## Cohort Selection

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

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Select appropriate response - Protocol version</td>
</tr>
<tr>
<td>2.</td>
<td>Select appropriate response - What cohort does the subject belong to?</td>
</tr>
</tbody>
</table>
**Header Text:** C4591001  
**Visit:** COHORT_SELECTION  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1231  
**Subject No:** 12313028  
**Generated By:** (b) (4)  

<table>
<thead>
<tr>
<th>eCRF Audit Trail History</th>
</tr>
</thead>
<tbody>
<tr>
<td>Informed Consent</td>
</tr>
<tr>
<td>1. Consent Was:</td>
</tr>
<tr>
<td>OBTAINED</td>
</tr>
<tr>
<td>Date Written Consent Obtained</td>
</tr>
<tr>
<td>Aug/21/2020</td>
</tr>
</tbody>
</table>
### eCRF Audit Trail History

#### Demography

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Subject ID</td>
</tr>
<tr>
<td>2.</td>
<td>Birth Date: (b) (6) 1990</td>
</tr>
<tr>
<td>3.</td>
<td>Sex: FEMALE</td>
</tr>
<tr>
<td>4.</td>
<td>Ethnicity: HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN</td>
</tr>
<tr>
<td>5.</td>
<td>Race: (Check X all that apply): WHITE</td>
</tr>
<tr>
<td>6.</td>
<td>Racial Designation:</td>
</tr>
<tr>
<td>Date of Visit</td>
<td>1. Date of Visit</td>
</tr>
<tr>
<td>---------------</td>
<td>---------------------</td>
</tr>
<tr>
<td></td>
<td>2. Erroneous Visit</td>
</tr>
</tbody>
</table>
Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclusion criteria (NO).

### 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.b</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>2.c</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>2.d</td>
<td>Receipt of medications intended to prevent COVID-19</td>
<td>NO</td>
<td>EX04A00</td>
</tr>
<tr>
<td>2.e</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>2.f</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>2.g</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>
<tr>
<td></td>
<td>Date of Completion/Discontinuation /Death</td>
<td>Aug/21/2020</td>
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</tr>
<tr>
<td>---</td>
<td>----------------------------------------</td>
<td>------------</td>
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</tr>
<tr>
<td>2.</td>
<td>Phase of Disposition:</td>
<td>SCREENING</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Status:</td>
<td>COMPLETED</td>
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</tr>
<tr>
<td>4.</td>
<td>Specify Status:</td>
<td>[ ]</td>
<td></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>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>[Familial hypercholesterolemia]</td>
<td>Jul/4/2015</td>
<td>YES</td>
</tr>
<tr>
<td>2</td>
<td>[Hypotiroidism]</td>
<td>Jul/4/2015</td>
<td>YES</td>
</tr>
<tr>
<td>3</td>
<td>[Migraines]</td>
<td>Jan/1/2003</td>
<td>YES</td>
</tr>
</tbody>
</table>
### Vital Signs

1. **Date:** Aug/21/2020  
2. **Weight:** [49.0] kg  
3. **Height:** [151.0] cm  
4. **Body Mass Index:** [21.5]

### Vital Signs Details

7.a  
- **Record Identifier:** 1  
- **Temperature:** [36.5] C  
- **Temperature Location:** ORAL CAVITY
**eCRF Audit Trail History**

**Lab Urinalysis**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Lab Panel: URINALYSIS</td>
</tr>
<tr>
<td>2.</td>
<td>Lab Sub-Panel: PREGNANCY</td>
</tr>
<tr>
<td>3.</td>
<td>Collection Date: Aug/21/2020</td>
</tr>
<tr>
<td>4.</td>
<td>Laboratory Name and Address (Derived): [STUDY SITE]</td>
</tr>
<tr>
<td>5.</td>
<td>Specimen Type: URINE</td>
</tr>
</tbody>
</table>

**Lab Result**

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

---

**Header Text:** C4591001  
**Visit:** V1_DAY1_VAX1_L  
**Form:** LAB URINALYSIS - PREGNANCY TEST  
**Form Version:** 21-Aug-2020 02:49  
**Site No:** 1231  
**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich  
**Subject No:** 12313028  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 20:20

---

**FDA-CBER-2021-5683-0872709**
<table>
<thead>
<tr>
<th>Disposition</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Randomization Date : Aug/21/2020</td>
</tr>
<tr>
<td>2. Randomization Number: [61543]</td>
</tr>
<tr>
<td>3. Randomization Group: []</td>
</tr>
</tbody>
</table>
### eCRF Audit Trail History

**Electronic Sample Tracking**

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Data Origin</td>
<td>SITE</td>
</tr>
<tr>
<td>2.</td>
<td>Sample Type</td>
<td>SERUM</td>
</tr>
<tr>
<td>3.</td>
<td>Sample Collected?</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td>Date of Collection:</td>
<td>Aug/21/2020</td>
</tr>
<tr>
<td>4.</td>
<td>If no sample was collected or sample was not collected according to protocol, please provide reason:</td>
<td>[]</td>
</tr>
</tbody>
</table>

#### Aliquot

Please enter barcode for each aliquot.

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5.a</td>
<td>Sample ID</td>
<td>[BHXWR5]</td>
</tr>
<tr>
<td>5.b</td>
<td>Sample ID</td>
<td>[BHXWR6]</td>
</tr>
<tr>
<td>5.c</td>
<td>Sample ID</td>
<td>[BHXWR7]</td>
</tr>
<tr>
<td>5.d</td>
<td>Sample ID</td>
<td>[BJ49H1]</td>
</tr>
<tr>
<td>5.e</td>
<td>Sample ID</td>
<td>[BJ49H0]</td>
</tr>
<tr>
<td>5.f</td>
<td>Sample ID</td>
<td>[BJ49GZ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td>Data Origin</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Sample Type</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Sample Collected?</td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>If no sample was collected or sample was not collected according to protocol, please provide reason:</td>
<td></td>
</tr>
</tbody>
</table>

**Aliquot**

Please enter barcode for each aliquot.

<table>
<thead>
<tr>
<th>5.a</th>
<th>Sample ID</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>[BHY62D]</td>
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</tbody>
</table>
### eCRF Audit Trail History

**Vaccination**

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

<table>
<thead>
<tr>
<th>No.</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Select appropriate response - Reactogenicity diary collection</td>
</tr>
<tr>
<td></td>
<td>NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT</td>
</tr>
</tbody>
</table>
## eCRF Audit Trail History

<table>
<thead>
<tr>
<th>Date of Visit</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Visit</td>
<td>Sep/11/2020</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>
### eCRF Audit Trail History

**Vital Signs**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Date: Sep/11/2020</td>
</tr>
</tbody>
</table>

**Vital Signs Details**

<p>| | |</p>
<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>2.a</td>
<td>Record Identifier: 1</td>
</tr>
<tr>
<td></td>
<td>Temperature: [37.1]</td>
</tr>
<tr>
<td></td>
<td>Unit: C</td>
</tr>
<tr>
<td></td>
<td>Temperature Location: ORAL CAVITY</td>
</tr>
</tbody>
</table>
**Lab Urinalysis**

1. Lab Panel: URINALYSIS
2. Lab Sub-Panel: PREGNANCY
3. Collection Date: Sep/11/2020
4. Laboratory Name and Address (Derived): [STUDY SITE]
5. Specimen Type: URINE

**Lab Result**

6.a

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

---

**eCRF Audit Trail History**

- Lab Urinalysis
- Form: LAB URINALYSIS - PREGNANCY TEST
- Form Version: 21-Aug-2020 02:49
- Form Status: Data Complete, Locked, Frozen, Verified
- Site No: 1231
- Site Name: (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich
- Subject No: 12313028
- Subject Initials: ---
- Generated By: [b] (4)
- Generated Time (GMT): 29-Mar-2021 20:20
- Site Generated Time (GMT): 29-Mar-2021 20:20
- Source Data Parsed: 29-Mar-2021 20:20
- Source Data Parsed Value: 29-Mar-2021 20:20
- Source Data Parsed End Value: 29-Mar-2021 20:20
- Final On: 01-Apr-2021 03:29 (GMT)
- Not Done: 090177e196ae2ef6
**Electronic Sample Tracking**

1. Data Origin | SITE

2. Sample Type | NASAL_SWAB

3. Sample Collected? | YES
   Date of Collection: Sep/11/2020

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

**Aliquot**

Please enter barcode for each aliquot.

| 5.a | Sample ID | [BP1Y4F] |
### eCRF Audit Trail History

#### Vaccination

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Was there a temporary delay of vaccination?</td>
<td>NO</td>
</tr>
<tr>
<td>2.</td>
<td>Treatment Name</td>
<td>[BLINDED THERAPY]</td>
</tr>
<tr>
<td>3.</td>
<td>Formulation:</td>
<td>INJECTION</td>
</tr>
<tr>
<td>4.</td>
<td>Dose Date Time:</td>
<td>Sep/11/2020 14:27</td>
</tr>
<tr>
<td>5.</td>
<td>Anatomical Location:</td>
<td>DELTOID MUSCLE</td>
</tr>
<tr>
<td>6.</td>
<td>Body Side:</td>
<td>LEFT</td>
</tr>
<tr>
<td>7.</td>
<td>Route:</td>
<td>INTRAMUSCULAR</td>
</tr>
<tr>
<td>8.</td>
<td>Actual Dose:</td>
<td>[ ]</td>
</tr>
<tr>
<td>9.</td>
<td>Unit:</td>
<td></td>
</tr>
<tr>
<td>10.</td>
<td>Timeframe Subject Was Observed</td>
<td>THE PROTOCOL SPECIFIED OBSERVATION PERIOD</td>
</tr>
<tr>
<td>11.</td>
<td>Was the subject observed for at least the protocol specified observation period after investigational product administration?</td>
<td>YES</td>
</tr>
</tbody>
</table>
## eCRF Audit Trail History

### Date of Visit

<table>
<thead>
<tr>
<th></th>
<th>Date of Visit</th>
<th>Oct/8/2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Date of Visit</td>
<td>Oct/8/2020</td>
</tr>
<tr>
<td>2</td>
<td>Erroneous Visit</td>
<td>Oct/8/2020</td>
</tr>
</tbody>
</table>
### eCRF Audit Trail History

#### Electronic Sample Tracking

<p>| | | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>1.</td>
<td>Data Origin</td>
<td>SITE</td>
</tr>
<tr>
<td>2.</td>
<td>Sample Type</td>
<td>SERUM</td>
</tr>
<tr>
<td>3.</td>
<td>Sample Collected?</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td>Date of Collection:</td>
<td>Oct/8/2020</td>
</tr>
<tr>
<td>4.</td>
<td>If no sample was collected or sample was not collected according to protocol, please provide reason:</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

#### Aliquot

Please enter barcode for each aliquot.

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5.a</td>
<td>Sample ID</td>
<td>[BPX0YX]</td>
</tr>
<tr>
<td>5.b</td>
<td>Sample ID</td>
<td>[BJ51CS]</td>
</tr>
<tr>
<td>5.c</td>
<td>Sample ID</td>
<td>[BJ51C4]</td>
</tr>
<tr>
<td>Date of Visit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Date of Visit</td>
<td>//</td>
<td></td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electronic Sample Tracking</td>
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<td></td>
</tr>
<tr>
<td>-----------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Data Origin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Sample Type</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Sample Collected?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. If no sample was collected or sample was not collected according to protocol, please provide reason:</td>
<td>[ ]</td>
<td></td>
</tr>
</tbody>
</table>

**Aliquot**

Please enter barcode for each aliquot.

<p>| 5. Sample ID | [ ] |</p>
<table>
<thead>
<tr>
<th>Date of Visit</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Visit</td>
<td>//</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
<tr>
<td><strong>Electronic Sample Tracking</strong></td>
<td></td>
</tr>
<tr>
<td>-------------------------------</td>
<td></td>
</tr>
<tr>
<td>1. Data Origin</td>
<td></td>
</tr>
<tr>
<td>2. Sample Type</td>
<td></td>
</tr>
<tr>
<td>3. Sample Collected?</td>
<td></td>
</tr>
<tr>
<td>4. If no sample was collected or sample was not collected according to protocol, please provide reason: [ ]</td>
<td></td>
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</table>

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

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

**Generated By:** (b) (4)
<table>
<thead>
<tr>
<th>Date of Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Visit //</td>
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<tr>
<td>2. Erroneous Visit</td>
</tr>
<tr>
<td>Electronic Sample Tracking</td>
</tr>
<tr>
<td>-----------------------------</td>
</tr>
<tr>
<td>1. Data Origin</td>
</tr>
<tr>
<td>2. Sample Type</td>
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<tr>
<td>3. Sample Collected?</td>
</tr>
<tr>
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<th>Aliquot</th>
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<tr>
<td>Please enter barcode for each aliquot.</td>
</tr>
<tr>
<td>5. Sample ID [ ]</td>
</tr>
<tr>
<td>Date of Visit</td>
</tr>
<tr>
<td>--------------</td>
</tr>
<tr>
<td>1. Date of Visit //</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
</tr>
</tbody>
</table>

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

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

Please enter barcode for each aliquot.

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<tr>
<td>5.</td>
<td>Sample ID [ ]</td>
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</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**

1. **Category of Clinical Event:**

2. **Was a diagnosis obtained for Potential COVID-19 Illness:**

3. **Toxicity Grade:**
<table>
<thead>
<tr>
<th>Date of Visit</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Visit</td>
<td>//</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>COVID-19 Illness Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. COVID-19 Illness Visit:</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 [ ]
<table>
<thead>
<tr>
<th>Date of Visit</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Visit</td>
<td>//</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
<tr>
<td>Unplanned Assessments</td>
<td></td>
</tr>
<tr>
<td>-----------------------</td>
<td>--</td>
</tr>
</tbody>
</table>
| 1. Assessments        | }
**Disposition - Treatment**

1. Date of Completion/Discontinuation/Death: Oct/8/2020
2. Phase of Disposition: VACCINATION
3. Status: COMPLETED
4. Specify Status: [ ]
<table>
<thead>
<tr>
<th>Disposition - Follow-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Completion/Discontinuation/Death: //</td>
</tr>
<tr>
<td>2. Phase of Disposition:</td>
</tr>
<tr>
<td>3. Status:</td>
</tr>
<tr>
<td>4. Specify Status: [ ]</td>
</tr>
<tr>
<td>Date of Visit</td>
</tr>
<tr>
<td>-----------------------</td>
</tr>
<tr>
<td>1. Date of Visit</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>COVID-19 Repeat Swab</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. COVID-19 Repeat Swab:</td>
</tr>
</tbody>
</table>

**Header Text:** C4591001
**Visit:** POT_COVID_REPEAT_SWAB - New Unscheduled Visit
**Form:** DATE OF VISIT - REPEAT SWAB

**Form Version:** 10-Oct-2020 15:57

**Site No:** 1231
**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich

**Subject No:** 12313028
**Generated By:** (b) (4)
**Generated Time (GMT):** 29-Mar-2021 20:20

**Form Status:** Not Started
**Subject Initials:** ---
**Electronic Sample Tracking**

1. Data Origin

2. Sample Type

3. Sample Collected?

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

**Aliquot**

Please enter barcode for each aliquot.

5. Sample ID
   - [ ]
**Header Text:** C4591001  
**Visit:** Unplanned Vaccination - Unscheduled  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1231  
**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich  
**Subject No:** 12313028  
**Generated By:** \(\text{(b) (4)}\)  
**Generated Time (GMT):** 29-Mar-2021 20:20

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

1. Date: //

**Vital Signs Details**

2. Record Identifier:
   - Temperature: [ ]
   - Unit:
   - Temperature Location:
<table>
<thead>
<tr>
<th><strong>Lab Urinalysis</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Lab Panel:</td>
</tr>
<tr>
<td>2. Lab Sub-Panel:</td>
</tr>
<tr>
<td>3. Collection Date: //</td>
</tr>
<tr>
<td>4. Laboratory Name and Address (Derived): []</td>
</tr>
<tr>
<td>5. Specimen Type:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Lab Result</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>6. Sponsor ID: []</td>
</tr>
<tr>
<td>Test:</td>
</tr>
<tr>
<td>Result:</td>
</tr>
<tr>
<td>Not Done:</td>
</tr>
</tbody>
</table>

---

**Header Text:** C4591001
**Visit:** Unplanned Vaccination - Unscheduled
**Form Version:** 20-Feb-2021 02:14
**Site No:** 1231
**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich
**Subject No:** 12313028
**Generated By:** (b) (4)
**Generated Time (GMT):** 29-Mar-2021 20:20

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

**Subject Initials:** ---

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FDA-CBER-2021-5683-0872744

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***Confidential***

FDA-CBER-2021-5683-0872744
<table>
<thead>
<tr>
<th>Vaccination</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Was there a temporary delay of vaccination?</td>
</tr>
<tr>
<td>2. Treatment Name</td>
</tr>
<tr>
<td>3. Formulation:</td>
</tr>
<tr>
<td>4. Dose Date Time:</td>
</tr>
<tr>
<td>5. Anatomical Location:</td>
</tr>
<tr>
<td>6. Body Side:</td>
</tr>
<tr>
<td>7. Route:</td>
</tr>
<tr>
<td>8. Actual Dose:</td>
</tr>
<tr>
<td>9. Unit:</td>
</tr>
<tr>
<td>10. Timeframe Subject Was Observed</td>
</tr>
<tr>
<td>11. Was the subject observed for at least the protocol specified observation period after investigational product administration?</td>
</tr>
<tr>
<td>Contact Outcome</td>
</tr>
<tr>
<td>-----------------</td>
</tr>
<tr>
<td>1. Contact Type:</td>
</tr>
<tr>
<td>2. Was contact made?</td>
</tr>
<tr>
<td>3. Comments:</td>
</tr>
</tbody>
</table>
### Contact Outcome

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

---

**Header Text:** C4591001  
**Visit:** Unplanned Vaccination - Unscheduled  
**Form Version:** 10-Oct-2020 16:01  
**Site No:** 1231  
**Subject No:** 12313028  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 20:20

**Form:** CONTACT OUTCOME - MONTH 6  
**Form Status:** Not Started  
**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich  
**Subject Initials:** ---

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### Date of Visit

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<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Date of Visit //</td>
</tr>
<tr>
<td>2.</td>
<td>Erroneous Visit</td>
</tr>
<tr>
<td>Informed Consent - Asymptomatic Surveillance</td>
<td></td>
</tr>
<tr>
<td>---------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>1. Consent Was:</td>
<td></td>
</tr>
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</table>
### Electronic Sample Tracking

<p>| | |</p>
<table>
<thead>
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<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>
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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>
**Electronic Sample Tracking**

1. **Data Origin**

2. **Sample Type**

3. **Sample Collected?**

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

   [ ]

**Aliquot**

Please enter barcode for each aliquot.

5. **Sample ID**

   [ ]
Date of Visit

1. Date of Visit //
2. Erroneous Visit
<table>
<thead>
<tr>
<th>Further Vaccination Confirmation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. <strong>Select appropriate response</strong> - Is participant willing to return for Vaccination 3?</td>
</tr>
<tr>
<td>#</td>
</tr>
<tr>
<td>----</td>
</tr>
<tr>
<td>1.</td>
</tr>
<tr>
<td>2.</td>
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<tr>
<td>3.</td>
</tr>
<tr>
<td>4.</td>
</tr>
<tr>
<td>5.</td>
</tr>
<tr>
<td>6.</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td><strong>1. Category:</strong></td>
</tr>
<tr>
<td><strong>2. AE ID:</strong></td>
</tr>
<tr>
<td><strong>3. Adverse Event:</strong></td>
</tr>
<tr>
<td>(If possible specify diagnosis, not individual symptoms)</td>
</tr>
<tr>
<td><strong>4. Start Date Time:</strong></td>
</tr>
<tr>
<td><strong>5. Is the adverse event still ongoing?</strong></td>
</tr>
<tr>
<td>End Date Time:</td>
</tr>
<tr>
<td><strong>6. Toxicity Grade:</strong></td>
</tr>
<tr>
<td><strong>7. Is the adverse event serious?</strong></td>
</tr>
<tr>
<td>Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).</td>
</tr>
<tr>
<td><strong>8. Is this adverse event the result of a study Medication Error?</strong></td>
</tr>
<tr>
<td>If Yes, NOTIFY PFIZER IMMEDIATELY.</td>
</tr>
<tr>
<td>If Yes, record the type of medication error on the Medication Error Log.</td>
</tr>
<tr>
<td><strong>9. Is this event related to study treatment:</strong></td>
</tr>
<tr>
<td>If Not Related to study treatment(s), this event is due to: OTHER</td>
</tr>
<tr>
<td>If Other, specify: [associated with visual aura, photophobia, photopsies, which are usually unilater]</td>
</tr>
<tr>
<td><strong>10. Latest Action Taken with Study Treatment:</strong></td>
</tr>
<tr>
<td><strong>11. Was a Concomitant Medication given?</strong></td>
</tr>
<tr>
<td><strong>12. Was a Non-Drug Treatment given?</strong></td>
</tr>
</tbody>
</table>
13. What was the outcome of this adverse event?: | RECOVERED/RESOLVED

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

15. Serious Adverse Event Number: For Pfizer Use Only: | [ ]
### Adverse Event Report

1. Category:  
   - ADVERSE EVENT

2. AE ID:  
   - [2]

3. Adverse Event:  
   - (If possible specify diagnosis, not individual symptoms)  
   - [Erythema at the injection site]

4. Start Date Time:  
   - Sep/12/2020 17:56

5. Is the adverse event still ongoing?  
   - NO  
   - End Date Time:  
     - Sep/15/2020 17:56

6. Toxicity Grade:  
   - 1

7. Is the adverse event serious?  
   - NO  
   - If Yes, NOTIFY PFIZER IMMEDIATELY.
     - Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

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

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

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

11. Was a Concomitant Medication given?  
    - NO

12. Was a Non-Drug Treatment given?  
    - NO

13. What was the outcome of this adverse event?:  
    - RECOVERED/RESOLVED
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>14.</td>
<td>Did the adverse event cause the subject to be discontinued from the study?</td>
</tr>
<tr>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>15.</td>
<td>Serious Adverse Event Number: For Pfizer Use Only</td>
</tr>
<tr>
<td>[ ]</td>
<td></td>
</tr>
</tbody>
</table>
### Adverse Event Report

1. **Category:** ADVERSE EVENT
2. **AE ID:** [3]
3. **Adverse Event:**
   (If possible specify diagnosis, not individual symptoms)
   
   [Axillary and cervical lymphadenopathy ipsilateral to the injection site]
4. **Start Date Time:** Sep/12/2020 18:01
5. **Is the adverse event still ongoing?** NO
   
   **End Date Time:**
   Sep/17/2020 18:01
6. **Toxicity Grade:** 1
7. **Is the adverse event serious?**
   
   If Yes, NOTIFY PFIZER IMMEDIATELY.
   
   Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).
   
   NO
8. **Is this adverse event the result of a study Medication Error?**
   
   If Yes, record the type of medication error on the Medication Error Log.
   
   NO
9. **Is this event related to study treatment:** RELATED
10. **Latest Action Taken with Study Treatment:** NOT APPLICABLE
11. **Was a Concomitant Medication given?** NO
12. **Was a Non-Drug Treatment given?** NO
13. **What was the outcome of this adverse event?:** RECOVERED/RESOLVED
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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<tbody>
<tr>
<td>14.</td>
<td>Did the adverse event cause the subject to be discontinued from the study?</td>
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<tr>
<td>15.</td>
<td>Serious Adverse Event Number: For Pfizer Use Only</td>
</tr>
<tr>
<td></td>
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<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td><strong>1. Category:</strong></td>
<td><strong>ADVERSE EVENT</strong></td>
</tr>
<tr>
<td><strong>2. AE ID:</strong></td>
<td>[4]</td>
</tr>
<tr>
<td><strong>3. Adverse Event:</strong></td>
<td>(If possible specify diagnosis, not individual symptoms) [Metrorrhagia]</td>
</tr>
<tr>
<td><strong>4. Start Date Time:</strong></td>
<td>Sep/13/2020 18:03</td>
</tr>
<tr>
<td><strong>5. Is the adverse event still ongoing?</strong></td>
<td>NO</td>
</tr>
<tr>
<td><strong>End Date Time:</strong></td>
<td>Sep/19/2020 18:04</td>
</tr>
<tr>
<td><strong>6. Toxicity Grade:</strong></td>
<td>1</td>
</tr>
<tr>
<td><strong>7. Is the adverse event serious?</strong></td>
<td>NO</td>
</tr>
<tr>
<td>If Yes, NOTIFY PFIZER IMMEDIATELY.</td>
<td></td>
</tr>
<tr>
<td>Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).</td>
<td></td>
</tr>
<tr>
<td><strong>8. Is this adverse event the result of a study Medication Error?</strong></td>
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</tr>
<tr>
<td>If Yes, record the type of medication error on the Medication Error Log.</td>
<td></td>
</tr>
<tr>
<td><strong>9. Is this event related to study treatment:</strong></td>
<td>NOT RELATED</td>
</tr>
<tr>
<td>If Not Related to study treatment(s), this event is due to:</td>
<td></td>
</tr>
<tr>
<td>OTHER</td>
<td></td>
</tr>
<tr>
<td>If Other, specify:</td>
<td></td>
</tr>
<tr>
<td>[unknown]</td>
<td></td>
</tr>
<tr>
<td><strong>10. Latest Action Taken with Study Treatment:</strong></td>
<td>NOT APPLICABLE</td>
</tr>
<tr>
<td><strong>11. Was a Concomitant Medication given?</strong></td>
<td>NO</td>
</tr>
<tr>
<td><strong>12. Was a Non-Drug Treatment given?</strong></td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>13.</td>
<td>What was the outcome of this adverse event?: <strong>RECOVERED/RESOLVED</strong></td>
</tr>
<tr>
<td>14.</td>
<td>Did the adverse event cause the subject to be discontinued from the study? <strong>NO</strong></td>
</tr>
<tr>
<td>15.</td>
<td>Serious Adverse Event Number: For Pfizer Use Only <strong>[ ]</strong></td>
</tr>
</tbody>
</table>
### Adverse Event Report

1. **Category:** ADVERSE EVENT
2. **AE ID:** [5]
3. **Adverse Event:**
   (If possible specify diagnosis, not individual symptoms)
   [slight increase in temperature at injection site]
4. **Start Date Time:** Sep/12/2020 17:56
5. **Is the adverse event still ongoing?** NO
   **End Date Time:** Sep/15/2020 17:56
6. **Toxicity Grade:** 1
7. **Is the adverse event serious?**
   If Yes, NOTIFY Pfizer IMMEDIATELY.
   Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).
   NO
8. **Is this adverse event the result of a study Medication Error?**
   If Yes, record the type of medication error on the Medication Error Log.
   NO
9. **Is this event related to study treatment:** RELATED
10. **Latest Action Taken with Study Treatment:** NOT APPLICABLE
11. **Was a Concomitant Medication given?**
    YES
12. **Was a Non-Drug Treatment given?**
    NO
13. **What was the outcome of this adverse event?**
    RECOVERED/RESOLVED
<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<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></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td><strong>Category:</strong></td>
<td>ADVERSE EVENT</td>
</tr>
<tr>
<td><strong>AE ID:</strong></td>
<td>[6]</td>
</tr>
<tr>
<td><strong>Adverse Event:</strong></td>
<td>[Optic Neuritis]</td>
</tr>
<tr>
<td><strong>Start Date Time:</strong></td>
<td>Dec/1/2020 21:00</td>
</tr>
<tr>
<td><strong>Is the adverse event still ongoing?</strong></td>
<td>YES</td>
</tr>
<tr>
<td><strong>Toxicity Grade:</strong></td>
<td>3</td>
</tr>
<tr>
<td><strong>Is the adverse event serious?</strong></td>
<td>YES</td>
</tr>
<tr>
<td>If Yes, NOTIFY PFIZER IMMEDIATELY.</td>
<td></td>
</tr>
<tr>
<td>Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).</td>
<td></td>
</tr>
<tr>
<td><strong>Is this serious event associated with congenital anomaly or birth defect?</strong></td>
<td>NO</td>
</tr>
<tr>
<td><strong>Did this serious event result in death?</strong></td>
<td>NO</td>
</tr>
<tr>
<td><strong>Did this serious event require or prolong hospitalization?</strong></td>
<td>YES</td>
</tr>
<tr>
<td><strong>Did this serious event result in persistent or significant disability/incapacity?</strong></td>
<td>NO</td>
</tr>
<tr>
<td><strong>Is this serious event life threatening?</strong></td>
<td>NO</td>
</tr>
<tr>
<td><strong>Other medically important serious event</strong></td>
<td>NO</td>
</tr>
<tr>
<td><strong>Is this adverse event the result of a study Medication Error?</strong></td>
<td>NO</td>
</tr>
<tr>
<td>If Yes, record the type of medication error on the Medication Error Log.</td>
<td></td>
</tr>
<tr>
<td><strong>Is this event related to study treatment:</strong></td>
<td>NOT RELATED</td>
</tr>
<tr>
<td>If Not Related to study treatment(s), this event is due to:</td>
<td></td>
</tr>
<tr>
<td>OTHER</td>
<td></td>
</tr>
<tr>
<td>If Other, specify:</td>
<td>[unknown]</td>
</tr>
<tr>
<td><strong>Latest Action Taken with Study Treatment:</strong></td>
<td>NOT APPLICABLE</td>
</tr>
<tr>
<td></td>
<td>Question</td>
</tr>
<tr>
<td>---</td>
<td>--------------------------------------------------------------------------</td>
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<tr>
<td>11</td>
<td>Was a Concomitant Medication given?</td>
</tr>
<tr>
<td>12</td>
<td>Was a Non-Drug Treatment given?</td>
</tr>
<tr>
<td>13</td>
<td>What was the outcome of this adverse event?</td>
</tr>
<tr>
<td>14</td>
<td>Did the adverse event cause the subject to be discontinued from the study?</td>
</tr>
<tr>
<td>15</td>
<td>Serious Adverse Event Number: For Pfizer Use Only</td>
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<tr>
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<td>Category</td>
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<td>---</td>
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<tr>
<td>1.</td>
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</tr>
</tbody>
</table>
**Medication Error**

1. **Category:**

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

3. **Start Date:** //

4. **Is the medication error still ongoing?**

5. **Latest Action Taken with Study Treatment:**

6. **Was a Concomitant Medication given?**

7. **Was a Non-Drug Treatment given?**

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

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

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

---

**Header Text:**
- **Visit:** Logs - Unscheduled
- **Form Version:** 22-Apr-2020 21:03
- **Site No:** 1231
- **Subject No:** 12313028
- **Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS
- **Form Status:** Not Started
- **Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich
- **Subject Initials:** ---
- **Generated Time (GMT):** 29-Mar-2021 20:20
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<th>Concomitant Medications Pre-specified</th>
<th>Name of Medication</th>
<th>Dose Description</th>
<th>Form Instance</th>
</tr>
</thead>
<tbody>
<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Repeating Pages</td>
</tr>
</tbody>
</table>
### Concomitant Medications

1. What is the medication identifier?  
   
2. Category:  
   
3. Concomitant Medications  
   Pre-specified:  
   
4. Medication:  
   Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).  
   
5. Dose:  
   
6. Dose Unit:  
   
7. Dose Frequency:  
   
8. Route:  
   
9. Start Date:  
   //  
   
10. Ongoing?
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<tr>
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<th>Category</th>
<th>Treatment Identifier</th>
<th>Con Non-Drug Treatments Pre-specified</th>
<th>Treatment</th>
<th>Start Date</th>
<th>Form Instance</th>
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</thead>
<tbody>
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<tr>
<td>2. What is the treatment Identifier?</td>
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<td>Date of Transfusion</td>
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<tr>
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<tr>
<td>1.</td>
<td>Repeating Pages</td>
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<tr>
<td>Back to Form</td>
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<td>2. Date of Transfusion:</td>
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**FDA-CBER-2021-5683-0872776**
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<tr>
<th>Date of Visit</th>
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</thead>
<tbody>
<tr>
<td>1. Date of Visit //</td>
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<tr>
<td>2. Erroneous Visit</td>
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</tbody>
</table>
1. Select appropriate response - Will the participant return for consent/eligibility assessment for the booster dose visit?
<table>
<thead>
<tr>
<th>Treatment Unblinded</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date Treatment Unblinded :</td>
</tr>
<tr>
<td>2. Primary Reason for Unblinding:</td>
</tr>
</tbody>
</table>

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

Generated Time (GMT): 29-Mar-2021 20:20
**Withdrawal Of Consent**

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

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

### Cause of Death

2. Cause of Death Status:

   Cause of Death: [ ]
**Header Text:** C4591001  
**Visit:** Subject Status - Unscheduled  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1231  
**Subject No:** 12313028  
**Generated By:** [Redacted]  
**Generated Time (GMT):** 29-Mar-2021 20:20

**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich  
**Subject Status Date:** Oct/8/2020  
**Subject Status:** FOLLOW-UP  

<table>
<thead>
<tr>
<th>Subject Status</th>
<th>Follow-Up</th>
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</thead>
<tbody>
<tr>
<td>1. Subject Status</td>
<td>FOLLOW-UP</td>
</tr>
<tr>
<td>2. Subject Status Date</td>
<td>Oct/8/2020</td>
</tr>
</tbody>
</table>

**eCRF Audit Trail History**
Audit Trail

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

<table>
<thead>
<tr>
<th>Name</th>
<th>Signature Meaning</th>
<th>Date</th>
<th>Type</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>(b) (6)</td>
<td>Approved</td>
<td>Jan-21-2021 23:54:51 (UTC-03:00) City of Buenos Aires</td>
<td>BOOK</td>
<td>Signed</td>
</tr>
</tbody>
</table>

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

- CRF_Sign

<table>
<thead>
<tr>
<th>Name</th>
<th>Signature Meaning</th>
<th>Date</th>
<th>Type</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Jan-21-2021 23:54:51 (UTC-03:00) City of Buenos Aires</td>
<td>BOOK</td>
<td>Signed</td>
</tr>
</tbody>
</table>

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

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

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

| (b) (6) | N/A | Dec-04-2020 10:24:08 (UTC-03:00) City of Buenos Aires | Edit - All signatures invalidated |

Affidavit:
N/A

| (b) (6) | Approved | Oct-23-2020 12:13:40 (UTC-03:00) City of Buenos Aires | BOOK | Signed |

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

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

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: 30 JUN 2020</td>
<td>Initial Entry</td>
</tr>
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</table>

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

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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
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### 1. Consent Was:

<table>
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<td>OBTAINED</td>
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<td></td>
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<td></td>
<td>Date Written Consent Obtained</td>
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<tr>
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<td>Aug/21/2020</td>
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### 1. Subject ID

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### 2. Birth Date:

<table>
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### 3. Sex:

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### 4. Ethnicity:

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### 5. Race: (Check X all that apply):

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**Data Entry:**
- **Inclusion Number:**
  - 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)
- **Criteria met:** YES
- **Criteria ID:** IN01A00
- **On ID:** (For Pfizer use only):

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**Data Entry:**
- 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 ID: (For Pfizer use only)**

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**1.b**

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**Criteria on Number:**
- YES

**Criteria on ID:**
- Inclusion Number: 2
- Inclusion Description: Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures

**Criteria on Meta:**
- Inclusion Number: 2
- Inclusion Description: Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures
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### 1.b Criterion Description:

Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures.

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### 1.c

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

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

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

**Generated Time (GMT):** 29-Mar-2021 20:20
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### 1.c Criterion Description:

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

### 1.c Criterion met?

Data Entry: YES

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

IN03A00

### 1.d

Data Entry: Inclusion 4 on Nu

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***Confidential***

FDA-CBER-2021-5683-0872793
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- **Value:** (b) (4), (b) (6)
- **Reason:** Initial Entry
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<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>
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**Subject No:** 12313028  
**Generated By:** (b) (4)
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Criterion Desc: Previous vaccination with any coronavirus vaccine
Criterion met?: NO
Criterion ID: (EX12A00 For Pfizer use only):
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**Criterion:** Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids

**Criterion met?:** No

**Criterion ID:** (For Pfizer use only): EX13A01

**Criterion ID:** (For Pfizer use only): EX13A01
### Exclusion Number:

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### Criterion met?

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**Criteria Description:** Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation.
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#### Exclusion Number: 17

**Criterion Description:**

Previous participation in other studies involving study intervention containing lipid nanoparticles

**Criterion met?:** NO

**Criterion ID: (For Pfizer use only)**

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#### Criterion ID: EX15A01

**Data Entry:** Initial Entry

**Exclusion Number:** 17

**Number:**

**Criterion Descripion:** Previous participation in other studies involving study intervention containing lipid nanoparticles

**Criterion met?:** NO

**Data Entry:** Initial Entry
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| Aug-22-2020 10:05:03 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Previous participation in other studies involving study intervention containing lipid nanoparticles |
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Criteri on Des criptio n: 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

Criteri on met ?: NO

Criteri on ID: EX21A01 (For Pfizer use only):
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***Confidential***
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### 1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

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

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</table>

**5. Specimen Type:**

<table>
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<tbody>
<tr>
<td>Aug-22-2020 10:07:07 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: URINE</td>
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</table>

**6.a**

<table>
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<th>Reason</th>
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<td>Aug-22-2020 10:07:07 (UTC-03:00) City of Buenos Aires</td>
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<td>auto calc (autocalc)</td>
<td>Data Entry: Sponsor-Defined 113 Identifier: Test:: Choriogonadotropin Beta_PX113</td>
<td>Initial Entry</td>
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### 6.a Sponsor ID:

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### 6.a Test:

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<td>Choriogonadotropin Beta PX113</td>
<td>Initial Entry</td>
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### 6.a Result:

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<td>(b) (4), (b) (6)</td>
<td>NEGATIVE</td>
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</table>
## 1. Randomization Date:

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<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Aug-22-2020 10:07:20</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Aug/21/2020</td>
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## 2. Randomization Number:

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<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>61543</td>
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### 1. Data Origin

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<tbody>
<tr>
<td>Aug-23-2020 17:09:06 (UTC-03:00) City of Buenos Aires</td>
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<td><strong>Data Entry:</strong> SITE</td>
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### 2. Sample Type

<table>
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### 3. Sample Collected?

<table>
<thead>
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<tbody>
<tr>
<td>Aug-23-2020 17:09:16 (UTC-03:00) City of Buenos Aires</td>
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<td>Query 1: Deleted</td>
<td>Close Auto Query</td>
</tr>
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<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Candidate</td>
<td>'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.</td>
</tr>
<tr>
<td>Aug-23-2020 17:09:06 (UTC-03:00) City of Buenos Aires</td>
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<td><strong>Data Entry:</strong> YES Date of Collection: Aug/21/2020</td>
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### 5.a

<table>
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<th>Reason</th>
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<tbody>
<tr>
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<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Sample ID: BHXWR5</td>
<td>Initial Entry</td>
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### 5.a Sample ID

<table>
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<td>Reason</td>
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<tr>
<td>Sep-02-2020 16:36:35</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
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### 5.e Sample ID

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### 5.f

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<td><strong>Data Entry:</strong> Sample ID: BJ49GZ</td>
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### 5.f Sample ID

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<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> BJ49GZ</td>
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### 1. Data Origin

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<th>Reason</th>
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<tbody>
<tr>
<td>Aug-24-2020 10:22:37 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: SITE</td>
<td>Initial Entry</td>
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### 2. Sample Type

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<td>auto calc (autocalc)</td>
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### 3. Sample Collected?

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<tbody>
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<td>Aug-25-2020 12:34:21 (UTC-03:00) City of Buenos Aires</td>
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<td>Query 1: Closed</td>
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<td>auto query (autoquery)</td>
<td>Query 1: Candidate</td>
<td>'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.</td>
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<td>Aug-24-2020 10:22:37 (UTC-03:00) City of Buenos Aires</td>
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### 5.a

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

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### 2. Treatment Name

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<td>auto calc (autocalc)</td>
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### 3. Formulation:

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### 4. Dose Date Time:

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<td>Data Entry: Aug/21/2020 20:00</td>
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### 5. Anatomical Location:

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<tbody>
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### 6. Body Side:

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### 7. Route:
10. Timeframe Subject Was Observed

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<th>User</th>
<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
<tr>
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<td>auto calc (autocalc)</td>
<td>Data Entry: INTRAMUSCULAR</td>
<td>Initial Entry</td>
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</table>

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

<table>
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<th>Date</th>
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<th>Reason</th>
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</thead>
<tbody>
<tr>
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<td>(b) (4), (b) (6)</td>
<td>[Data Entry: YES]</td>
<td>Initial Entry</td>
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</table>
1. Select appropriate response - Reactogenicity diary collection

<table>
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<tbody>
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<td>Aug-22-2020 10:07:39</td>
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<td>(b)</td>
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<td>NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT</td>
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**Form:** REACTOGENICITY DIARY - 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:** 12313028

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:20
## Date of Visit

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**Form:** DATE OF VISIT - eCRF Audit Trail History  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1231  
**Subject No:** 12313028  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 20:20  

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

C4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1231

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

Subject No: 12313028

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 20:20

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### Back to Form

1. **Date:**

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<tbody>
<tr>
<td>Sep-11-2020 16:43:36 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PF6FP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Sep/11/2020</td>
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2.a

<table>
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2.a Temperature:

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2.a Temperature Location:

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***Confidential***
<table>
<thead>
<tr>
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### 1. Lab Panel:

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### 2. Lab Sub-Panel:

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### 3. Collection Date:

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

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### 5. Specimen Type:

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### 6.a

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**6.a Sponsor ID:**

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**6.a Result:**

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Result: NEGATIVE
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### 2. Sample Type

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### 3. Sample Collected?

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<tr>
<td>Sep-11-2020 19:37:41</td>
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<td>auto query (autoquery)</td>
<td>Query 1: Deleted</td>
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<tr>
<td>Sep-11-2020 16:43:48</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Candidate</td>
</tr>
<tr>
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<td><strong>Data Entry:</strong> YES Date of Collection: Sep/11/2020</td>
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### 5.a

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<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Sample ID: BP1Y4F</td>
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### 5.a Sample ID

<table>
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***Confidential***
<table>
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**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit

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

**Site No:** 1231

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

**Subject No:** 12313028

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 20:20
### 1. Was there a temporary delay of vaccination?

<table>
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<th>Value</th>
<th>Reason</th>
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<tbody>
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### 2. Treatment Name

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### 3. Formulation:

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### 4. Dose Date Time:

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### 5. Anatomical Location:

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### 6. Body Side:

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### 10. Timeframe Subject Was Observed

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

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### 1. Date of Visit

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<td>Oct-14-2020 02:25:16 (UTC-03:00)</td>
<td>City of Buenos Aires</td>
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<td>(b) (4) (b) (6)</td>
<td>Query 1: Closed As per site confirmation - updated PD tracker</td>
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<td>Oct-13-2020 16:34:57 (UTC-03:00)</td>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4) (b) (6)</td>
<td>Query 1: Answered Original value is correct</td>
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<td>Oct-13-2020 03:51:17 (UTC-03:00)</td>
<td>City of Buenos Aires</td>
<td>ACV0PFEINFP6000.InFormAdapter.Discrepancy</td>
<td>PFE SDQ PROD (b) (4)</td>
<td>Query 1: Opened PDQ: Date of visit at V3_MONTH1_POSTVAX2_L is out of window for -1 days from V2_VAX2_L DOV or V2 Vaccination date. Please verify and update. Else, confirm in query response appropriately. (b) (4)</td>
</tr>
<tr>
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### 1. Data Origin

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### 2. Sample Type

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### 3. Sample Collected?

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### 5.a

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### 5.a Sample ID

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5.b

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5.b Sample ID

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5.c

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5.c Sample ID

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

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### 2. Phase of Disposition:

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### 3. Status:

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<td>Data Entry: ADVERSE EVENT</td>
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### 2. AE ID:

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### 3. Adverse Event:

*If possible specify diagnosis, not individual symptoms*

<table>
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<td>(b) (4), (b) (6)</td>
<td>Query 5: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 5: Answered</td>
<td>It was a single episode with bilateral presentation, which woke her up from deep sleep and was not associated with the usual symptoms of migraine.</td>
</tr>
<tr>
<td>Oct-13-2020 03:36:20 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000.InFormAdapter.Discrepancy</td>
<td>PFE SDQ PROD (b) (4)</td>
<td>Query 5: Opened</td>
<td>The AE Migraine was reported but is also listed in Medical History. Please clarify if this is a worsening of the baseline condition, and if so, please</td>
</tr>
<tr>
<td>Date/Time</td>
<td>Event Description</td>
<td></td>
<td></td>
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<tr>
<td>---------------------------</td>
<td>-----------------------------------------------------------------------------------</td>
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<td>(UTC-03:00) City of Buenos Aires</td>
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<tr>
<td>Query 3: Closed Response</td>
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<td>(UTC-03:00) City of Buenos Aires</td>
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<td>Query 4: Closed Discrepancy has been closed.</td>
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<td>Oct-12-2020 12:57:39</td>
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<td>Oct-12-2020 12:57:29</td>
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<td>(UTC-03:00) City of Buenos Aires</td>
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<td>Oct-11-2020 02:41:45</td>
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<td>(UTC-03:00) City of Buenos Aires</td>
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<tr>
<td>Query 4: Opened Special Characters: Verbatim Term contains embedded non-compliant characters.</td>
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<tr>
<td>Oct-06-2020 21:02:10</td>
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<td>(UTC-03:00) City of Buenos Aires</td>
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</table>
Subject states migraine episodes since 2003 associated to visual aura, photophobia, photopsies. All usually unilateral...

please clarify if migraine with the onset of 2003 should be added to the medical history.

Oct-06-2020
11:59:44
(UTC-03:00)
City of Buenos Aires

ACV0PFEINFP6000

(b) (4), (b) (8)

Query 3: Candidate

CLINQUERY, based on prior query response
"Subject states migraine episodes since 2003 associated to visual aura, photophobia, photopsies. All usually unilateral...

please clarify if migraine with the onset of 2003 should be added to the medical history.

Oct-05-2020
19:35:18
(UTC-03:00)
City of Buenos Aires

ACV0PFEINFP6000

Samuel Dychter
(b) (4)

Query 2: Closed

Response satisfies query

Oct-05-2020
09:12:52
(UTC-03:00)
City of Buenos Aires

ACV0PFEINFP6000

(b) (4), (b) (6)

Query 1: Closed

Response satisfies query

Oct-05-2020
08:54:44
(UTC-03:00)
City of Buenos Aires

ACV0PFEINFP6000

(b) (4), (b) (6)

Query 2: Answered

Subject states migraine episodes since 2003 associated...
### 4. Start Date Time:

<table>
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<th>Reason</th>
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<td>Initial Entry</td>
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5. Is the adverse event still ongoing?

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<th>Reason</th>
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<td>Initial Entry</td>
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<td>End Date Time: Aug/22/2020 04:00</td>
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6. Toxicity Grade:

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<td>(UTC-03:00) City of Buenos Aires</td>
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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>
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<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>
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8. Is this adverse event the result of a study Medication Error?

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

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<th>User</th>
<th>Value</th>
<th>Reason</th>
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9. Is this event related to study treatment:

<table>
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<th>User</th>
<th>Value</th>
<th>Reason</th>
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<td>Oct-05-2020 12:32:21</td>
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<td>Data Entry: NOT RELATED</td>
<td>New Information</td>
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<tr>
<td>(UTC-03:00) City of Buenos Aires</td>
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<td></td>
<td>If Not Related to study treatment(s) , this event is due to:</td>
<td></td>
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</table>
OTHER
If Other, specify:
associated with visual aura, photophobia, photopsies, which are usually unilateral

Oct-05-2020 08:54:57 (UTC-03:00) City of Buenos Aires
ACV0PFEINFP6000 (b) (4), (b) (6)
Data Entry: RELATED
New Information

Oct-01-2020 14:09:50 (UTC-03:00) City of Buenos Aires
ACV0PFEINFP6000 (b) (4), (b) (6)
Query 1: Closed
Response satisfies query

Oct-01-2020 12:49:03 (UTC-03:00) City of Buenos Aires
ACV0PFEINFP6000 auto query (autoquery)
Query 1: Answered
New Information

Oct-01-2020 12:49:03 (UTC-03:00) City of Buenos Aires
ACV0PFEINFP6000 (b) (4), (b) (6)
Data Entry: NOT RELATED
If Not Related to study treatment(s), this event is due to:
OTHER
If Other, specify:
associated with previous pathology (chronic migraine)
New Information

Oct-01-2020 10:50:05 (UTC-03:00) City of Buenos Aires
ACV0PFEINFP6000 (b) (4), (b) (6)
Query 1: Opened
DM: The response for "Is this event related to study treatment" is reported as 'Not Related', however response for, 'Please indicate what this event is due to' is missing. Kindly review and update.

Sep-30-2020 12:09:54 (UTC-03:00) City of Buenos Aires
ACV0PFEINFP6000 (b) (4), (b) (6)
Data Entry: NOT RELATED
Initial Entry

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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***Confidential***

FDA-CBER-2021-5683-0872854
### 11. Was a Concomitant Medication given?

<table>
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### 12. Was a Non-Drug Treatment given?

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

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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: RECOVERED/RESOLVED</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-30-2020 12:09:54</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
</tr>
</tbody>
</table>
### 1. Category:

<table>
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<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-13-2020 18:16:48 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: ADVERSE EVENT</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

### 2. AE ID:

<table>
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<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-13-2020 18:16:48 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: 2</td>
<td>Initial Entry</td>
</tr>
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</table>

### 3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-15-2020 21:30:50 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000.InFormAdapter.Discrepancy</td>
<td>PFETMS Oracle (b) (4)</td>
<td>Query 1: Closed</td>
<td>Discrepancy has been closed.</td>
</tr>
<tr>
<td>Oct-15-2020 15:22:19 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Answered</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Oct-14-2020 11:09:08 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000.InFormAdapter.Discrepancy</td>
<td>PFETMS Oracle (b) (4)</td>
<td>Query 1: Opened</td>
<td>Multiple actions for ERYTHEMA WITH A SLIGHT RISE IN TEMPERATURE AT THE INJECTION SITE. Are you reporting ERYTHEMA WITH A SLIGHT WARMTH AT THE INJECTION SITE? If so, update the</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>Oct-13-2020 18:16:48 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4) (6)</td>
<td>Data Entry: Sep/12/2020 17:56</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>Oct-13-2020 18:16:48 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4) (6)</td>
<td>Data Entry: NO</td>
<td>Initial Entry</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>Oct-13-2020 18:16:48 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4) (6)</td>
<td>Data Entry: 1</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

Verbatim term as such and split into erythema at the injection site and slight warmth at the injection site and submit separately. Otherwise clarify the part rise in temperature in the context and edit the verbatim accordingly. Thank you.
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>Oct-13-2020 18:16:48 (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>

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>Oct-13-2020 18:16:48 (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>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-13-2020 18:16:48 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</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>Oct-13-2020 18:16:48 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NOT APPLICABLE</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

11. Was a Concomitant Medication given?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-13-2020 18:16:48 (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>
<tr>
<td>Date</td>
<td>Location</td>
<td>User</td>
<td>Value</td>
<td>Reason</td>
</tr>
<tr>
<td>-----------------------</td>
<td>---------------------------------</td>
<td>-------------</td>
<td>---------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>Oct-13-2020 18:16:48</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td>Initial Entry</td>
</tr>
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</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>Oct-13-2020 18:16:48</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: RECOVERED/RESOLVED</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></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>Oct-13-2020 18:16:48</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>
1. Category:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-13-2020 19:23:23 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: ADVERSE EVENT</td>
<td>Initial Entry</td>
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</tbody>
</table>

2. AE ID:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-13-2020 19:23:23 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: 3</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-13-2020 19:23:23 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Axillary and cervical lymphadenopathy ipsilateral to the injection site</td>
<td>Initial Entry</td>
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</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>Oct-13-2020 19:23:23 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Sep/12/2020 18:01</td>
<td>Initial Entry</td>
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</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>Oct-13-2020 19:23:23 (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>

6. Toxicity Grade:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
</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>Oct-13-2020 19:23:23 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (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>
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<tbody>
<tr>
<td>Oct-13-2020 19:23:23 (UTC-03:00) City of Buenos Aires</td>
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<td>(b) (4), (6)</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
</tr>
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</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-13-2020 19:23:23 (UTC-03:00) City of Buenos Aires</td>
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<td>(b) (4), (6)</td>
<td>Data Entry: RELATED</td>
<td>Initial Entry</td>
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### 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>Oct-13-2020 19:23:23 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
<td>Data Entry: NOT APPLICABLE</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

### 11. Was a Concomitant Medication given?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<td></td>
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</table>
12. Was a Non-Drug Treatment given?

<table>
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<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Oct-13-2020 19:23:23</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
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</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>Oct-13-2020 19:23:23</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: RECOVERED/RESOLVED</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-13-2020 19:23:23</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
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</table>
1. **Category:**

<table>
<thead>
<tr>
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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-13-2020 19:36:34 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> ADVERSE EVENT</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

2. **AE ID:**

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-13-2020 19:36:34 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>4</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

3. **Adverse Event:**

(If possible specify diagnosis, not individual symptoms)

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-13-2020 19:36:34 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Metrorrhagia</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>Oct-13-2020 19:36:34 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Sep/13/2020 18:03</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>Oct-13-2020 19:36:34 (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>

End Date Time:

Sep/19/2020 18:04

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>Oct-13-2020 19:36:34 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 7. Is the adverse event serious?

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

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</thead>
<tbody>
<tr>
<td>Oct-13-2020 19:36:34 (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>

### 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>
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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Oct-13-2020 19:36:34 (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>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-19-2020 02:57:49 (UTC-03:00) City of Buenos Aires</td>
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<td>Query 1: Closed</td>
<td>Response satisfies query</td>
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<tr>
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<td>(b) (4), (b) (6)</td>
<td>Query 1: Answered</td>
<td>Original value is correct</td>
</tr>
<tr>
<td>Oct-15-2020 09:23:15 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Reissued:Opened</td>
<td>DM1: Please consider to elaborate the response to 'If Other, specify' with any details available. Thanks</td>
</tr>
<tr>
<td>Oct-14-2020 19:24:04 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Answered</td>
<td>New Information</td>
</tr>
<tr>
<td>Date Time</td>
<td>Location</td>
<td>User</td>
<td>Value</td>
<td>Reason</td>
</tr>
<tr>
<td>--------------</td>
<td>---------------------------</td>
<td>--------</td>
<td>-------------</td>
<td>-------------------------------</td>
</tr>
<tr>
<td>Oct-14-2020 19:24:04 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: unknown</td>
<td></td>
</tr>
<tr>
<td>Oct-14-2020 08:22:13 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Opened</td>
<td></td>
</tr>
<tr>
<td>Oct-13-2020 19:36:34 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NOT RELATED</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date Time</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-13-2020 19:36:34 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NOT APPLICABLE</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

### 11. Was a Concomitant Medication given?

<table>
<thead>
<tr>
<th>Date Time</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-13-2020 19:36:34 (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>

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

<table>
<thead>
<tr>
<th>Date Time</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-13-2020 19:36:34 (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>
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>Oct-13-2020 19:36:34 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: RECOVERED/RESOLVED</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-15-2020 04:21:43 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Oct-14-2020 17:25:39 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Answered</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>Oct-14-2020 17:25:39 (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>
<tr>
<td>Oct-14-2020 08:22:42 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Opened</td>
<td>DM: The response for Data item#14 are missing. Kindly review and update.</td>
</tr>
</tbody>
</table>
### 1. Category:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-16-2020 17:17:01 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: ADVERSE EVENT</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

### 2. AE ID:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-16-2020 17:17:01 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: 5</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-16-2020 17:17:01 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: slight increase in temperature at injection site</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>Oct-16-2020 17:17:01 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Sep/12/2020 17:56</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>Oct-16-2020 17:17:01 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO End Date Time: Sep/15/2020 17:56</td>
<td>Initial Entry</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>
</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>Oct-16-2020 17:17:01 (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>

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>Oct-16-2020 17:17:01 (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>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-16-2020 17:17:01 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</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>Oct-16-2020 17:17:01 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NOT APPLICABLE</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

11. Was a Concomitant Medication given?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
</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>Oct-16-2020 17:17:01 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
<td>Data Entry: YES</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>Oct-16-2020 17:17:01 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
<td>Data Entry: RECOVERED/RESOLVED</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-16-2020 17:17:01 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>
### 1. Category:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec-04-2020 10:24:08 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: ADVERSE EVENT</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

### 2. AE ID:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec-04-2020 10:24:08 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: 6</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-03-2021 00:11:45 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 3: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Jan-23-2021 10:27:29 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 3: Answered</td>
<td>Test results are not yet available. When the volunteer sends them, an SAE security update will be sent. Thank you.</td>
</tr>
<tr>
<td>Jan-21-2021 10:48:15 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 3: Opened</td>
<td>CLINICAL Please submit results of visual evoked potential testing for optic neuritis, if performed, as a SAE safety update</td>
</tr>
<tr>
<td>Dec-10-2020 14:04:40 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Dec-10-2020 13:56:18 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Dec-09-2020 16:52:18 (UTC-03:00) City of</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Answered</td>
<td>On 12/08/2020, a serious adverse event</td>
</tr>
</tbody>
</table>
**Header Text:** C4591001  
**Visit:** Logs - Unscheduled  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1231  
**Subject No:** 12313028  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 20:20

<table>
<thead>
<tr>
<th>Date/Time</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec-09-2020 16:52:07 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Answered</td>
<td>monitoring form is sent with the evolution of the event and the pertinent clarifications. Thanks.</td>
</tr>
<tr>
<td>Dec-07-2020 17:20:46 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Opened</td>
<td>On 12/08/2020, a serious adverse event monitoring form is sent with the evolution of the event and the pertinent clarifications. Thanks.</td>
</tr>
<tr>
<td>Dec-07-2020 17:19:49 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Opened</td>
<td>CLINICAL Please submit results of visual evoked potential testing for optic neuritis, if performed, as a SAE safety update.</td>
</tr>
<tr>
<td>Dec-04-2020 10:24:08 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Optic Neuritis</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

4. **Start Date Time:**

<table>
<thead>
<tr>
<th>Date/Time</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec-04-2020 10:24:08 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Dec/1/2020 21:00</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date/Time</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec-04-2020 10:24:08 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: YES</td>
<td>Initial Entry</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>Dec-04-2020 10:24:08</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: 3</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>Dec-20-2020 20:40:29</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 3: Closed</td>
</tr>
<tr>
<td>Dec-18-2020 17:20:19</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 3: Answered</td>
</tr>
<tr>
<td>Dec-18-2020 00:11:30</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 3: Reissued:Opened</td>
</tr>
<tr>
<td>Dec-13-2020 18:53:04</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 3: Answered</td>
</tr>
<tr>
<td>Dec-10-2020 14:07:23</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Closed</td>
</tr>
<tr>
<td>Dec-10-2020 14:03:16</td>
<td>(UTC-03:00) City of</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 3: Reissued:Opened</td>
</tr>
</tbody>
</table>

Dec-18-2020 20:40:29
(UTC-03:00) City of Buenos Aires
ACV0PFEINFP6000
(b) (4), (b) (6)
Query 3: Closed
Response satisfies query

Dec-18-2020 17:20:19
(UTC-03:00) City of Buenos Aires
ACV0PFEINFP6000
(b) (4), (b) (6)
Query 3: Answered
In the FU that was sent on DEC 16, all studies were added. Thank you

Dec-18-2020 00:11:30
(UTC-03:00) City of Buenos Aires
ACV0PFEINFP6000
(b) (4), (b) (6)
Query 3: Reissued:Opened
CLINICAL Thank you. Please submit a SAE safety followup with these 3 studies in the lab section, results pending.

Dec-13-2020 18:53:04
(UTC-03:00) City of Buenos Aires
ACV0PFEINFP6000
(b) (4), (b) (6)
Query 3: Answered
Tests performed (dates unknown): -Anti MOG antibody -Antibodies to aquaporin-4 (AQP4-Ab) -Oligoclonal bands on cerebrospinal fluid The volunteer not provided yet the results and the epicrisis. We are awaiting for the patient to provide information.

Dec-10-2020 14:07:23
(UTC-03:00) City of Buenos Aires
ACV0PFEINFP6000
(b) (4), (b) (6)
Query 2: Closed
Response satisfies query

Dec-10-2020 14:03:16
(UTC-03:00) City of
ACV0PFEINFP6000
(b) (4), (b) (6)
Query 3: Reissued:Opened
CLINICAL Thank you; 'Immunology test'
Buenos Aires | ACV0PFEINFP6000 | Query 3: Answered
---|---|---
Dec-09-2020 16:54:50 (UTC-03:00) City of Buenos Aires | | There is no etiology of hypothyroidism (2015). Immunological analysis was performed (negative result, type of antibodies and date unknown). The patient reported that immunological studies have not been done subsequently.

Dec-09-2020 16:53:02 (UTC-03:00) City of Buenos Aires | | Query 2: Answered
Dec-07-2020 17:05:41 (UTC-03:00) City of Buenos Aires | | Query 3: Opened
Dec-07-2020 16:53:00 (UTC-03:00) City of Buenos Aires | | Query 2: Opened

negative is noted in the SAE; does this refer to an immunology test evaluating a cause of Hyperthyroidism, or a cause of Optic Neuritis?

On 12/08/2020, a serious adverse event monitoring form is sent with the evolution of the event and the pertinent clarifications. Thanks.

Clinical SAE reports med Hx of hypothyroidism from 2015 (age 25); please update SAE with etiology for this condition; including any immunology test results (including Neg) for possible autoimmune causes

Clinical COVID test status (yes/no) during Hosp was not reported in the SAE. Please submit a follow-up SAE form [#2020480885] to document if COVID testing was performed (YES/NO or info not
<table>
<thead>
<tr>
<th>Date/Time</th>
<th>Action</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec-07-2020 07:07:37 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
</tr>
<tr>
<td>Dec-04-2020 10:24:08 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
</tr>
<tr>
<td>Dec-04-2020 10:24:08 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

8. Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.
<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec-04-2020 10:24:08</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
</tr>
</tbody>
</table>

9. Is this event related to study treatment:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec-04-2020 10:24:08</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NOT RELATED</td>
</tr>
</tbody>
</table>

   - If Not Related to study treatment(s), this event is due to:
     - OTHER
     - If Other, specify:
       - unknown

10. Latest Action Taken with Study Treatment:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec-04-2020 10:24:08</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NOT APPLICABLE</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>Dec-04-2020 10:24:08</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: YES</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>Dec-04-2020 10:24:08</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</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>Dec-04-2020 10:24:08</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: RECOVERING/RESOLVING</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>Dec-04-2020 10:24:08 (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>

15. Serious Adverse Event Number: For Pfizer Use Only

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec-07-2020 07:07:37 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> 2020480885</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>Oct-12-2020 14:25:50</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: FOLLOW-UP</td>
</tr>
<tr>
<td>Aug-22-2020 10:07:20</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: ENROLLED/RANDOMIZED</td>
</tr>
<tr>
<td>Aug-22-2020 10:05:11</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: SCREENED</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>Oct-12-2020 14:25:50</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: Oct/8/2020</td>
</tr>
<tr>
<td>Aug-22-2020 10:07:20</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: Aug/21/2020</td>
</tr>
<tr>
<td>Aug-22-2020 10:05:11</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: Aug/21/2020</td>
</tr>
</tbody>
</table>
### 1. Casebook Signature

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-23-2020 12:13:27 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Click Here to Enable</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History  
**Form Version:** 22-Apr-2020 21:04  
**Form Status:** Data Complete, Signed, Verified  
**Site No:** 1231  
**Site Name:** (1231) Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich  
**Subject No:** 12313028  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 20:20  
**Generated Time (GMT):** 01-Apr-2021 03:29