**Cohort Selection**

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

1. Select appropriate response - Protocol version
   - Protocol version: 30 JUN 2020

2. Select appropriate response - What cohort does the subject belong to?
   - STAGE 3 COHORTS
<table>
<thead>
<tr>
<th><strong>eCRF Audit Trail History</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Informed Consent</strong></td>
</tr>
<tr>
<td>1. Consent Was:</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
### Demography

1. **Subject ID**: [12311815]
2. **Birth Date**: (b) (6) /1960
3. **Sex**: FEMALE
4. **Ethnicity**: HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5. **Race**: (Check X all that apply): WHITE
6. **Racial Designation**: 

---

**eCRF Audit Trail History**

<table>
<thead>
<tr>
<th>Record</th>
<th>Description</th>
<th>Action</th>
<th>Time (GMT)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(b) (4)</td>
<td></td>
<td></td>
<td>01-Apr-2021 03:19</td>
</tr>
</tbody>
</table>

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**Header Text**: C4591001  
**Visit**: COHORT_SELECTION  
**Form**: DEMOGRAPHY  
**Form Version**: 06-Jul-2020 21:55  
**Site No**: 1231  
**Site Name**: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich  
**Subject No**: 12311815  
**Generated By**: (b) (4)  
**Generated Time (GMT)**: 29-Mar-2021 16:45
### eCRF Audit Trail History

**Date of Visit**

<table>
<thead>
<tr>
<th></th>
<th>Date of Visit</th>
<th>Aug/17/2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Date of Visit</td>
<td>Aug/17/2020</td>
</tr>
</tbody>
</table>
| 2 | Erroneous Visit | }
## Inclusion Criteria

<table>
<thead>
<tr>
<th>Inclusion Number</th>
<th>Criterion Description</th>
<th>Criterion met?</th>
<th>Criterion ID: (For Pfizer use only)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.a</td>
<td>Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)</td>
<td>YES</td>
<td>IN01A00</td>
</tr>
<tr>
<td>1.b</td>
<td>Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures</td>
<td>YES</td>
<td>IN02A00</td>
</tr>
<tr>
<td>1.c</td>
<td>Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study</td>
<td>YES</td>
<td>IN03A00</td>
</tr>
<tr>
<td>1.d</td>
<td>Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol</td>
<td>YES</td>
<td>IN04A00</td>
</tr>
</tbody>
</table>

## Exclusion Criteria

<table>
<thead>
<tr>
<th>Exclusion Number</th>
<th>Criterion Description</th>
<th>Criterion met?</th>
<th>Criterion ID: (For Pfizer use only)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.a</td>
<td>Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation</td>
<td>NO</td>
<td>EX01A00</td>
</tr>
<tr>
<td>Exclusion Number</td>
<td>Criterion Description</td>
<td>Criterion met?</td>
<td>Criterion ID: (For Pfizer use only)</td>
</tr>
<tr>
<td>------------------</td>
<td>----------------------------------------------------------------------------------------</td>
<td>----------------</td>
<td>-----------------------------------</td>
</tr>
<tr>
<td>2</td>
<td>Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)</td>
<td>NO</td>
<td>EX02A00</td>
</tr>
<tr>
<td>3</td>
<td>History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)</td>
<td>NO</td>
<td>EX03A00</td>
</tr>
<tr>
<td>4</td>
<td>Receipt of medications intended to prevent COVID-19</td>
<td>NO</td>
<td>EX04A00</td>
</tr>
<tr>
<td>8</td>
<td>Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination</td>
<td>NO</td>
<td>EX08A00</td>
</tr>
<tr>
<td>10</td>
<td>Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection</td>
<td>NO</td>
<td>EX10A00</td>
</tr>
<tr>
<td>11</td>
<td>Women who are pregnant or breastfeeding</td>
<td>NO</td>
<td>EX11A00</td>
</tr>
<tr>
<td>Exclusion Number</td>
<td>Criterion Description</td>
<td>Criterion met?</td>
<td>Criterion ID: (For Pfizer use only)</td>
</tr>
<tr>
<td>------------------</td>
<td>----------------------------------------------------------------------------------------</td>
<td>----------------</td>
<td>-------------------------------------</td>
</tr>
<tr>
<td>12</td>
<td>Previous vaccination with any coronavirus vaccine</td>
<td>NO</td>
<td>EX12A00</td>
</tr>
<tr>
<td>13</td>
<td>Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids</td>
<td>NO</td>
<td>EX13A01</td>
</tr>
<tr>
<td>15</td>
<td>Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study</td>
<td>NO</td>
<td>EX14A01</td>
</tr>
<tr>
<td>16</td>
<td>Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation</td>
<td>NO</td>
<td>EX15A01</td>
</tr>
<tr>
<td>17</td>
<td>Previous participation in other studies involving study intervention containing lipid nanoparticles</td>
<td>NO</td>
<td>EX16A01</td>
</tr>
<tr>
<td>22</td>
<td>Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members</td>
<td>NO</td>
<td>EX21A01</td>
</tr>
</tbody>
</table>
eCRF Audit Trail History

### Disposition - Screening

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Date of Completion/Discontinuation/Death</td>
</tr>
<tr>
<td>2.</td>
<td>Phase of Disposition:</td>
</tr>
<tr>
<td>3.</td>
<td>Status:</td>
</tr>
<tr>
<td>4.</td>
<td>Specify Status:</td>
</tr>
</tbody>
</table>
### Medical History Details

<table>
<thead>
<tr>
<th>Line/MH Number</th>
<th>Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies</th>
<th>Start Date</th>
<th>Ongoing</th>
<th>End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>[1]</td>
<td>smoker</td>
<td>Jan/1/1982</td>
<td>YES</td>
<td></td>
</tr>
</tbody>
</table>
### Vital Signs

1. **Date:** Aug/17/2020
2. **Weight:** [50.9] kg
3. **Height:** [165.0] cm
4. **Body Mass Index:** [18.7]

### Vital Signs Details

7.a **Record Identifier:** 1
- **Temperature:** [37.1] C
- **Temperature Location:** ORAL CAVITY
### Lab Urinalysis

| 1. | Lab Panel: | URINALYSIS |
| 2. | Lab Sub-Panel: | PREGNANCY |
| 3. | Collection Date: | Aug/17/2020 |
| 4. | Laboratory Name and Address (Derived) | [STUDY SITE] |
| 5. | Specimen Type: | URINE |

### Lab Result

| 6.a | Sponsor ID: | [113] |
|     | Test: | Choriogonadotropin Beta_PX113 |
|     | Result: | NEGATIVE |
|     | Not Done: | |

---

**eCRF Audit Trail History**

**Lab Urinalysis**

**1. Lab Panel:** URINALYSIS

**2. Lab Sub-Panel:** PREGNANCY

**3. Collection Date:** Aug/17/2020

**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**

<table>
<thead>
<tr>
<th>Disposition</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Randomization Date : Aug/17/2020</td>
</tr>
<tr>
<td>2. Randomization Number: [230740]</td>
</tr>
<tr>
<td>3. Randomization Group: [ ]</td>
</tr>
</tbody>
</table>
**eCRF Audit Trail History**

**Electronic Sample Tracking**

1. **Data Origin**: SITE
2. **Sample Type**: SERUM
3. **Sample Collected?**: YES  
   **Date of Collection**: Aug/17/2020
4. **If no sample was collected or sample was not collected according to protocol, please provide reason**: []

**Aliquot**

Please enter barcode for each aliquot.

<table>
<thead>
<tr>
<th></th>
<th>Sample ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.a</td>
<td>[BPHZ47]</td>
</tr>
<tr>
<td>5.b</td>
<td>[BPHZ48]</td>
</tr>
<tr>
<td>5.c</td>
<td>[BPHZ49]</td>
</tr>
<tr>
<td>5.d</td>
<td>[BP15HL]</td>
</tr>
<tr>
<td>5.e</td>
<td>[BP15HM]</td>
</tr>
<tr>
<td>5 f</td>
<td>[BP15HN]</td>
</tr>
</tbody>
</table>
### eCRF Audit Trail History

#### Electronic Sample Tracking

<table>
<thead>
<tr>
<th></th>
<th>Data Origin</th>
<th>Sample Type</th>
<th>Sample Collected?</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>[]</td>
</tr>
</tbody>
</table>

#### Aliquot

Please enter barcode for each aliquot.

<table>
<thead>
<tr>
<th>5.a</th>
<th>Sample ID</th>
<th>[BHWSNZ]</th>
</tr>
</thead>
</table>
# eCRF Audit Trail History

## Vaccination

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</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/17/2020 16:40</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</td>
<td>YES</td>
</tr>
<tr>
<td>observation period after investigational product administration?</td>
<td></td>
</tr>
<tr>
<td>eCRF Audit Trail History</td>
<td></td>
</tr>
<tr>
<td>--------------------------</td>
<td></td>
</tr>
<tr>
<td>Reactogenicity Diary</td>
<td></td>
</tr>
</tbody>
</table>

1. Select appropriate response - Reactogenicity diary collection
   NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
### eCRF Audit Trail History

**Date of Visit**

<table>
<thead>
<tr>
<th></th>
<th>Date of Visit</th>
<th>Nov/5/2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Date of Visit</td>
<td>Nov/5/2020</td>
</tr>
<tr>
<td>2</td>
<td>Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>
### Vital Signs Details

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Date:</td>
<td>Nov/5/2020</td>
</tr>
<tr>
<td>2.a</td>
<td>Record Identifier:</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Temperature:</td>
<td>[36.4]</td>
</tr>
<tr>
<td></td>
<td>Unit:</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td>Temperature Location:</td>
<td>ORAL CAVITY</td>
</tr>
</tbody>
</table>
### Lab Urinalysis

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

### Lab Result

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>6.a</td>
<td>Sponsor ID:</td>
<td>Not Done</td>
</tr>
<tr>
<td></td>
<td>Test:</td>
<td>Not Done</td>
</tr>
<tr>
<td></td>
<td>Choriogonadotropin Beta_PX113</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Result:</td>
<td>Not Done</td>
</tr>
<tr>
<td></td>
<td>Not Done:</td>
<td>Not Done</td>
</tr>
</tbody>
</table>
**Form Comments**

**eCRF Audit Trail History**

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

**Aliquot**

Please enter barcode for each aliquot.

<table>
<thead>
<tr>
<th><strong>5.a Sample ID</strong></th>
<th><strong>[BPT838]</strong></th>
</tr>
</thead>
</table>
### eCRF Audit Trail History

**Vaccination**

<table>
<thead>
<tr>
<th></th>
<th>Question</th>
<th>Answer</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Was there a temporary delay of vaccination?</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Date of First Delay:</td>
<td>Sep/7/2020</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Reason(s) for Temporary Delay of Vaccination</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>FEVER OR ACUTE ILLNESS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Treatment Name</td>
<td>[ ]</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Formulation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Dose Date Time</td>
<td>Not Done</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>//</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Anatomical Location</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Body Side</td>
<td>Not Done</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Route</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Actual Dose</td>
<td>[ ]</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Unit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Timeframe Subject Was Observed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Was the subject observed for at least the protocol specified observation period after investigational product administration?</td>
<td>Not Done</td>
<td></td>
</tr>
<tr>
<td>Date of Visit</td>
<td>Dec/9/2020</td>
<td></td>
<td></td>
</tr>
<tr>
<td>--------------</td>
<td>------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Date of Visit</td>
<td>Dec/9/2020</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## eCRF Audit Trail History

### Electronic Sample Tracking

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.</strong> Data Origin</td>
<td>SITE</td>
</tr>
<tr>
<td><strong>2.</strong> Sample Type</td>
<td>SERUM</td>
</tr>
</tbody>
</table>
| **3.** Sample Collected? | YES  
   Date of Collection: Dec/9/2020 |
| **4.** If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ] |

### Aliquot

Please enter barcode for each aliquot.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>5.a</strong> Sample ID</td>
<td>[BPWSX6]</td>
</tr>
<tr>
<td><strong>5.b</strong> Sample ID</td>
<td>[BRVP6K]</td>
</tr>
<tr>
<td><strong>5.c</strong> Sample ID</td>
<td>[BRVP6C]</td>
</tr>
<tr>
<td>Date of Visit</td>
<td></td>
</tr>
<tr>
<td>---------------</td>
<td>---</td>
</tr>
<tr>
<td>1. Date of Visit</td>
<td>//</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>
Electronic Sample Tracking

1. Data Origin

2. Sample Type

3. Sample Collected?

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

Aliquot

Please enter barcode for each aliquot.

5. Sample ID [ ]
### Electronic Sample Tracking

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

### Aliquot

Please enter barcode for each aliquot.

5. Sample ID [ ]
<table>
<thead>
<tr>
<th>Date of Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Visit //</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
</tr>
</tbody>
</table>

Form: DATE OF VISIT
Form Status: Not Started
Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 16:45

<table>
<thead>
<tr>
<th>Subject No: 12311815</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject Initials: ---</td>
</tr>
</tbody>
</table>

Visit: V6_MONTH24_L
Form Version: 22-Apr-2020 21:02
Site No: 1231

FDA-CBER-2021-5683-0863932
### Electronic Sample Tracking

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Data Origin</td>
</tr>
<tr>
<td>2.</td>
<td>Sample Type</td>
</tr>
<tr>
<td>3.</td>
<td>Sample Collected?</td>
</tr>
<tr>
<td>4.</td>
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</tr>
</tbody>
</table>

### Aliquot

Please enter barcode for each aliquot.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5.</td>
<td>Sample ID</td>
</tr>
</tbody>
</table>
**Header Text:** C4591001  
**Visit:** POT_COVID_ILL - New Unscheduled Visit  
**Form:** DATE OF VISIT - ILLNESS ONSET  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1231  
**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich  
**Subject No:** 12311815  
**Generated By:**  
**Generated Time (GMT):** 29-Mar-2021 16:45

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

<table>
<thead>
<tr>
<th>COVID-19 Illness Visit</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>3. COVID-19 Illness Visit:</strong></td>
<td></td>
</tr>
<tr>
<td>Signs and Symptoms</td>
<td></td>
</tr>
<tr>
<td>--------------------</td>
<td></td>
</tr>
<tr>
<td>1. Date of Assessment: //</td>
<td></td>
</tr>
<tr>
<td>2. Date of First Symptom Started: //</td>
<td></td>
</tr>
<tr>
<td>3. Symptoms Ongoing?</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Symptoms - Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>5. Symptoms - Other Text: [ ]</td>
</tr>
</tbody>
</table>
**Header Text:** C4591001  
**Visit:** POT_COVID_ILL - New Unscheduled Visit  
**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF  
**Form Version:** 22-Apr-2020 21:03  
**Form Status:** Not Started  
**Site No:** 1231  
**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich  
**Subject No:** 1231815  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 16:45

### Electronic Sample Tracking

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

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

1. **Data Origin**

2. **Sample Type**

3. **Sample Collected?**

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

**Aliquot**

Please enter barcode for each aliquot.

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

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

**Health Care Utilization Other**

2. Other Type of Practitioner Specify: [ ]

**Health Care Utilization**

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

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

### COVID-19 Illness Visit

| 3. COVID-19 Illness Visit: | |
### Electronic Sample Tracking

1. **Data Origin**

2. **Sample Type**

3. **Sample Collected?**

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

#### Aliquot

Please enter barcode for each aliquot.

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

1. Assessments
### Disposition - Treatment

<table>
<thead>
<tr>
<th></th>
<th>Date of Completion/Discontinuation/Death:</th>
<th>Sep/6/2020</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.</td>
<td>Phase of Disposition:</td>
<td>VACCINATION</td>
<td>Comments</td>
</tr>
<tr>
<td>3.</td>
<td>Status:</td>
<td>ADVERSE EVENT</td>
<td>Comments</td>
</tr>
<tr>
<td>4.</td>
<td>Specify Status:</td>
<td>[ ]</td>
<td>Comments</td>
</tr>
</tbody>
</table>

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**Form Comments**

**eCRF Audit Trail History**

---

**Header Text:** C4591001  
**Visit:** End of Treatment - Unscheduled  
**Form Version:** 15-Sep-2020 21:55  
**Site No:** 1231  
**Subject No:** 12311815  
**Generated By:** [Redacted]  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 16:45

---

**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich
### Disposition - Follow-Up

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

COVID-19 Repeat Swab

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

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

### Aliquot

Please enter barcode for each aliquot.

<p>| | |</p>
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>5.</td>
<td>Sample ID</td>
</tr>
</tbody>
</table>
### Date of Visit

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

| Vital Signs Details
<table>
<thead>
<tr>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2.</strong> Record Identifier:</td>
</tr>
<tr>
<td>Temperature:</td>
</tr>
<tr>
<td>Unit:</td>
</tr>
<tr>
<td>Temperature Location:</td>
</tr>
</tbody>
</table>

---

**FDA-CBER-2021-5683-0863949**
### Lab Urinalysis

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

### Lab Result

6. Sponsor ID: [] 
   Test: 
   Result: 
   Not Done: 

---

**Header Text:** C4591001  
**Visit:** Unplanned Vaccination - Unscheduled  
**Form Version:** 20-Feb-2021 02:14  
**Site No:** 1231  
**Subject No:** 12311815  
**Generated By:** [redacted]  
**Generated Time (GMT):** 29-Mar-2021 16:45

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich  
**Subject Initials:** ---

**Form:** LAB URINALYSIS - PREGNANCY TEST  
**Form Status:** Not Started  
**Generated Time (GMT):** 01-Apr-2021 03:19 (GMT)
### Vaccination

1. Was there a temporary delay of vaccination?

2. Treatment Name
   - [ ]

3. Formulation:

4. Dose Date Time:
   - //

5. Anatomical Location:

6. Body Side:

7. Route:

8. Actual Dose:
   - [ ]

9. Unit:

10. Timeframe Subject Was Observed

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

---

**Form:** VACCINATION  
**Form Status:** Not Started  
**Site No:** 1231  
**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich  
**Subject No:** 12311815  
**Subject Initials:** ---  
**Generated By:** [Redacted]  
**Generated Time (GMT):** 29-Mar-2021 16:45
<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>
</tbody>
</table>
### Contact Outcome

1. Contact Type:  
2. Was contact made?  
3. Comments: [ ]
<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>

**Header Text:** C4591001  
**Visit:** V201_SURVEIL_CONSENT - Unscheduled  
**Form:** DATE OF VISIT  
**Form Version:** 22-Apr-2020 21:02  
**Form Status:** Not Started  
**Site No:** 1231  
**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich  
**Subject No:** 12311815  
**Subject Initials:** ---  
**Generated By:**  
**Generated Time (GMT):** 29-Mar-2021 16:45  
**Final On:** 01-Apr-2021 03:19 (GMT)
Informed Consent - Asymptomatic Surveillance

1. Consent Was:

---

FDA-CBER-2021-5683-0863955
Electronic Sample Tracking

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

Aliquot

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

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

### Aliquot

Please enter barcode for each aliquot.

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

<table>
<thead>
<tr>
<th>1.</th>
<th>Select appropriate response - Is participant willing to return for Vaccination 3?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>#</td>
<td>Category</td>
</tr>
<tr>
<td>---</td>
<td>------------------</td>
</tr>
<tr>
<td>1</td>
<td>ADVERSE EVENT</td>
</tr>
<tr>
<td>2</td>
<td>ADVERSE EVENT</td>
</tr>
</tbody>
</table>

**Form:** ADVERSE EVENT REPORT

**Visit:** Logs

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

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311815

**Subject Initials:** ---

**Generated By:**

**Generated Time (GMT):** 29-Mar-2021 16:45

---
### Adverse Event Report

<table>
<thead>
<tr>
<th>1. Category:</th>
<th>ADVERSE EVENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. AE ID:</td>
<td>[1]</td>
</tr>
<tr>
<td>3. Adverse Event: (If possible specify diagnosis, not individual symptoms)</td>
<td>[REACTIVE LYMPHOID PROLIFERATION SUPRACLAVICULAR]</td>
</tr>
<tr>
<td>4. Start Date Time:</td>
<td>Sep/6/2020 15:00</td>
</tr>
<tr>
<td>5. Is the adverse event still ongoing?</td>
<td>YES</td>
</tr>
<tr>
<td>6. Toxicity Grade:</td>
<td>1</td>
</tr>
<tr>
<td>7. Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY.</td>
<td>NO</td>
</tr>
</tbody>
</table>

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).

<p>| 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: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Unknown] |
| 10. Latest Action Taken with Study Treatment: | DRUG WITHDRAWN |
| 11. Was a Concomitant Medication given? | NO |
| 12. Was a Non-Drug Treatment given? | NO |</p>
<table>
<thead>
<tr>
<th>Q</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>13.</td>
<td>What was the outcome of this adverse event?</td>
</tr>
<tr>
<td>14.</td>
<td>Did the adverse event cause the subject to be discontinued from the study?</td>
</tr>
<tr>
<td>15.</td>
<td>Serious Adverse Event Number: For Pfizer Use Only</td>
</tr>
</tbody>
</table>
### Adverse Event Report

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Category: ADVERSE EVENT</td>
</tr>
<tr>
<td>2.</td>
<td>AE ID: [2]</td>
</tr>
<tr>
<td>3.</td>
<td>Adverse Event: (If possible specify diagnosis, not individual symptoms) [Pain in injection site]</td>
</tr>
<tr>
<td>4.</td>
<td>Start Date Time: Sep/18/2020 07:00</td>
</tr>
<tr>
<td>5.</td>
<td>Is the adverse event still ongoing? NO</td>
</tr>
<tr>
<td></td>
<td>End Date Time: Sep/18/2020 19:00</td>
</tr>
<tr>
<td>6.</td>
<td>Toxicity Grade: 1</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: NOT APPLICABLE</td>
</tr>
<tr>
<td>11.</td>
<td>Was a Concomitant Medication given? YES</td>
</tr>
<tr>
<td>12.</td>
<td>Was a Non-Drug Treatment given? NO</td>
</tr>
</tbody>
</table>
### Table

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<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>
<tr>
<td>#</td>
<td>Category</td>
</tr>
<tr>
<td>---</td>
<td>----------</td>
</tr>
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<td>1.</td>
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</table>

**Header Text:** C4591001

**Visit:** Logs

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1231

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12311815

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 16:45

---

**Final On:** 01-Apr-2021 03:19 (GMT)

---

**FDA-CBER-2021-5683-0863965**
Medication Error

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Category:</td>
</tr>
<tr>
<td>2.</td>
<td>Medication Error (Type of Medication Error): [ ]</td>
</tr>
<tr>
<td>3.</td>
<td>Start Date: //</td>
</tr>
<tr>
<td>4.</td>
<td>Is the medication error still ongoing?</td>
</tr>
<tr>
<td>5.</td>
<td>Latest Action Taken with Study Treatment:</td>
</tr>
<tr>
<td>6.</td>
<td>Was a Concomitant Medication given?</td>
</tr>
<tr>
<td>7.</td>
<td>Was a Non-Drug Treatment given?</td>
</tr>
<tr>
<td>8.</td>
<td>Did the Medication Error cause the subject to be discontinued from the study?</td>
</tr>
<tr>
<td>9.</td>
<td>Was this medication error associated with any adverse events?</td>
</tr>
<tr>
<td>10.</td>
<td>Serious Adverse Event Number: For Pfizer Use Only [ ]</td>
</tr>
<tr>
<td>#</td>
<td>Sponsor-Defined Identifier</td>
</tr>
<tr>
<td>----</td>
<td>----------------------------</td>
</tr>
<tr>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>
### Concomitant Medications

1. **What is the medication identifier?**
   
   [ ]

2. **Category:**

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

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

5. **Date:**
   
   //
<table>
<thead>
<tr>
<th>#</th>
<th>Sponsor-Defined Identifier</th>
<th>Category for Medication</th>
<th>Concomitant Medications Pr-e-specified</th>
<th>Name of Medication</th>
<th>Dose Description</th>
<th>Form Instance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td></td>
<td></td>
<td></td>
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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?**
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**Form: RADIATION TREATMENT**

**Visit:** Logs - Unscheduled  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1231  
**Subject No:** 12311815  
**Generated By:** (b) (4)  

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 16:45
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Visit: UNPLANNED_BOOSTER_CONTACT - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02
Site No: 1231
Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich
Subject No: 12311815
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 16:45

Date of Visit

1. Date of Visit
2. Erroneous Visit
Booster Dose Trigger Form

1. Select appropriate response - Will the participant return for consent/eligibility assessment for the booster dose visit?
### Treatment Unblinded

1. **Date Treatment Unblinded:** //
2. **Primary Reason for Unblinding:**

---

**Header Text:** C4591001  
**Visit:** Disposition - Unscheduled  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1231  
**Subject No:** 12311815  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 16:45
Withdrawal Of Consent

1. Withdrawal of Consent Date: //
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<tbody>
<tr>
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<table>
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<th><strong>Cause of Death</strong></th>
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<td>2. Cause of Death Status:</td>
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**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1231  
**Subject No:** 12311815  
**Generated By:** (b) (4)  

**Form:** SUBJECT STATUS  
**Form Status:** Data Complete, Verified  
**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 16:45

**eCRF Audit Trail History**

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**Casebook Signature Form**

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

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

- CRF_Sign

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<tr>
<th>Name</th>
<th>Signature Meaning</th>
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<td>BOOK</td>
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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.
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<th>User</th>
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### VITAL SIGNS - TEMP - Comments

**Form Version:** 21-Aug-2020 02:51  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1231  
**Subject No:** 12311815  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 16:45

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Visit: V2_VAX2_L
Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments
Form Version: 22-Apr-2020 21:03
Site No: 1231
Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich
Subject No: 12311815
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 16:45

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Back to Form
**Header Text:** C4591001  
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**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB -  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1231  
**Subject No:** 12311815  
**Generated By:** [Redacted]  
**Generated Time (GMT):** 29-Mar-2021 16:45

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Comments**

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

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### Item 1

**Date**: Sep-08-2020 19:33:31 (UTC-03:00) City of Buenos Aires

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

**Comment**: Causes: Febrile illness (more than 38 °C) or current acute illness (in the last 48 hours) and/or symptoms compatible with a possible COVID-19 case.
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**Header Text:** C4591001  
**Visit:** V2_VAX2_L  
**Form:** VACCINATION - Comments  
**Form Version:** 22-Apr-2020 21:04  
**Site No:** 1231  
**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich  
**Subject No:** 12311815  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 16:45
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- **CRF_Sign**

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<td>BOOK</td>
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**Affidavit:**
By my dated signature below, I, [Signature], verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

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

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

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

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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.

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### 1. Select appropriate response - Protocol version

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<tbody>
<tr>
<td>Aug-17-2020 19:29:40</td>
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### 2. Select appropriate response - What cohort does the subject belong to?

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<td>Data Entry: OBTAINED Date Written Consent Obtained</td>
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### 1. Subject ID

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### 2. Birth Date:

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**Data Entry:**
- Inclusion Number: 1
- Criterion: Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)

### 1.a Criterion Description:

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**Data Entry:**
- Criterion: Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)
### 1.a Criterion met?

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### 1.b Criterion met?

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Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study

Criteron met?: YES

Criteron ID: IN03A00

(For Pfizer use only):
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### 1.c Criterion met?

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- Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the IC D and in this protocol.

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 16:45
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- Criterion met?: NO
- Criterion Descriptio: Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation

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**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History  
**Site No:** 1231  
**Subject No:** 12311815  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 16:45

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**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich  
**Subject Initials:** ---

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**Reason:** Initial Entry
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Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination

Criterion Desc: Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination

Criterion met?: NO

Criterion ID: EX08A00

(For Pfizer use only):
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Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1231
Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich
Subject No: 12311815
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 16:45
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**Criterion Description:** Women who are pregnant or breastfeeding
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Criterion Description: Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids  
Criterion met?: NO  
Criterion ID: (For Pfizer use only): EX13A01 |  
Initial Entry |
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**Data Entry:** Exclusion Number: 16

**Criterio:** Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation

**Criterio met?:** NO

**Criterio ID:** (For Pfizer use only): EX15A01
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**Criterion Description:** Previous participation in other studies involving study intervention containing lipid nanoparticles.
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### 1. Date of Completion/Discontinuation/Death

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<th>Reason</th>
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<tbody>
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### 2. Phase of Disposition:

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### 3. Status:

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### 1.a

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<td>Jan/1/1982</td>
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### 1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

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<td>Reason</td>
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<td>New Information</td>
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<tr>
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<td>Medical History Term: Demyelinating disease produced by a meningitis, paraparesis and paresthesia of the 4th and 5th fingers</td>
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**1.b Line/MH Number:**

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

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<tr>
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<td>Discrepancy has been closed.</td>
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<td></td>
<td>auto query</td>
<td>Query 1: Answered</td>
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DEMYELINATING DISEASE PRODUCED BY A MENINGITIS, PARESIS AND PARESTHESIA OF THE 4TH AND 5TH FINGERS. Split the term into DEMYELINATING DISEASE and MENINGITIS and PARESIS and PARESTHESIA OF THE 4TH AND 5TH FINGERS and report as 4 separate entries. Thank you.
1.b Start Date:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
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1.b Ongoing:

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1.c

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<td>Data Entry: Line/MH Number 3: demyelinating disease</td>
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<td>Medical History Term: demyelinating disease</td>
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<tr>
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<td></td>
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<td>Medical History Term: demyelinating disease</td>
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<td>Transcription Error</td>
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**Medical History Term:** demyelinating disease
**Start Date:**
**Ongoing:**

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### 1.c Line/MH Number:

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

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<td>Discrepancy has been closed.</td>
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<td>Query 1: Answered</td>
<td>Transcription Error</td>
</tr>
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<td>Oct-23-2020 19:57:41 (UTC-03:00) City of Buenos Aires</td>
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<td>Martina Davalli (b) (4)</td>
<td>Data Entry: demyelinating disease</td>
<td>Transcription Error</td>
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### 1.c Start Date:

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1.c Ongoing:

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1.d

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<td>Line/MH 4</td>
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<td>Medical Hi paresthesias in 4th and 5th fingers of the left hand</td>
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<td>Martina Davalli (b) (4)</td>
<td>Data Entry:</td>
<td>Initial Entry</td>
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<td>Line/MH 4</td>
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<td>Medical Hi paresthesias in 4th and 5th fingers of the left hand</td>
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<td>Oct-23-2020 13:40:46 (UTC-03:00) City of Buenos Aires</td>
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### 1.d Line/MH Number:

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<th>Reason</th>
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### 1.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

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<th>Value</th>
<th>Reason</th>
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<tbody>
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<td><strong>Data Entry:</strong> paresthesias in 4th and 5th fingers of the left hand</td>
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<th>Reason</th>
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<tbody>
<tr>
<td>Oct-23-2020 14:25:17 (UTC-03:00) City of Buenos Aires</td>
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<td>Martina Davalli (b) (4)</td>
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### 1.d Ongoing:

<table>
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<th>Value</th>
<th>Reason</th>
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<td>Initial Entry</td>
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<td>DM: Please complete this item. Thank you.</td>
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#### Location: City of Buenos Aires
#### User: ACV0PFEINFP6000
#### Value: Data Entry: 18.7
#### Reason: Initial Entry

#### 7.a Record Identifier:

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**ORAL CAVITY**

**FDA-CBER-2021-5683-0864056**

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Page 152 of 207
### 1. Lab Panel:

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**5.a**

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**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
**Audit Trail History**

**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1231  
**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich  
**Subject No:** 12311815  
**Subject Initials:** ---  
**Generated By:** 

**Generated Time (GMT):** 29-Mar-2021 16:45

**FDA-CBER-2021-5683-0864064**
### 1. Was there a temporary delay of vaccination?

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### 5. Anatomical Location:

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### 10. Timeframe Subject Was Observed

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

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<td>Oct-28-2020 07:12:55 (UTC-03:00) City of Buenos Aires</td>
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<td>Query 1: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Oct-27-2020 09:25:16 (UTC-03:00) City of Buenos Aires</td>
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<td>Query 1: Answered</td>
<td>Volunteer who has a lymphadenopathy under study and is going to be removed, awaiting confirmation of appointment for surgery / biopsy. Thank you.</td>
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<tr>
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<td>Please kindly consider to keep the query open and respond when data is available.</td>
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<td>This subject is in a temporary delay. No new information will be available until resuming visit. Thank you.</td>
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the subject is a temporary delay due to an adverse event diagnosed as Supraclavicular vascularized tumor. Thank you.

DM: Kindly complete the form to avoid yellow traffic light. Thank you.

Vital signs Date 08/Sep/2020 is not same as Date of Visit 07/Sep/2020. Please review and update as appropriate or clarify.

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<tr>
<td>Sep-08-2020 19:32:21 (UTC-03:00) City of Buenos Aires</td>
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</table>

### 2.a Unit:

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<th>Reason</th>
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<tbody>
<tr>
<td>Nov-07-2020 19:33:36 (UTC-03:00) City of Buenos Aires</td>
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</tr>
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<tr>
<td>Oct-27-2020 09:25:50 (UTC-03:00) City of Buenos Aires</td>
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<th>Reason</th>
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<tbody>
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<td>[Redacted]</td>
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<td>Initial Entry</td>
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<tr>
<td>Nov-07-2020 19:33:01 (UTC-03:00) City of Buenos Aires</td>
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<td>[Redacted]</td>
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<td>Initial Entry</td>
</tr>
<tr>
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<td>ACV0PFEINFP6000</td>
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<td>Initial Entry</td>
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<tr>
<td>Sep-10-2020 17:58:20 (UTC-03:00) City of Buenos Aires</td>
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<td>Transcription Error</td>
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### 1. Lab Panel:

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<tr>
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<tbody>
<tr>
<td>Nov-08-2020</td>
<td>(UTC-03:00) City of Buenos Aires</td>
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<td>Data Entry: Not Done</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>Sep-10-2020</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>auto calc</td>
<td>Data Entry: Transcription Error</td>
<td></td>
</tr>
<tr>
<td>Sep-08-2020</td>
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### 2. Lab Sub-Panel:

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<td>auto calc</td>
<td>Data Entry: Not Done</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>Sep-10-2020</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>auto calc</td>
<td>Data Entry: Transcription Error</td>
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</tr>
<tr>
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### 3. Collection Date:

<table>
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<td>Initial Entry</td>
</tr>
<tr>
<td>Nov-08-2020</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>(b) (4), (b) (6)</td>
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</tr>
<tr>
<td>Sep-18-2020</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Closed</td>
<td>Response satisfies query</td>
</tr>
</tbody>
</table>
### 4. Laboratory Name and Address (Derived)

<table>
<thead>
<tr>
<th>Date</th>
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<tbody>
<tr>
<td>Nov-08-2020 10:50:30 (UTC-03:00) City of Buenos Aires</td>
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<td>auto calc (autocalc)</td>
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</tr>
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### 5. Specimen Type:

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<td>Initial Entry</td>
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<td>Initial Entry</td>
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### 6.a

<table>
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<td><strong>Data Entry:</strong> Choriogonadotropin Beta_PX113</td>
<td>Transcription Error</td>
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<td>ACV0PFEINFP6000</td>
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<td><strong>Data Entry:</strong> Choriogonadotropin Beta_PX113</td>
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<td>auto calc (autocalc)</td>
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<td>Initial Entry</td>
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### 6.a Result:

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<th>Reason</th>
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<tbody>
<tr>
<td>Nov-08-2020 10:50:30</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Not Done</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>Sep-10-2020 17:58:52</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry:</td>
<td>Transcription Error</td>
</tr>
<tr>
<td></td>
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<td>Negative</td>
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### 6.a Not Done:

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

<table>
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<tr>
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<td>auto calc</td>
<td>Data Entry: SITE</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>Nov-08-2020 10:47:12</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>(b) (4), (b) (6)</td>
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<td>Initial Entry</td>
</tr>
<tr>
<td>Oct-27-2020 09:26:04</td>
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<td>(b) (4), (b) (6)</td>
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### 2. Sample Type

<table>
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<td>auto calc</td>
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<td>Initial Entry</td>
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<tr>
<td>Nov-08-2020 10:47:12</td>
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<td>(b) (4), (b) (6)</td>
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<td>(b) (4), (b) (6)</td>
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<td>Initial Entry</td>
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</table>

### 3. Sample Collected?

<table>
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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Nov-09-2020 08:09:23</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>auto query</td>
<td>Query 1: Closed</td>
<td>Close Auto Query</td>
</tr>
<tr>
<td>Nov-08-2020 17:18:34</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Opened</td>
<td>'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.</td>
</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>
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<td>Initial Entry</td>
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<td>Initial Entry</td>
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5.a Sample ID

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<th>Value</th>
<th>Reason</th>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: Sample ID: BPT838</td>
<td>Initial Entry</td>
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<tr>
<td>Header Text: C4591001</td>
<td>Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF</td>
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<td></td>
<td></td>
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<tr>
<td>----------------------</td>
<td>--------------------------------------------------</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Visit: V2_VAX2_L</td>
<td>Audit Trail History</td>
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</tr>
<tr>
<td>Form Version: 22-Apr-2020 21:03</td>
<td>Form Status: Data Complete, Locked, Frozen, Verified</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Site No: 1231</td>
<td>Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subject No: 12311815</td>
<td>Subject Initials: ---</td>
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<td></td>
</tr>
<tr>
<td>Generated By: (b) (4)</td>
<td>Generated Time (GMT): 29-Mar-2021 16:45</td>
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</table>
### 1. Was there a temporary delay of vaccination?

<table>
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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Sep-21-2020 10:04:40 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>Marjorie Buonanno (b) (4)</td>
<td>Query 2: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Sep-21-2020 10:03:57 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>Marjorie Buonanno (b) (4)</td>
<td>Query 1: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Sep-18-2020 13:35:36 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Answered</td>
<td>the subject is a temporary delay due to an adverse event diagnosed as</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Supraclavicular vascularized tumor. Thank you.</td>
</tr>
<tr>
<td>Sep-18-2020 13:35:14 (UTC-03:00) City of Buenos Aires</td>
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<td>Query 1: Answered</td>
<td>the subject is a temporary delay due to an adverse event diagnosed as</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Supraclavicular vascularized tumor. Thank you.</td>
</tr>
<tr>
<td>Sep-11-2020 17:03:17 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>Marjorie Buonanno (b) (4)</td>
<td>Query 2: Opened</td>
<td>GPD CLin: f above response is fever, per protocol Section 8.13, Fever</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>is listed as a potential COVID-19 Illness symptom. As such</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>regardless of the cause a COVID-19 illness visit should occur,</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>and a Nasal Swab should be collected as soon as possible</td>
</tr>
<tr>
<td>Sep-11-2020 17:01:25 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>Marjorie Buonanno (b) (4)</td>
<td>Query 1: Opened</td>
<td>GPD CLin: Please confirm if temp delay is due to fever or acute illness</td>
</tr>
</tbody>
</table>
provide detail of acute illness.

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>Marjorie Buonanno (b) (4)</td>
<td>Query 1: Closed</td>
</tr>
<tr>
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<td>ACV0PFEINFP6000</td>
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<td>Query 1: Answered</td>
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4. Dose Date Time:

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<th>Reason</th>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>The EA is still ongoing, without diagnosis, for that reason the temporary delay continues until next visit to her surgeon in 30 days, or until a certain diagnosis.</td>
</tr>
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### 6. Body Side:

<table>
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<tr>
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<th>Value</th>
<th>Reason</th>
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| Oct-27-2020 09:26:37
(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Marjorie Buonanno (b) (4) | Data Entry: Not Done | Initial Entry |

GPD Clin: Please confirm if subject will return for VXN 2 dose and provide date

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

<table>
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<th>Value</th>
<th>Reason</th>
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</table>
| Oct-27-2020 09:26:48
(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Marjorie Buonanno (b) (4) | Data Entry: Not Done | Initial Entry |
### Date of Visit

<table>
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<th>Value</th>
<th>Reason</th>
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<td><strong>Data Entry:</strong> Dec/9/2020</td>
<td>Initial Entry</td>
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### 1. Data Origin

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<tbody>
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### 2. Sample Type

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<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
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### 3. Sample Collected?

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<td>Dec-10-2020 15:12:54</td>
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<td>auto query (autoquery)</td>
<td>Query 1: Deleted</td>
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### 5.a

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### 5.a Sample ID
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**5.b**

**Date** | **Location** | **User** | **Value** | **Reason**
--- | --- | --- | --- | ---
Dec-10-2020 15:24:03 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Alan Colombo | Data Entry: Sample ID: BRVP6K | Initial Entry

**5.b Sample ID**

**Date** | **Location** | **User** | **Value** | **Reason**
--- | --- | --- | --- | ---
Dec-10-2020 15:24:03 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Alan Colombo | Data Entry: BRVP6K | Initial Entry

**5.c**

**Date** | **Location** | **User** | **Value** | **Reason**
--- | --- | --- | --- | ---
Dec-10-2020 15:42:10 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BRVP6C | Initial Entry

**5.c Sample ID**

**Date** | **Location** | **User** | **Value** | **Reason**
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<td>Santiago Corradetti</td>
<td>Data Entry: Nov/5/2020</td>
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<td>Santiago Corradetti</td>
<td>Data Entry: Not Applicable</td>
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<td>Data Entry:</td>
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<td>(b) (4)</td>
<td></td>
<td>Subject has V3 scheduled for</td>
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<td>DEC-9, so the EOT was uploaded</td>
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<td>erroneously. It will</td>
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<td>Nov-18-2020 12:40:49</td>
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### 2. Phase of Disposition:

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### 3. Status:

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<td>auto calc (autocalc)</td>
<td>Subject has V3 scheduled for DEC-9, so the EOT was uploaded erroneously. It will be completed on that date.</td>
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<tr>
<td>Nov-18-2020 12:40:49</td>
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<td>Subject No</td>
<td>Form Status</td>
<td>Query</td>
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### DISPOSITION - TREATMENT - eCRF Audit Trail History

**Visit:** End of Treatment - Unscheduled  
**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1231  
**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich  
**Subject No:** 12311815  
**Subject Initials:** ---  
**Generated By:** Generated Time (GMT): 29-Mar-2021 16:45

<table>
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<td>Dec-01-2020 15:39:47 (UTC-03:00)</td>
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### 4. Specify Status:

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<td>(b) (4), (b) (6)</td>
<td>Data Entry: Supraclavicular lymph node.</td>
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<td>Dec-01-2020 16:33:31 (UTC-03:00) City of Buenos Aires</td>
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<td>Hayley Wyper (b) (4)</td>
<td>Query 1: Closed</td>
<td>query raised on matching AE entry</td>
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<tr>
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<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Answered</td>
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</tr>
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<td>Santiago Corradetti (b) (4)</td>
<td>Data Entry: Supraclavicular lymph node, with FANB that informed reactive lymphoid proliferation.</td>
<td>Initial Entry</td>
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<tr>
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<td>ACV0PFEINFP6000</td>
<td>Hayley Wyper (b) (4)</td>
<td>Query 1: Reissued:Opened</td>
<td>CLINQUERY: Subject hasn't received vaccination 2. If subject won't receive vax 2 then the EOT page should be completed with the data related to why vax 2 will not be administered. Does not wait for V3.</td>
</tr>
<tr>
<td>Dec-01-2020 10:48:55</td>
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***Confidential***  
FDA-CBER-2021-5683-0864092
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<td>Corradetti</td>
<td>auto query</td>
<td>Query 1: Answered</td>
<td>The information uploaded is erroneous. The subject has the V3 scheduled for DEC-9, so EOT should not be completed until that date.</td>
</tr>
<tr>
<td>Dec-01-2020 10:48:33</td>
<td>Santiago Corradetti</td>
<td>Data Entry:</td>
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<td>The information uploaded is erroneous. The subject has the V3 scheduled for DEC-9, so EOT should not be completed until that date.</td>
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<tr>
<td>Nov-30-2020 13:29:45</td>
<td>Hayley Wyper</td>
<td>Query 1: Opened</td>
<td>CLINQUERY: Please review and clarify if the decision to cease treatment was linked to the AE, REACTIVE LYMPHOID PROLIFERATION SUPRACLAVICULAR. If so, please review Status selection for EOT (if related to an AE, then ADVERSE EVENT to be selected)</td>
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<td>Data Entry:</td>
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<td>CLINQUERY: Please review and clarify if the decision to cease treatment was linked to the AE, REACTIVE LYMPHOID PROLIFERATION SUPRACLAVICULAR. If so, please review Status selection for EOT (if related to an AE, then ADVERSE EVENT to be selected)</td>
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<tr>
<td>Nov-18-2020 12:40:49</td>
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<td>(b) (4), (b) (6)</td>
<td>ot be ruled out.</td>
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**Back to Form**

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### 3. Adverse Event:

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

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<td>Query 3: Closed</td>
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<td>Response satisfies query</td>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 3: Opened</td>
</tr>
<tr>
<td></td>
<td>Buenos Aires</td>
<td></td>
<td></td>
<td>clinical: please provide</td>
</tr>
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<td>additional information</td>
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<td>as to subject signs/sx</td>
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<td></td>
<td>eg size of mass, painful</td>
</tr>
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<td></td>
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<td>or not and update CRF</td>
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<td>with side that was</td>
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<td>involved ie right vs</td>
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<td></td>
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<td>left.</td>
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<td>(b) (4), (b)</td>
<td>Data Entry:</td>
</tr>
<tr>
<td></td>
<td>Buenos Aires</td>
<td></td>
<td>(6)</td>
<td>REACTIVELY MPH OID PROLI</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>FERATION SUPR</td>
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<tr>
<td>Nov-06-2020 08:29:41</td>
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***Confidential***
<table>
<thead>
<tr>
<th>Date/Time</th>
<th>City</th>
<th>User/Module</th>
<th>Event Type</th>
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<tr>
<td>Nov-04-2020 11:08:59</td>
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<td>ACV0PFEINFP6000.InFormAdapter.Discrepancy</td>
<td>Discrepancy</td>
<td>Discrepancy has been closed.</td>
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<tr>
<td>Nov-04-2020 09:27:21</td>
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<td>auto query (autoquery)</td>
<td>Transcription Error</td>
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<tr>
<td>Nov-04-2020 09:27:21</td>
<td>City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: REACTIVE LYMPHOID PROLIFERATION or any other possible relevant term. Else clarify.</td>
</tr>
<tr>
<td>Nov-04-2020 04:42:55</td>
<td>City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>Query</td>
<td>Coding Query: Kindly update the underlying condition due to which process happened. Kindly update the term to REACTIVE LYMPHOID HYPERPLASIA or REACTIVE LYMPHOID PROLIFERATION or any other possible relevant term. Else clarify.</td>
</tr>
<tr>
<td>Oct-29-2020 15:09:38</td>
<td>City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Answered. The subject underwent a fine needle aspiration cytology, which is not the method of choice to rule out lymphoproliferative...</td>
</tr>
<tr>
<td>Date/Time</td>
<td>User/Event/Reason</td>
<td>Details</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------------------</td>
<td>--------------------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>City of Buenos Aires</td>
<td>PFETMS Oracle</td>
<td>Query 2: Opened</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Clarify REACTIVE LYMPHOID PROCESS (DUE TO PATHOLOGICAL ANATOMY) as follows...Term is unclear. Are you reporting REACTIVE LYMPHOID HYPERPLASIA? Or REACTIVE LYMPHOID PROLIFERATION? Or other? Please update the verbatim term to clarify. Thank you.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oct-29-2020 10:30:18</td>
<td>ACV0PFEINFP6000</td>
<td>Data Entry: Reactive lymphoid process (due to pathological anatomy)</td>
<td></td>
<td></td>
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<tr>
<td>City of Buenos Aires</td>
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<td>New Information</td>
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<td></td>
</tr>
<tr>
<td>Sep-21-2020 12:16:17</td>
<td>ACV0PFEINFP6000</td>
<td>Query 1: Answered</td>
<td></td>
<td></td>
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<tr>
<td>City of Buenos Aires</td>
<td>Gary Steven Friedman</td>
<td>Response satisfies query</td>
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<tr>
<td>Sep-18-2020 13:34:16</td>
<td>ACV0PFEINFP6000</td>
<td>Query 1: Answered</td>
<td></td>
<td></td>
</tr>
<tr>
<td>City of Buenos Aires</td>
<td></td>
<td>the subject has a pending biopsy of the lesion. has turn for 09/30/2020</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sep-15-2020 11:14:24</td>
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<td></td>
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<tr>
<td>City of Buenos Aires</td>
<td></td>
<td>SUPRACLAVICULAR VASCULARIZED TUMOR (ONGOING):</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
please confirm histopathological specimen HAS or HAS NOT been obtained to determine if MALIGNANCY is present.

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
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<tr>
<td>City of Buenos Aires</td>
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### 4. Start Date Time:

<table>
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<tbody>
<tr>
<td>Oct-29-2020 15:50:52</td>
<td>City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>Marjorie Buonanno</td>
<td>Query 2: Closed</td>
</tr>
<tr>
<td>(UTC-03:00)</td>
<td></td>
<td></td>
<td>(b) (4)</td>
<td>Medical Monitor to follow up for further detail</td>
</tr>
<tr>
<td>Oct-29-2020 10:31:12</td>
<td>City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Answered</td>
</tr>
<tr>
<td>(UTC-03:00)</td>
<td></td>
<td></td>
<td></td>
<td>Reactive lymphoid process due to pathological anatomy of 30sep2020.</td>
</tr>
<tr>
<td>Oct-28-2020 16:11:32</td>
<td>City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>Marjorie Buonanno</td>
<td>Query 2: Opened</td>
</tr>
<tr>
<td>(UTC-03:00)</td>
<td></td>
<td></td>
<td>(b) (4)</td>
<td>GPD Clin: After medical monitor review, requesting further detail on biopsy result. What was the actual tissue biopsied i.e. was it a lymph node?</td>
</tr>
<tr>
<td>Oct-27-2020 16:22:02</td>
<td>City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>Marjorie Buonanno</td>
<td>Query 1: Closed</td>
</tr>
<tr>
<td>(UTC-03:00)</td>
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<td></td>
<td>(b) (4)</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Oct-27-2020 09:05:04</td>
<td>City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Answered</td>
</tr>
<tr>
<td>(UTC-03:00)</td>
<td></td>
<td></td>
<td></td>
<td>The biopsy is described as &quot;LYMPHOID REACTIVE PROCESS&quot;</td>
</tr>
</tbody>
</table>
**Header Text:** C4591001

**Visit:** Logs - Unscheduled  
**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1231  
**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich  
**Subject No:** 12311815  
**Generated By:**  
**Generated Time (GMT):** 29-Mar-2021 16:45

<table>
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<th>User</th>
<th>Value</th>
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<td>Marjorie Buonanno</td>
<td>(b) (4)</td>
<td><strong>Query 1:</strong> Reissued:Opened</td>
</tr>
<tr>
<td>(UTC-03:00) City of Buenos Aires</td>
<td></td>
<td></td>
<td></td>
<td>GPD Clin: Thank you for your response, you indicate the biopsy result is available however you have not provided the result. Please enter the biopsy result.</td>
</tr>
<tr>
<td>Oct-22-2020 18:52:05</td>
<td>ACV0PFEINFP6000</td>
<td>Marjorie Buonanno</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Query 1:</strong> Answered</td>
</tr>
<tr>
<td>(UTC-03:00) City of Buenos Aires</td>
<td></td>
<td></td>
<td></td>
<td>information is now available in the medical record</td>
</tr>
<tr>
<td>Oct-20-2020 16:01:39</td>
<td>ACV0PFEINFP6000</td>
<td>Marjorie Buonanno</td>
<td>(b) (4)</td>
<td><strong>Query 1:</strong> Opened</td>
</tr>
<tr>
<td>(UTC-03:00) City of Buenos Aires</td>
<td></td>
<td></td>
<td></td>
<td>GPD Clin: Please provide biopsy results from skin tumor biopsy done 30Sep20 if available. thank you</td>
</tr>
<tr>
<td>Sep-10-2020 13:04:59</td>
<td>ACV0PFEINFP6000</td>
<td>Marjorie Buonanno</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Sep/6/2020 15:00</td>
</tr>
<tr>
<td>(UTC-03:00) City of Buenos Aires</td>
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<td></td>
<td></td>
<td><strong>Initial Entry</strong></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
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<tbody>
<tr>
<td>Nov-06-2020 10:57:46</td>
<td>ACV0PFEINFP6000</td>
<td>Marjorie Buonanno</td>
<td>Query 1: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>(UTC-03:00) City of Buenos Aires</td>
<td></td>
<td></td>
<td></td>
<td>Changed data per query</td>
</tr>
<tr>
<td>Nov-06-2020 08:29:53</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Answered</td>
<td>GDP Clin: Please add the anatomical location &quot;SUPRACLAVICULAR&quot; back into the CRF with AE term REACTIVE LYMPHOID PROLIFERATION. thank you</td>
</tr>
<tr>
<td>(UTC-03:00) City of Buenos Aires</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Nov-05-2020 21:10:43</td>
<td>ACV0PFEINFP6000</td>
<td>Marjorie Buonanno</td>
<td>Query 1: Opened</td>
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<tr>
<td>(UTC-03:00) City of Buenos Aires</td>
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<td></td>
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<td>(b) (4), (b) (6)</td>
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<td>(UTC-03:00) City of Buenos Aires</td>
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<td></td>
<td></td>
<td><strong>Initial Entry</strong></td>
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**FDA-CBER-2021-5683-0864101**
6. Toxicity Grade:

<table>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: 1</td>
<td>Initial Entry</td>
</tr>
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</table>

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
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<tr>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
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</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>Sep-10-2020 13:04:59 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

9. Is this event related to study treatment:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: NOT RELATED</td>
<td>Initial Entry</td>
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</table>

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

OTHER

If Other, specify:

Unknown

10. Latest Action Taken with Study Treatment:

<table>
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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>
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</table>
### 11. Was a Concomitant Medication given?

<table>
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<tr>
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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
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<td>City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
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#### Data Entry: NO

#### Reason:
- Initial Entry

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

<table>
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<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Sep-10-2020 13:04:59</td>
<td>City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
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#### Data Entry: NO

#### Reason:
- Initial Entry

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

<table>
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<th>Location</th>
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<th>Value</th>
<th>Reason</th>
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<td>(b) (4), (b) (6)</td>
<td>Query 1: Closed</td>
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#### Reason:
- Confirm the AE is
<table>
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<th>Event Type</th>
<th>Notes</th>
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<tbody>
<tr>
<td>Dec-06-2020 13:51:04</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>Query 1: Reissued/Opened</td>
<td>ongoing. Subject in follow-up, when new data is available it will be provided. Thank you.</td>
</tr>
<tr>
<td>Dec-05-2020 10:32:03</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>Query 2: Closed</td>
<td>Close Auto Query</td>
</tr>
<tr>
<td>Dec-04-2020 20:52:58</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>Query 2: Opened</td>
<td>For AE REACTIVE LYMPHOID PROLIFERATION SUPRACLAVICULAR: Response to &quot;What was the outcome of this adverse event?&quot; is 'Unknown' but End Date/Time is provided or &quot;Is the adverse event still ongoing?&quot; is marked &quot;Yes&quot;.</td>
</tr>
<tr>
<td>Dec-04-2020 20:52:58</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>Query 1: Answered</td>
<td>New Information</td>
</tr>
<tr>
<td>Dec-04-2020 20:52:58</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>Data Entry: UNKNOWN</td>
<td>New Information</td>
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<tr>
<td>Dec-04-2020 14:38:11</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>Query 1: Opened</td>
<td>clinical: pls confirm AE ongoing, or update CRF with end date.</td>
</tr>
<tr>
<td>Sep-10-2020 13:04:59</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>Data Entry: NOT RECOVERED/NOT RESOLVED</td>
<td>Initial Entry</td>
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### 14. Did the adverse event cause the subject to be discontinued from the study?

<table>
<thead>
<tr>
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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
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<td>(b) (4), (b) (6)</td>
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<td>Initial Entry</td>
</tr>
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### 1. Category:

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<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
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<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: ADVERSE EVENT</td>
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</table>

### 2. AE ID:

<table>
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<tr>
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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-30-2020 09:34:47</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: 2</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-05-2020 10:49:16</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>Marjorie Buonanno</td>
<td>Query 1: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Oct-03-2020 16:53:04</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>auto query (autoquery)</td>
<td>Query 1: Answered</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Oct-03-2020 16:53:04</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>Mabel Berrueta</td>
<td>Data Entry: Pain in injection site</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Oct-02-2020 16:34:33</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Opened</td>
<td>GPD Clin: Please report as pain in injection site rather than pain in &quot;application&quot; site. thank you</td>
</tr>
<tr>
<td>Oct-02-2020 16:02:44</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>Marjorie Buonanno</td>
<td>Query 1: Candidate</td>
<td>GPD Clin: Please report as pain in injection site rather than pain in &quot;application&quot; site. thank you</td>
</tr>
<tr>
<td>Sep-30-2020 09:34:47</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Initial Entry</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>
4. Start Date Time:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-30-2020 09:34:47 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Sep/18/2020 07:00</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

5. Is the adverse event still ongoing?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-30-2020 09:34:47 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> NO</td>
<td>End Date Time: Sep/18/2020 19:00</td>
</tr>
</tbody>
</table>

6. Toxicity Grade:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-30-2020 09:34:47 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> 1</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

7. Is the adverse event serious?

*If Yes, NOTIFY PFIZER IMMEDIATELY.*

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-30-2020 09:34:47 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> NO</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-30-2020 09:34:47 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> NO</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>
**Header Text:** C4591001
**Visit:** Logs - Unscheduled  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1231  
**Subject No:** 12311815  
**Generated By:** **(b) (4)**  
**Generated Time (GMT):** 29-Mar-2021 16:45

### 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>Sep-30-2020 09:34:47 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td><strong>(b) (4), (b) (6)</strong></td>
<td>Data Entry: RELATED</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-30-2020 09:34:47 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td><strong>(b) (4), (b) (6)</strong></td>
<td>Data Entry: NOT APPLICABLE</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

### 11. Was a Concomitant Medication given?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-30-2020 09:34:47 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td><strong>(b) (4), (b) (6)</strong></td>
<td>YES</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-30-2020 09:34:47 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td><strong>(b) (4), (b) (6)</strong></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>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-30-2020 09:34:47 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td><strong>(b) (4), (b) (6)</strong></td>
<td>Data Entry: RECOVERED/RESOLVED</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-30-2020 09:34:47 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td><strong>(b) (4), (b) (6)</strong></td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>
**1. Subject Status**

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec-01-2020 15:40:27 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000 auto calc (autocalc)</td>
<td>Data Entry: DISCONTINUED</td>
<td>Transcription Error</td>
<td></td>
</tr>
<tr>
<td>Dec-01-2020 15:39:47 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000 auto calc (autocalc)</td>
<td>Data Entry: DISCONTINUED</td>
<td>Initial Entry</td>
<td></td>
</tr>
<tr>
<td>Dec-01-2020 10:50:58 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000 auto calc (autocalc)</td>
<td>Data Entry: ENROLLED/RANDOMIZED</td>
<td>Subject has V3 scheduled for DEC-9, so the EOT was uploaded erroneously. It will be completed on that date.</td>
<td></td>
</tr>
<tr>
<td>Nov-18-2020 12:40:49 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000 auto calc (autocalc)</td>
<td>Data Entry: DISCONTINUED</td>
<td>Initial Entry</td>
<td></td>
</tr>
<tr>
<td>Aug-17-2020 19:32:24 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000 auto calc (autocalc)</td>
<td>Data Entry: ENROLLED/RANDOMIZED</td>
<td>Initial Entry</td>
<td></td>
</tr>
<tr>
<td>Aug-17-2020 19:30:55 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000 auto calc (autocalc)</td>
<td>Data Entry: SCREENED</td>
<td>Initial Entry</td>
<td></td>
</tr>
</tbody>
</table>

**2. Subject Status Date**

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec-01-2020 15:42:36 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000 auto calc (autocalc)</td>
<td>Data Entry: Sep/6/2020</td>
<td>Transcription Error</td>
<td></td>
</tr>
<tr>
<td>Dec-01-2020 15:40:27 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000 auto calc (autocalc)</td>
<td>Data Entry: Nov/5/2020</td>
<td>Transcription Error</td>
<td></td>
</tr>
<tr>
<td>Dec-01-2020 15:39:47 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000 auto calc (autocalc)</td>
<td>Data Entry: Nov/5/2020</td>
<td>Initial Entry</td>
<td></td>
</tr>
<tr>
<td>Dec-01-2020 10:51:45</td>
<td>ACV0PFEINFP6000 auto calc (autocalc)</td>
<td>Data Entry:</td>
<td>Subject has V3</td>
<td></td>
</tr>
</tbody>
</table>
### SUBJECT STATUS - eCRF Audit Trail History

<table>
<thead>
<tr>
<th>Date/Time</th>
<th>Site</th>
<th>ACV0PFEINFP6000</th>
<th>Data Entry</th>
<th>Data Entry Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aug-17-2020 19:30:55</td>
<td>Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>Aug/17/2020</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>Dec-01-2020 10:50:58</td>
<td>Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>Aug/17/2020</td>
<td>Subject has V3</td>
</tr>
</tbody>
</table>

- **Scheduled for DEC-9, so the EOT was uploaded erroneously. It will be completed on that date.**
- **Scheduled for DEC-9, so the EOT was uploaded erroneously. It will be completed on that date.**
- **Initial Entry**
### 1. Casebook Signature

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-06-2020 19:10:40</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Click Here to Enable</td>
</tr>
</tbody>
</table>