was symptom present?

**Date** | **Location** | **User** | **Value** | **Reason**
--- | --- | --- | --- | ---
Jan-04-2021 13:16:58 (UTC-08:00) Pacific Time (US & Canada) | ACV0PF0EINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry

### 4.b

**Date** | **Location** | **User** | **Value** | **Reason**
--- | --- | --- | --- | ---
Jan-04-2021 13:16:58 (UTC-08:00) Pacific Time (US & Canada) | ACV0PF0EINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR INCREASED COUGH
Symptom Present: NO | Initial Entry
<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
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<tbody>
<tr>
<td>Jan-04-2021 13:16:58 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NEW OR INCREASED COUGH</td>
<td>Initial Entry</td>
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</table>

<table>
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<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Jan-04-2021 13:16:58 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
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</table>

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Jan-04-2021 13:16:58 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NEW OR INCREASED SHORTNESS OF BREATH</td>
<td>Initial Entry</td>
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<table>
<thead>
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<th>Date</th>
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<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Jan-04-2021 13:16:58 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
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</table>
### 4.d Symptoms:

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<tr>
<td>Jan-04-2021 13:16:58</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: CHILLS</td>
<td>Initial Entry</td>
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<table>
<thead>
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<th>Location</th>
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<th>Reason</th>
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<tbody>
<tr>
<td>Jan-04-2021 13:16:58</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: YES</td>
<td>Initial Entry</td>
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### 4.e

<table>
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<th>Location</th>
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<th>Reason</th>
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<tbody>
<tr>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NEW OR INCREASED MUSCLE PAIN</td>
<td>Initial Entry</td>
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### 4.e Symptoms:

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<th>Value</th>
<th>Reason</th>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: NEW OR INCREASED MUSCLE PAIN</td>
<td>Initial Entry</td>
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### 4.e Was symptom present?

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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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### 4.f Symptoms:

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<td>(b) (4), (b) (6)</td>
<td>Data Entry: Symptoms</td>
<td>Initial Entry</td>
</tr>
<tr>
<td></td>
<td>(UTC-08:00) Pacific Time</td>
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<td>NEW LOSS OF TASTE OR SMELL</td>
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<td></td>
<td>(US &amp; Canada)</td>
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<td>Symptom Present: NO</td>
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### 4.f Was symptom present?

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<td>Data Entry: NO</td>
<td>Initial Entry</td>
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<td>(UTC-08:00) Pacific</td>
<td>(US &amp; Canada)</td>
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<td>Time (US &amp; Canada)</td>
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### 4.g

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<td>Data Entry: Symptoms</td>
<td>Initial Entry</td>
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<td>(US &amp; Canada)</td>
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<td>NEW OR INCREASED SORE THROAT</td>
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<tr>
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<td>Symptom Present: NO</td>
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### 4.g Symptoms:

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### 4.g Was symptom present?

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### 4.h

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<tbody>
<tr>
<td>Jan-04-2021 13:16:58</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4)</td>
<td>DIARRHEA</td>
<td>Initial Entry</td>
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### 4.h Symptoms:

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<tbody>
<tr>
<td>Jan-04-2021 13:16:58</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4)</td>
<td>DIARRHEA</td>
<td>Initial Entry</td>
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### 4.h Was symptom present?

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<tbody>
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<td>(b) (4)</td>
<td>NO</td>
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### 4.i

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<th>Reason</th>
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<tbody>
<tr>
<td>Jan-04-2021 13:16:58</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4)</td>
<td>VOMITING</td>
<td>Initial Entry</td>
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### 4.i Symptoms:

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<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Jan-04-2021 13:16:58</td>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: VOMITING</td>
<td>Initial Entry</td>
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### 4.i Was symptom present?

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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>
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### 5.a

<table>
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<th>Date</th>
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<th>Reason</th>
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<tr>
<td>Jan-04-2021 13:17:10</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Symptoms - Other: Fatigue</td>
<td>Initial Entry</td>
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### 5.a Symptoms - Other Text:

<table>
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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Jan-04-2021 13:17:10</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Fatigue</td>
<td>Initial Entry</td>
</tr>
</tbody>
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### 5.b

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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Symptoms - Other: Nausea</td>
<td>Initial Entry</td>
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### 5.b Symptoms - Other Text:

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<td>Data Entry: Nausea</td>
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**Header Text:** c4591001

**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/04/2021

**Form:** MICROBIOLOGY SPECIMEN - Audit Trail

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1022

**Subject No:** 10221053

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

**Site Name:** (1022) Wenatchee Valley Hospital Clinics

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44
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### 2. Specimen Type:

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### 4. Assay Code and Description:

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<td>Data Entry: SEVERE ACUTE RESP SYNDROME ME CORONAVIRUS 2</td>
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### 5. Device Type:

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### 6. Trade Name:

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7. Test Result:

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9. Trade Name Other, Specify:

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### Sample Type

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### Sample Collected?

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<td>auto query (autoquery)</td>
<td>Query 1: Deleted</td>
<td>Close Auto Query</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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<td><strong>Data Entry:</strong> YES</td>
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### 5.a

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<td><strong>Data Entry:</strong> Sample ID: CV10058</td>
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Date: Jan-04-2021 14:49:51 (UTC-08:00) Pacific Time (US & Canada)

User: (b) (4), (b) (6)

Value: Data Entry: CV10058
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### 2. Sample Type

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### 3. Sample Collected?

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

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<th>Value</th>
<th>Reason</th>
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<tr>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: COVID test and self swab collecte d</td>
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### 1.a

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<td>(b) (4), (b) (6)</td>
<td>Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO</td>
<td>Initial Entry</td>
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### 1.a Physician or Healthcare Professional:

<table>
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<th>Reason</th>
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### 1.a Occurrence of Visits or Contacts:

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### 1.b

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<td>(b) (4), (b) (6)</td>
<td>Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: NO</td>
<td>Initial Entry</td>
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1.b Physician or Healthcare Professional:

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1.b Occurrence of Visits or Contacts:

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1.c Physician or Healthcare Professional:

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**1.d Occurrence of Visits or Contacts:**

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Occurrence of Visits or Contacts:

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### 1.e Physician or Healthcare Professional:

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### 1.e Occurrence of Visits or Contacts:

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### 1.f

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### 3. Has the subject been hospitalized due to potential COVID-19 illness?

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*Form:* RESPIRATORY TREATMENT - eCRF Audit Trail History  
*Form Version:* 06-Jul-2020 21:53  
*Form Status:* Data Complete, Frozen  
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*Site Name:* (1022) Wenatchee Valley Hospital Clinics  
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*Generated Time (GMT):* 29-Mar-2021 04:44

**Back to Form**

### 1. What is the treatment Identifier?

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Respiratory Illness Diagnosis:  
COVID-19  
Date of Diagnosis:  
Jan/4/2021 | Transcription Error |
| Jan-05-2021 08:14:28 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | CLINQUERY: Since local SARS-CoV-2-NAAT test was positive on 04JAN2021, please consider updating the date of the COVID-19 diagnosis as 04JAN2021. |
| Jan-04-2021 13:29:21 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | **Data Entry:** YES  
Respiratory Illness Diagnosis: | New Information |
**Header Text:** c4591001  
**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/04/2021  
**Form Version:** 06-Jul-2020 21:52  
**Site No:** 1022  
**Subject No:** 10221053  
**Generated By:** (b) (4)  

**Visit Details:**  
- **Form:** ILLNESS DETAILS - eCRF Audit Trail History  
- **Form Status:** Data Complete  
- **Site Name:** (1022) Wenatchee Valley Hospital Clinics  
- **Subject Initials:** ---  
- **Generated Time (GMT):** 29-Mar-2021 04:44  

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**COVID-19**  
**Date of Diagnosis:**  
**Jan/3/2021**  

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### 3. Was a diagnosis obtained?

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### 4. Toxicity Grade:

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### 2. Laboratory Name and Address

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- **Sponsor-Defined Identifier:** Not Done
- **Test::** Not Done
- **Result::** Not Done
- **Not Done::** Not Done
- **Lab Normal Range::** Not Done

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**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Site No:** 1022

**Subject No:** 10221053

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

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

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**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/04/2021

**Site Name:** (1022) Wenatchee Valley Hospital Clinics

**Subject Initials:** ---

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen
5.b Sponsor ID:

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**Form Status:** Data Complete, Frozen
**Site Name:** (1022) Wenatchee Valley Hospital Clinics
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**Form Version:** 21-Aug-2020 02:51  
**Site No:** 1022  
**Subject No:** 10221053  
**Generated By:** [b] (4)  
**Generated Time (GMT):** 29-Mar-2021 04:44  

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**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 04:44

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Page 332 of 397
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Form Version: 21-Aug-2020 02:51
Site No: 1022
Subject No: 10221053
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**Form Status:** Data Complete, Frozen

**Site Name:** (1022) Wenatchee Valley Hospital Clinics

**Generated Time (GMT):** 29-Mar-2021 04:44
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### 2.a Respiratory Rate in respirations/minute:

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### 2.a Heart Rate in beats/minute:

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### 2.a SPO2 Pulse Oximetry %

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### 2. Arterial Blood Gases PaO2 (mmHg):

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### 3. FiO2 (Fraction of Inhaled Oxygen):

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### 3. Concomitant Medications Pre-specified:

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### 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).*

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### 5. Start Date:

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### 6. Ongoing?

**b) (4)**

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**Confidential**

FDA-CBER-2021-5683-0899961
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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/04/2021
Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF
Audit Trail History
Form Status: Data Complete, Frozen
Site Name: (1022) Wenatchee Valley Hospital Clinics
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 04:44
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## 2. Location of Assessment:

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## 3. Type of Imaging Exam:

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### COVID-19 Illness Visit:

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1. Date of Completion/Discontinuation/Death:

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- **Visit**: Logs - Unscheduled
- **Form**: ADVERSE EVENT REPORT - Audit Trail
- **Form Version**: 22-Apr-2020 21:02
- **Site No**: 1022
- **Site Name**: (1022) Wenatchee Valley Hospital Clinics
- **Subject No**: 10221053
- **Subject Initials**: ---
- **Generated By**: (b) (4)
- **Site No**: 1022
- **Generated Time (GMT)**: 29-Mar-2021 04:44

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### 3. Adverse Event:

*(If possible specify diagnosis, not individual symptoms)*

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### 4. Start Date Time:

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

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### 6. Toxicity Grade:

<table>
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

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

<table>
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9. Is this event related to study treatment:

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10. Latest Action Taken with Study Treatment:

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11. Was a Concomitant Medication given?

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

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

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

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### 3. Adverse Event:  
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<th>Reason</th>
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<td><strong>Data Entry:</strong> Moderate Headache</td>
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### 4. Start Date Time:

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

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### 6. Toxicity Grade:

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### 7. Is the adverse event serious?

*If Yes, NOTIFY PFIZER IMMEDIATELY.*

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

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### 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.*

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

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

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### 11. Was a Concomitant Medication given?

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**Header Text:** c4591001
**Visit:** Logs - Unscheduled
**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History
**Form Version:** 22-Apr-2020 21:02
**Site No:** 1022
**Subject No:** 10221053
**Generated By:** (b) (4)

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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-19-2021 13:46:09 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>ACV0PFEINFP6000</td>
<td>NO</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
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<td>ACV0PFEINFP6000</td>
<td>RECOVERED/RESOLVED</td>
<td>Initial Entry</td>
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</table>

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

<table>
<thead>
<tr>
<th>Date</th>
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<th>Reason</th>
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<tbody>
<tr>
<td>Feb-19-2021 13:46:09 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
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<td>ACV0PFEINFP6000</td>
<td>NO</td>
<td>Initial Entry</td>
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<tr>
<td>Date</td>
<td>Location</td>
<td>User</td>
<td>Value</td>
<td>Reason</td>
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<td>Initial Entry</td>
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<tr>
<td>(UTC-08:00) Pacific Time</td>
<td>(US &amp; Canada)</td>
<td>(autocalc)</td>
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### AE ID:

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<th>Date</th>
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<th>Value</th>
<th>Reason</th>
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<td>(autocalc)</td>
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### Adverse Event:

*If possible specify diagnosis, not individual symptoms*

<table>
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<tr>
<th>Date</th>
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<th>Value</th>
<th>Reason</th>
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### Start Date Time:

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<th>Reason</th>
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<td>Data Entry: Feb/1/2021 19:00</td>
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### Is the adverse event still ongoing?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
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<th>Reason</th>
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<tbody>
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<td>Data Entry: NO</td>
<td>Initial Entry</td>
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<tr>
<td>(UTC-08:00) Pacific Time</td>
<td>(US &amp; Canada)</td>
<td>(b) (6)</td>
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</table>

### Toxicity Grade:

<table>
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<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
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</table>
7. Is the adverse event serious?

*If Yes, NOTIFY Pfizer IMMEDIATELY.*

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

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<tr>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
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</tbody>
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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>
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<tr>
<td>Feb-19-2021 13:47:24</td>
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<td>Initial Entry</td>
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9. Is this event related to study treatment:

<table>
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<tr>
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<th>Reason</th>
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<tbody>
<tr>
<td>Feb-19-2021 13:47:24</td>
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<td>Initial Entry</td>
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10. Latest Action Taken with Study Treatment:

<table>
<thead>
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<th>Date</th>
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<th>Reason</th>
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<tbody>
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<td>Initial Entry</td>
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11. Was a Concomitant Medication given?

<table>
<thead>
<tr>
<th>Date</th>
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<tr>
<td>Feb-19-2021 13:47:24</td>
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12. Was a Non-Drug Treatment given?

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13. What was the outcome of this adverse event?

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

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<tr>
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<td>Initial Entry</td>
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</table>
1. **Category:**

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<th>Reason</th>
</tr>
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<tbody>
<tr>
<td>Feb-19-2021 13:48:12 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
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<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>
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<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> 4</td>
<td>Initial Entry</td>
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3. **Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

<table>
<thead>
<tr>
<th>Date</th>
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<tr>
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<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Injection Site Pain</td>
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4. **Start Date Time:**

<table>
<thead>
<tr>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Feb/1/2021 19:00</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

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<thead>
<tr>
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<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> NO</td>
<td>Initial Entry</td>
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</tbody>
</table>

End Date Time: Feb/4/2021 19:00

6. **Toxicity Grade:**

<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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***Confidential***

FDA-CBER-2021-5683-0899982
### 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).

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### 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.*

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<td>(b) (4), (b) (6)</td>
<td>Data Entry: DRUG WITHDRAWN</td>
<td>Initial Entry</td>
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### 11. Was a Concomitant Medication given?

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<tbody>
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<td>(b) (4), (b) (6)</td>
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### 12. Was a Non-Drug Treatment given?

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<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
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### 13. What was the outcome of this adverse event?

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<td>Data Entry: RECOVERED/RESOLVED</td>
<td>Initial Entry</td>
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### 14. Did the adverse event cause the subject to be discontinued from the study?

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1. Category:

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<tbody>
<tr>
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3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

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4. Start Date Time:

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5. Is the adverse event still ongoing?

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<td>(UTC-08:00) Pacific Time (US &amp; Canada)</td>
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6. Toxicity Grade:

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### 7. Is the adverse event serious?

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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).

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</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-19-2021 13:50:34</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4),</td>
<td>NO</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-08:00) Pacific</td>
<td></td>
<td>(b) (6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
<td></td>
<td></td>
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</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-19-2021 13:50:34</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4),</td>
<td>RELATED</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-08:00) Pacific</td>
<td></td>
<td>(b) (6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
<td></td>
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<td></td>
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</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>Feb-24-2021 04:56:39</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4),</td>
<td>Query 1: Closed</td>
<td>DM: Reason for treatment discontinuation is recorded as AE on EOT2 form.</td>
</tr>
<tr>
<td>(UTC-08:00) Pacific</td>
<td></td>
<td>(b) (6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feb-23-2021 14:19:43</td>
<td>ACV0PFEINFP6000</td>
<td>Hayley Wyper</td>
<td>Query 2: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>(UTC-08:00)</td>
<td></td>
<td>(b) (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Query</td>
<td>Time</td>
<td>Date/Time</td>
<td>User</td>
<td>Response</td>
</tr>
<tr>
<td>-------</td>
<td>------</td>
<td>--------------------</td>
<td>--------------</td>
<td>----------</td>
</tr>
<tr>
<td>2</td>
<td>29-Mar-2021 04:44</td>
<td>Feb-23-2021 12:06:39 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Feb-23-2021 09:47:26 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Hayley Wyper</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Feb-23-2021 07:03:15 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
</tr>
</tbody>
</table>

- Query 2: I used the date of V102 for the EOT2 date and AE was the reason. If you could check to make sure it is correct, that would be great. Thanks!
- Query 2: CLINQUERY: Thanks for confirming AE entries are correct. The EOT2 page works the same as first EOT - table in 8.57 of guidelines. EOT2 to be dated day of decision to discontinue Rx and status field matching to these AE reports.
- Query 2: I am currently waiting on the study team to tell me how to fill out the EOT2 page properly in this case since the eCRF guidelines do not specify such an instance. Once I get proper instruction, I
<table>
<thead>
<tr>
<th>Date/Time</th>
<th>User</th>
<th>Query</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-23-2021 03:26:25</td>
<td>Hayley Wyper</td>
<td>Query 2</td>
<td>Opened&lt;br&gt;<strong>CLINQUERY:</strong> Multiple AEs are reported as DRUG WITHDRAWN which matches to comment applied at Vax4 visit. Please update EOT2 page to report end of treatment if vax4 will not be given in the future.</td>
</tr>
<tr>
<td>Feb-22-2021 07:37:27</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1</td>
<td>Answered&lt;br&gt;Please advise. Is this in regard to the EOT2 page? I have asked the study team for help with this. Do you have instruction that could help? All of these AE's (1-5) are why the patient opted out of the second vaccine.</td>
</tr>
<tr>
<td>Feb-21-2021 23:30:27</td>
<td>PFE SDQ PROD</td>
<td>Query 1</td>
<td>Opened&lt;br&gt;The Adverse Event Action Taken is DRUG WITHDRAWN but reason for treatment discontinuation is not reported as ADVERSE EVENT or DEATH. Please review and clarify. (b) (4)</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>Feb-19-2021 13:50:34 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

12. Was a Non-Drug Treatment given?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
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<tbody>
<tr>
<td>Feb-19-2021 13:50:34 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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>
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<tbody>
<tr>
<td>Feb-19-2021 13:50:34 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: RECOVERED/RESOLVED</td>
<td>Initial Entry</td>
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</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-19-2021 13:50:34 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>
## 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>Feb-24-2021 09:17:14 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Jan/5/2021</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Feb-01-2021 12:48:46 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Feb/1/2021</td>
<td>Initial Entry</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>
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</thead>
<tbody>
<tr>
<td>Feb-01-2021 12:48:59</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4)</td>
<td>Data Entry: Participant is willing to return for Vaccination 3</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-08:00) Pacific</td>
<td></td>
<td>(b) (6)</td>
<td>Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2</td>
<td></td>
</tr>
<tr>
<td>Time (US &amp; Canada)</td>
<td></td>
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</table>
1. Date Treatment Unblinded:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-24-2021 15:44:29 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000.InFormAdapter.Discrepancy</td>
<td>DMW QUERY (b) (4)</td>
<td>Query 1: Closed</td>
<td>Auto closed by Validation Check: VC_DS001_36</td>
</tr>
<tr>
<td>Feb-24-2021 09:17:36 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Answered</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Feb-24-2021 09:17:36 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry : Jan/15/2021</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Feb-23-2021 04:26:55 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000.InFormAdapter.Discrepancy</td>
<td>DMW QUERY (b) (4)</td>
<td>Query 1: Opened</td>
<td>DMW7351984: Date Treatment Unblinded should be equal to or after DOV in REVAX CONTACT visit when Reason is ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION. Please review and update as appropriate.</td>
</tr>
<tr>
<td>Feb-01-2021 12:48:31 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry : Jan/14/2021</td>
<td>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>Feb-01-2021 12:48:31</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1022

**Subject No:** 10221053

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

**Generated Time (GMT):** 29-Mar-2021 04:44
### 1. Date of Visit

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
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<th>Reason</th>
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<tbody>
<tr>
<td>Feb-01-2021 12:49:08 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Feb/1/2021</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>
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</thead>
<tbody>
<tr>
<td>Feb-01-2021 12:49:17 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4) (6)</td>
<td><strong>Data Entry:</strong> Obtained Date Written Consent Obtained</td>
<td>Initial Entry</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Feb/1/2021</td>
<td></td>
</tr>
</tbody>
</table>
### 1. Date of Completion/Discontinuation/Death:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
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<tbody>
<tr>
<td>Feb-01-2021 12:49:39</td>
<td>(UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Initial Entry</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ACV0PFEINFP6000</td>
<td>Data Entry: Feb/1/2021</td>
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</table>

### 2. Phase of Disposition:

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<th>Reason</th>
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<tbody>
<tr>
<td>Feb-01-2021 12:49:39</td>
<td>(UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Initial Entry</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ACV0PFEINFP6000</td>
<td>Data Entry: REPEAT SCREENING 1</td>
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### 3. Status:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
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<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-01-2021 12:49:39</td>
<td>(UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Initial Entry</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ACV0PFEINFP6000</td>
<td>Data Entry: COMPLETED</td>
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</table>
### 3. Collection Date:

<table>
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<tr>
<th>Date</th>
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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Feb-01-2021 12:50:02 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4)</td>
<td>Data Entry: Not Done</td>
<td>Initial Entry</td>
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</table>

### 6.a

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-01-2021 12:49:53 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: Sponsor-Defined Identifier: 113</td>
<td>Initial Entry</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Test:: Choriogonadotropin Beta_PX113 Result:: NOT DONE</td>
<td></td>
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### 6.a Sponsor 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-01-2021 12:49:53 (UTC-08:00) Pacific 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:

<table>
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<th>Reason</th>
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<tbody>
<tr>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Choriogonadotropin Beta_PX113</td>
<td>Initial Entry</td>
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</table>

### 6.a Not Done:

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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Feb-01-2021 12:49:53 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NOT DONE</td>
<td>Initial Entry</td>
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</table>
### 1. Data Origin

<table>
<thead>
<tr>
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<th>User</th>
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<th>Reason</th>
</tr>
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<tbody>
<tr>
<td>Feb-01-2021 12:50:37</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td><strong>Data Entry:</strong> SITE</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td></td>
<td>(autocalc)</td>
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</table>

### 2. Sample Type

<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>Feb-01-2021 12:50:37</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td><strong>Data Entry:</strong> SERUM</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td></td>
<td>(autocalc)</td>
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### 3. Sample Collected?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
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<tbody>
<tr>
<td>Feb-01-2021 12:50:37</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> NO</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td></td>
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</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-01-2021 12:50:37</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Patient lab samples were scanned into her COVID convalescent visit.</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td></td>
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</table>
### 1. Data Origin

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
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<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-01-2021 12:50:49</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td>Data Entry: SITE</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td></td>
<td>(autocalc)</td>
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### 2. Sample Type

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Feb-01-2021 12:50:49</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td>Data Entry: NASAL_SWAB</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td></td>
<td>(autocalc)</td>
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### 3. Sample Collected?

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### 5.a

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**Form Details**

- **Header Text**: c4591001
- **Visit**: V101_VAX3
- **Form**: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
- **Form Version**: 22-Apr-2020 21:03
- **Form Status**: Data Complete, Frozen, Verified
- **Site No**: 1022
- **Site Name**: (1022) Wenatchee Valley Hospital Clinics
- **Subject No**: 10221053
- **Generated By**: (b) (4)
- **Generated Time (GMT)**: 29-Mar-2021 04:44

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

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**Reason:**
- Data Entry: NO

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**Reason:**
- Initial Entry

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**Reason:**
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**Reason:**
- Initial Entry

### 5. Anatomical Location:

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**Reason:**
- Initial Entry

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**Reason:**
- Initial Entry
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### 10. Timeframe Subject Was Observed

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<td><strong>Data Entry:</strong> 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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<tr>
<td>Date</td>
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<td>Reason</td>
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<td>Feb-23-2021 00:12:57 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
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<td>Query 1: Closed</td>
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<td>(b) (4), (b) (6)</td>
<td>Query 1: Answered</td>
<td>The dose is out of window due to the patient contracting COVID. This has been reported appropriately.</td>
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<tr>
<td>Feb-21-2021 21:39:29 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000.InFormAdapter.Discrepancy</td>
<td>PFE SDQ PROD (b) (4)</td>
<td>Query 1: Opened</td>
<td>PDQ: Date of visit V102_VAX4 is out of window for 1 days from V101_VAX3 Dose Date. Please verify and update. Else, confirm in query response appropriately. (b) (4)</td>
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<tr>
<td>Feb-19-2021 11:37:01 (UTC-08:00) Pacific Time (US &amp; Canada)</td>
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#### 6.a

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<td>Test:: Choriogonadotropin Beta_PX113</td>
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<td>Result::</td>
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### 1. Data Origin

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### 5.a

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*Form Version: 22-Apr-2020 21:03*  
*Form Status: Data Complete, Frozen, Verified*  
*Site No: 1022*  
*Site Name: (1022) Wenatchee Valley Hospital Clinics*  
*Subject No: 10221053*  
*Generated By: (b) (4)*  
*Generated Time (GMT): 29-Mar-2021 04:44*
### 1. Was there a temporary delay of vaccination?

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### 4. Dose Date Time:

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### 5. Anatomical Location:

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### 6. Body Side:

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Page 393 of 397
<table>
<thead>
<tr>
<th>Date</th>
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<tr>
<td>Feb-19-2021 11:38:13</td>
<td>ACV0PFEINFP6000</td>
<td>(b)</td>
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### 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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1. Date of Completion/Discontinuation/Death:

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<tbody>
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<td>Feb-23-2021 12:05:13</td>
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2. Phase of Disposition:

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<tbody>
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<td>Feb-23-2021 12:05:13</td>
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<td>Data Entry: OPEN LABEL TREATMENT</td>
<td>Initial Entry</td>
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3. Status:

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</table>
### 1. Subject Status

<table>
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<tbody>
<tr>
<td>Oct-16-2020 12:43:26</td>
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<td>(UTC-08:00) Pacific Time (US &amp; Canada)</td>
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<td>(autocalc)</td>
<td>FOLLOW-UP</td>
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<td>(autocalc)</td>
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### 2. Subject Status Date

<table>
<thead>
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<td><strong>Data Entry:</strong> Click Here to Enable</td>
<td>Initial Entry</td>
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**Casebook Signature**