## Cohort Selection

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

1. Select appropriate response  
   - Protocol version  
     30 JUN 2020

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

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

<table>
<thead>
<tr>
<th>Demography</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Subject ID</td>
</tr>
<tr>
<td>[12411410]</td>
</tr>
<tr>
<td>2. Birth Date:</td>
</tr>
<tr>
<td>(b) (6) 1975</td>
</tr>
<tr>
<td>3. Sex:</td>
</tr>
<tr>
<td>FEMALE</td>
</tr>
<tr>
<td>4. Ethnicity:</td>
</tr>
<tr>
<td>NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN</td>
</tr>
<tr>
<td>5. Race: (Check X all that apply):</td>
</tr>
<tr>
<td>BLACK OR AFRICAN AMERICAN</td>
</tr>
<tr>
<td>AMERICAN INDIAN OR ALASKA NATIVE</td>
</tr>
<tr>
<td>6. Racial Designation:</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
**Header Text**: c4591001  
**Visit**: V1_DAY1_VAX1_L  
**Form**: DATE OF VISIT  
**Form Version**: 22-Apr-2020 21:02  
**Form Status**: Data Complete, Locked, Frozen, Verified  
**Site No**: 1241  
**Site Name**: (1241) Hospital Irma Dulce  
**Subject No**: 12411410  
**Subject Initials**:  
**Generated By**: (b) (4)  
**Generated Time (GMT)**: 29-Mar-2021 19:09

**eCRF Audit Trail History**

**Date of Visit**

<table>
<thead>
<tr>
<th></th>
<th>Date of Visit</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Date of Visit</td>
<td>Aug/24/2020</td>
</tr>
<tr>
<td>2</td>
<td>Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>
### 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>
</tbody>
</table>
### Inclusion Criteria

<table>
<thead>
<tr>
<th>Inclusion Number:</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criterion Description:</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>
</tr>
<tr>
<td>Criterion met?</td>
<td>YES</td>
</tr>
<tr>
<td>Criterion ID: (For Pfizer use only)</td>
<td>IN04A00</td>
</tr>
</tbody>
</table>

### Exclusion Criteria

#### 2.a

<table>
<thead>
<tr>
<th>Exclusion Number:</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criterion Description:</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>
</tr>
<tr>
<td>Criterion met?</td>
<td>NO</td>
</tr>
<tr>
<td>Criterion ID: (For Pfizer use only)</td>
<td>EX01A00</td>
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</tbody>
</table>

#### 2.b

<table>
<thead>
<tr>
<th>Exclusion Number:</th>
<th>2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criterion Description:</td>
<td>Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)</td>
</tr>
<tr>
<td>Criterion met?</td>
<td>NO</td>
</tr>
<tr>
<td>Criterion ID: (For Pfizer use only)</td>
<td>EX02A00</td>
</tr>
<tr>
<td>2.c</td>
<td>Exclusion Number:</td>
</tr>
<tr>
<td>-----</td>
<td>------------------</td>
</tr>
<tr>
<td>Criterion Description:</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>
</tr>
<tr>
<td>Criterion met?</td>
<td>NO</td>
</tr>
<tr>
<td>Criterion ID: (For Pfizer use only)</td>
<td>EX03A00</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2.d</th>
<th>Exclusion Number:</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criterion Description:</td>
<td>Receipt of medications intended to prevent COVID-19</td>
<td></td>
</tr>
<tr>
<td>Criterion met?</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>Criterion ID: (For Pfizer use only)</td>
<td>EX04A00</td>
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<table>
<thead>
<tr>
<th>2.e</th>
<th>Exclusion Number:</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criterion Description:</td>
<td>Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination</td>
<td></td>
</tr>
<tr>
<td>Criterion met?</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>Criterion ID: (For Pfizer use only)</td>
<td>EX08A00</td>
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<tr>
<td>2.f</td>
<td>Exclusion Number:</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Criterion Description:</td>
<td>Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection</td>
</tr>
<tr>
<td></td>
<td>Criterion met?</td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td>Criterion ID: (For Pfizer use only)</td>
<td>EX10A00</td>
</tr>
</tbody>
</table>

| 2.g | Exclusion Number: | 11 |
|     | Criterion Description: | Women who are pregnant or breastfeeding |
|     | Criterion met? | NO |
|     | Criterion ID: (For Pfizer use only) | EX11A00 |

| 2.h | Exclusion Number: | 12 |
|     | Criterion Description: | Previous vaccination with any coronavirus vaccine |
|     | Criterion met? | NO |
|     | Criterion ID: (For Pfizer use only) | EX12A00 |

<p>| 2.i | Exclusion Number: | 13 |
|     | Criterion Description: | Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids |
|     | Criterion met? | NO |
|     | Criterion ID: (For Pfizer use only) | EX13A01 |</p>
<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.j 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>2.k 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>2.l 17</td>
<td>Previous participation in other studies involving study intervention containing lipid nanoparticles</td>
<td>NO</td>
<td>EX16A01</td>
</tr>
<tr>
<td>Exclusion Number:</td>
<td>22</td>
<td></td>
<td></td>
</tr>
<tr>
<td>------------------</td>
<td>----</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Criterion Description:</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></td>
<td></td>
</tr>
<tr>
<td>Criterion met?:</td>
<td>NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Criterion ID: (For Pfizer use only)</td>
<td>EX21A01</td>
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<tr>
<td>eCRF Audit Trail History</td>
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<tr>
<td>--------------------------</td>
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<td></td>
</tr>
<tr>
<td><strong>Disposition - Screening</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Date of Completion/Discontinuation/Death</td>
<td>Aug/24/2020</td>
<td></td>
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<tr>
<td>2. Phase of Disposition:</td>
<td>SCREENING</td>
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<td></td>
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<tr>
<td>3. Status:</td>
<td>COMPLETED</td>
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<tr>
<td>4. Specify Status:</td>
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### eCRF Audit Trail History

#### Medical History Details

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<th>Line/MH Number:</th>
<th>[1]</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:</td>
<td>[Shellfish allergy]</td>
</tr>
<tr>
<td></td>
<td>Start Date:</td>
<td>UNK/UNK/2013</td>
</tr>
<tr>
<td></td>
<td>Ongoing:</td>
<td>YES</td>
</tr>
</tbody>
</table>
**Vital Signs**

1. **Date:** Aug/24/2020
2. **Weight:** [73.3]
3. **Unit:** kg
4. **Height:** [155.0]
5. **Unit:** cm
6. **Body Mass Index:** [30.5]

**Vital Signs Details**

<table>
<thead>
<tr>
<th>7.a</th>
<th>Record Identifier:</th>
<th>1</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Temperature:</td>
<td>[37.0]</td>
</tr>
<tr>
<td></td>
<td>Unit:</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td>Temperature Location:</td>
<td>ORAL CAVITY</td>
</tr>
</tbody>
</table>
**eCRF Audit Trail History**

<table>
<thead>
<tr>
<th>Lab Urinalysis</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>Lab Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.a 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:** V1_DAY1_VAX1_L

**Form:** RANDOMIZATION

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411410

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

## eCRF Audit Trail History

### Disposition

<table>
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<tr>
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<th>Randomization Date</th>
<th>Aug/24/2020</th>
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<tbody>
<tr>
<td>2.</td>
<td>Randomization Number</td>
<td>[63197]</td>
</tr>
<tr>
<td>3.</td>
<td>Randomization Group</td>
<td>[ ]</td>
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</tbody>
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**FDA-CBER-2021-5683-0994535**
## eCRF Audit Trail History

### Electronic Sample Tracking

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

### Aliquot

Please enter barcode for each aliquot.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5.a</td>
<td>Sample ID</td>
</tr>
<tr>
<td>5.b</td>
<td>Sample ID</td>
</tr>
<tr>
<td>5.c</td>
<td>Sample ID</td>
</tr>
<tr>
<td>5.d</td>
<td>Sample ID</td>
</tr>
<tr>
<td>5.e</td>
<td>Sample ID</td>
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</table>
### Electronic Sample Tracking

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

### Aliquot

Please enter barcode for each aliquot.

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>5.a</td>
<td>Sample ID</td>
<td>[BP5T7L]</td>
</tr>
<tr>
<td>6.b</td>
<td>Sample ID</td>
<td>[BLCH0P]</td>
</tr>
</tbody>
</table>
### Vaccination

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

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

<table>
<thead>
<tr>
<th>Date of Visit</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Visit</td>
<td>Sep/14/2020</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>
## Vital Signs Audit Trail History

### Vital Signs

<table>
<thead>
<tr>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep/14/2020</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Vital Signs Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Record Identifier:</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>Temperature: [36.1]</td>
</tr>
<tr>
<td>Unit: C</td>
</tr>
<tr>
<td>Temperature Location: ORAL CAVITY</td>
</tr>
</tbody>
</table>

---

***Confidential***
### eCRF Audit Trail History

**Lab Urinalysis**

1. Lab Panel: UＲINALYSIＳ  
2. Lab Sub-Panel: PREGNANCY  
3. Collection Date: Sep/14/2020  
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:
**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

#### Vaccination

1. **Was there a temporary delay of vaccination?**
   - NO
2. **Treatment Name**
   - [BLINDED THERAPY]
3. **Formulation:**
   - INJECTION
4. **Dose Date Time:**
   - Sep/14/2020 10:21
5. **Anatomical Location:**
   - DELTOID MUSCLE
6. **Body Side:**
   - LEFT
7. **Route:**
   - INTRAMUSCULAR
8. **Actual Dose:**
   - [ ]
9. **Unit:**
10. **Timeframe Subject Was Observed**
    - THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11. **Was the subject observed for at least the protocol specified observation period after investigational product administration?**
    - YES
**Header Text:** c4591001  
**Visit:** V3_MONTH1_POSTVAX2_L  
**Form:** DATE OF VISIT  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1241  
**Site Name:** (1241) Hospital Irma Dulce  
**Subject No:** 12411410  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 19:09

### eCRF Audit Trail History

#### Date of Visit

<table>
<thead>
<tr>
<th></th>
<th>Date of Visit</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Date of Visit</td>
<td>Oct/14/2020</td>
</tr>
<tr>
<td>2.</td>
<td>Erroneous Visit</td>
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</tbody>
</table>
### eCRF Audit Trail History

Electronic Sample Tracking

<p>| | | |</p>
<table>
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<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>1.</td>
<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>
<td>YES</td>
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<tr>
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<td>Date of Collection:</td>
<td>Oct/14/2020</td>
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<tr>
<td>4.</td>
<td>If no sample was collected or sample was not collected according to protocol, please provide reason:</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

Aliquot

Please enter barcode for each aliquot.

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>5.a</td>
<td>Sample ID</td>
<td>[BRD40C]</td>
</tr>
<tr>
<td>5.b</td>
<td>Sample ID</td>
<td>[BRXGTM]</td>
</tr>
<tr>
<td>5.c</td>
<td>Sample ID</td>
<td>[BRXGTN]</td>
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<td>Jan/13/2021</td>
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<tr>
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</tr>
<tr>
<td></td>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
<tr>
<td>COVID-19 Illness Visit</td>
<td>3. COVID-19 Illness Visit:</td>
<td>COVID_A</td>
</tr>
</tbody>
</table>

**eCRF Audit Trail History**

**Date of Visit**

1. Date of Visit: Jan/13/2021
2. Erroneous Visit
3. COVID-19 Illness Visit: COVID_A
**Signs and Symptoms**

1. **Date of Assessment:** Jan/13/2021

2. **Date of First Symptom Started:** Jan/8/2021

3. **Symptoms Ongoing?** NO  
   **Date of Last Symptom Resolved:** Jan/18/2021

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Was symptom present?</th>
</tr>
</thead>
<tbody>
<tr>
<td>FEVER</td>
<td>NO</td>
</tr>
<tr>
<td>NEW OR INCREASED COUGH</td>
<td>NO</td>
</tr>
<tr>
<td>NEW OR INCREASED SHORTNESS OF BREATH</td>
<td>NO</td>
</tr>
<tr>
<td>CHILLS</td>
<td>NO</td>
</tr>
<tr>
<td>NEW OR INCREASED MUSCLE PAIN</td>
<td>NO</td>
</tr>
</tbody>
</table>
### 4.f Symptoms
- **Symptoms:** NEW LOSS OF TASTE OR SMELL
- **Was symptom present?** NO

### 4.g Symptoms
- **Symptoms:** NEW OR INCREASED SORE THROAT
- **Was symptom present?** YES

### 4.h Symptoms
- **Symptoms:** DIARRHEA
- **Was symptom present?** NO

### 4.i Symptoms
- **Symptoms:** VOMITING
- **Was symptom present?** NO

### Symptoms - Other
- **Symptoms - Other Text:** [Runny nose]
<table>
<thead>
<tr>
<th>#</th>
<th>Date of Collection</th>
<th>Specimen Type</th>
<th>Specimen Collection Location</th>
<th>Assay Code and Description</th>
<th>Device Type</th>
<th>Form Instance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Jan/14/2021</td>
<td>SWABBED MATERIAL</td>
<td>NASOPHARYNX</td>
<td>SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2</td>
<td>SARS-COV-2 DIAGNOSTIC TEST</td>
<td>Repeating Pages</td>
</tr>
</tbody>
</table>
**Microbiology Specimen**

1. **Actual Date of Collection:** Jan/14/2021
2. **Specimen Type:** SWABBED MATERIAL
3. **Specimen Collection Location:** NASOPHARYNX
4. **Assay Code and Description:** SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5. **Device Type:** SARS-COV-2 DIAGNOSTIC TEST
6. **Trade Name:** ABBOTT MOLECULAR REALTIME SARS-COV-2 ASSAY
7. **Test Result:** POSITIVE
8. **Comments/Findings/Details:** []
9. **Trade Name Other, Specify:** []
**Header Text:** c4591001  
**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1241  
**Subject No:** 12411410  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 19:09

**eCRF Audit Trail History**

**Electronic Sample Tracking**

<p>| | |</p>
<table>
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<tr>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>1.</td>
<td>Data Origin</td>
</tr>
<tr>
<td>2.</td>
<td>Sample Type</td>
</tr>
</tbody>
</table>
| 3. | Sample Collected? | YES  
Date of Collection: Jan/13/2021 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

**Aliquot**

Please enter barcode for each aliquot.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5.a</td>
<td>Sample ID</td>
</tr>
</tbody>
</table>
**Header Text:** c4591001

**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

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

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

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411410

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

---

**eCRF Audit Trail History**

---

**Electronic Sample Tracking**

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

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**Aliquot**

Please enter barcode for each aliquot.

<p>| | |</p>
<table>
<thead>
<tr>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5.</td>
<td>Sample ID</td>
</tr>
<tr>
<td></td>
<td>Physician or Healthcare Professional:</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>1.a</td>
<td>SPECIALIST</td>
</tr>
<tr>
<td>1.b</td>
<td>EMERGENCY ROOM</td>
</tr>
<tr>
<td>1.c</td>
<td>PRIMARY CARE PHYSICIAN</td>
</tr>
<tr>
<td>1.d</td>
<td>URGENT CARE</td>
</tr>
<tr>
<td>1.e</td>
<td>TELEPHONE CONSULTATION</td>
</tr>
<tr>
<td>1.f</td>
<td>Physician or Healthcare Professional:</td>
</tr>
<tr>
<td>-----</td>
<td>-------------------------------------</td>
</tr>
<tr>
<td></td>
<td>Occurrence of Visits or Contacts:</td>
</tr>
</tbody>
</table>

### Health Care Utilization Other

2. Other Type of Practitioner Specify: [ ]

### Health Care Utilization

3. Has the subject been hospitalized due to potential COVID-19 illness? | NO |
<table>
<thead>
<tr>
<th>#</th>
<th>Treatment Identifier</th>
<th>Con Non-Drug Treatments Pre-specified</th>
<th>Treatment</th>
<th>Treatment Start Date</th>
<th>Form Instance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Repeating Pages</td>
</tr>
</tbody>
</table>
Respiratory Treatment

1. What is the treatment Identifier? [ ]
2. Concomitant Non-drug Treatment Pre-specified:
3. Treatment:
4. Treatment: [ ]
5. Start Date: //
6. Ongoing?
**eCRF Audit Trail History**

### Illness Details

<table>
<thead>
<tr>
<th></th>
<th>Category of Clinical Event:</th>
<th>POTENTIAL COVID-19 ILLNESS</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.</td>
<td>Was a diagnosis obtained for Potential COVID-19 Illness?</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td>Respiratory Illness Diagnosis:</td>
<td>[Covid-19]</td>
</tr>
<tr>
<td></td>
<td>Date of Diagnosis:</td>
<td>Jan/14/2021</td>
</tr>
<tr>
<td>3.</td>
<td>Toxicity Grade:</td>
<td>1</td>
</tr>
<tr>
<td>#</td>
<td>Category of Clinical Event</td>
<td>Subcategory of Clinical Event</td>
</tr>
<tr>
<td>---</td>
<td>---------------------------</td>
<td>-------------------------------</td>
</tr>
<tr>
<td>1.</td>
<td></td>
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</tr>
</tbody>
</table>

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**Header Text:** c4591001
Visit: POT_COVID_ILL 1
Form: ILLNESS DETAILS - SEVERE
Form Version: 17-Jul-2020 21:55
Site No: 1241
Site Name: (1241) Hospital Irma Dulce
Subject No: 12411410
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 19:09
## Illness Details

1. **Category of Clinical Event:**

2. **Subcategory of Clinical Event:**

3. **Was a diagnosis obtained?**

4. **Toxicity Grade:**
<table>
<thead>
<tr>
<th>#</th>
<th>Category for Lab Test</th>
<th>Vendor Name</th>
<th>Collection Date</th>
<th>Specimen Type</th>
<th>Lab Result</th>
<th>Form Instance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Sponsor-Defined Identifier Test: Result:</td>
<td>Repeating Pages</td>
</tr>
</tbody>
</table>

---

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### Lab Chemistry Details

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

### Lab Result

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>5.</td>
<td>Sponsor ID: [ ]</td>
</tr>
<tr>
<td></td>
<td>Test:</td>
</tr>
<tr>
<td></td>
<td>Result: [ ]</td>
</tr>
<tr>
<td></td>
<td>Not Done:</td>
</tr>
<tr>
<td></td>
<td>LNMT Low [ ]</td>
</tr>
<tr>
<td></td>
<td>High [ ]</td>
</tr>
<tr>
<td></td>
<td>Unit [ ]</td>
</tr>
<tr>
<td>#</td>
<td>Category for Lab Test</td>
</tr>
<tr>
<td>----</td>
<td>----------------------</td>
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</table>
**Laboratory Data Hematology**

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<td>Laboratory Name and Address</td>
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<td>Collection Date:</td>
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<td>//</td>
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<td>4.</td>
<td>Specimen Type:</td>
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**Lab Result**

<p>| | |</p>
<table>
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<tbody>
<tr>
<td>5.</td>
<td>Sponsor ID:</td>
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<td>[ ]</td>
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<tr>
<td></td>
<td>Test:</td>
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<td>Result:</td>
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<td>[ ]</td>
</tr>
<tr>
<td></td>
<td>Not Done:</td>
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<tr>
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<td></td>
</tr>
<tr>
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<td>LNMT</td>
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<td></td>
<td>Unit</td>
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<tr>
<td></td>
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</tr>
<tr>
<td>#</td>
<td>Date:</td>
</tr>
<tr>
<td>---</td>
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<tr>
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<td></td>
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</tbody>
</table>
**Vital Signs**

1. **Date:** //

**Vital Signs Details**

2. **Record Identifier:**

   **Systolic:** [ ]

   **Diastolic:** [ ]

   **Respiratory Rate in respirations/minute:** [ ]

   **Heart Rate in beats/minute:** [ ]
<table>
<thead>
<tr>
<th>#</th>
<th>Date:</th>
<th>Vital Signs Details</th>
<th>Form Instance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td>Record Identifier: Oxygen Saturation</td>
<td>Repeating Pages</td>
</tr>
</tbody>
</table>
### Vital Signs

1. **Date:** //

### Vital Signs Details

2. **Record Identifier:**
   - **SPO2 Pulse Oximetry %:** [ ]

---

**Header Text:** c4591001

**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

**Form:** VITAL SIGNS - PULSE OX ROOM AIR

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1241

**Subject No:** 12411410

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

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

---

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FDA-CBER-2021-5683-0994568
<table>
<thead>
<tr>
<th>#</th>
<th>Date Time of Assessment</th>
<th>Arterial Blood Gases PaO2</th>
<th>FiO2 (Fraction of Inhaled Oxygen)</th>
<th>Form Instance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td></td>
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<td>Repeating Pages</td>
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</tbody>
</table>
### Oxygenation Parameters

<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>1</td>
<td>Date Time of Assessment: //</td>
</tr>
<tr>
<td>2</td>
<td>Arterial Blood Gases PaO2 (mmHg): [ ]</td>
</tr>
<tr>
<td>3</td>
<td>FiO2 (Fraction of Inhaled Oxygen): [ ]</td>
</tr>
<tr>
<td></td>
<td>Sponsor-Defined Identifier</td>
</tr>
<tr>
<td>---</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>1.</td>
<td></td>
</tr>
</tbody>
</table>
### Concomitant Medications

1. **What is the medication identifier?**  
   
2. **Category:**  
   
3. **Concomitant Medications Pre-specified:**  
   
4. **Medication:**  
   
   Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).  
   
5. **Start Date:**  
   //  
   
6. **Ongoing?**
<table>
<thead>
<tr>
<th>#</th>
<th>Date of Assessment</th>
<th>Location of Assessment</th>
<th>Imaging Method</th>
<th>Overall Assessment</th>
<th>Form Instance</th>
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<tbody>
<tr>
<td>1</td>
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<td>Repeating Pages</td>
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**Header Text:** c4591001  
**Visit:** POT_COVID_ILL 1  
**Form:** IMAGING  
**Form Version:** 06-Jul-2020 21:53  
**Site No:** 1241  
**Site Name:** (1241) Hospital Irma Dulce  
**Subject No:** 12411410  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 19:09
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<table>
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<tbody>
<tr>
<td>1. Date of Assessment:</td>
<td>//</td>
</tr>
<tr>
<td>2. Location of Assessment:</td>
<td></td>
</tr>
<tr>
<td>3. Type of Imaging Exam:</td>
<td></td>
</tr>
<tr>
<td>4. Assessment:</td>
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</tbody>
</table>
**Header Text:** c4591001  
**Visit:** POT_COVID_CONV A 1 - Unscheduled Visit on Feb/11/2021  
**Form Version:** 22-Apr-2020 21:04  
**Form:** DATE OF VISIT - ILLNESS CONVALESCENT  
**Site No:** 1241  
**Site Name:** (1241) Hospital Irma Dulce  
**Subject No:** 12411410  
**Generated By:** (b) (4)  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 19:09

---

### eCRF Audit Trail History

#### Date of Visit

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<tbody>
<tr>
<td>1.</td>
<td>Date of Visit</td>
</tr>
<tr>
<td></td>
<td>Feb/11/2021</td>
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<tr>
<td>2.</td>
<td>Erroneous Visit</td>
</tr>
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</table>

#### COVID-19 Illness Visit

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<table>
<thead>
<tr>
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<tbody>
<tr>
<td>3.</td>
<td>COVID-19 Illness Visit:</td>
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<tr>
<td></td>
<td>COVID_A1</td>
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### eCRF Audit Trail History

#### Electronic Sample Tracking

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<th>Data Origin</th>
<th>SITE</th>
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<tbody>
<tr>
<td>2</td>
<td>Sample Type</td>
<td>SERUM</td>
</tr>
<tr>
<td>3</td>
<td>Sample Collected?</td>
<td>YES&lt;br&gt;Date of Collection: Feb/11/2021</td>
</tr>
<tr>
<td>4</td>
<td>If no sample was collected or sample was not collected according to protocol, please provide reason:</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

#### Aliquot

Please enter barcode for each aliquot.

<table>
<thead>
<tr>
<th></th>
<th>Sample ID</th>
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<tbody>
<tr>
<td>5.a</td>
<td>[BRKF2H]</td>
</tr>
<tr>
<td>5.b</td>
<td>[BS2Y65]</td>
</tr>
<tr>
<td>5.c</td>
<td>[BS2Y66]</td>
</tr>
</tbody>
</table>
**Header Text:** c4591001  
**Visit:** Unplanned - New Unscheduled Visit  
**Form:** DATE OF VISIT  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1241  
**Subject No:** 1241410  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 19:09

**Site Name:** (1241) Hospital Irma Dulce  
**Subject Initials:** ---  
**Form Status:** Not Started

<table>
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<tr>
<th>Date of Visit</th>
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<tbody>
<tr>
<td>1. Date of Visit</td>
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<tr>
<td>2. Erroneous Visit</td>
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<tr>
<td>Unplanned Assessments</td>
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<td>1. Assessments</td>
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</table>
### Disposition - Treatment

<p>| | |</p>
<table>
<thead>
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</thead>
<tbody>
<tr>
<td>1.</td>
<td>Date of Completion/Discontinuation/Death: Oct/14/2020</td>
</tr>
<tr>
<td>2.</td>
<td>Phase of Disposition: VACCINATION</td>
</tr>
<tr>
<td>3.</td>
<td>Status: COMPLETED</td>
</tr>
<tr>
<td>4.</td>
<td>Specify Status: [ ]</td>
</tr>
<tr>
<td>Disposition - Follow-Up</td>
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</tr>
<tr>
<td>-------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>1. Date of Completion/Discontinuation/Death: //</td>
<td></td>
</tr>
<tr>
<td>2. Phase of Disposition:</td>
<td></td>
</tr>
<tr>
<td>3. Status:</td>
<td></td>
</tr>
<tr>
<td>4. Specify Status: [ ]</td>
<td></td>
</tr>
<tr>
<td>Date of Visit</td>
<td></td>
</tr>
<tr>
<td>-----------------------</td>
<td>---------------</td>
</tr>
<tr>
<td>1. Date of Visit</td>
<td>//</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
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</table>

<table>
<thead>
<tr>
<th>COVID-19 Repeat Swab</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. COVID-19 Repeat Swab:</td>
</tr>
<tr>
<td>Electronic Sample Tracking</td>
</tr>
<tr>
<td>----------------------------</td>
</tr>
<tr>
<td>1. Data Origin</td>
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<tr>
<td>2. Sample Type</td>
</tr>
<tr>
<td>3. Sample Collected?</td>
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<tr>
<td>4. If no sample was collected or sample was not collected according to protocol, please provide reason:</td>
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<table>
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<tr>
<td>1.</td>
<td>ADVERSE EVENT</td>
</tr>
<tr>
<td>2.</td>
<td>ADVERSE EVENT</td>
</tr>
<tr>
<td>3.</td>
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</tr>
<tr>
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<tr>
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<td>5.</td>
<td>ADVERSE EVENT</td>
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### Adverse Event Report

<p>| | |</p>
<table>
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<tbody>
<tr>
<td>1.</td>
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</tr>
<tr>
<td>2.</td>
<td>AE ID: [1]</td>
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<tr>
<td>3.</td>
<td>Adverse Event: [Injection site pain]</td>
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<td>4.</td>
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<tr>
<td>5.</td>
<td>Is the adverse event still ongoing? NO</td>
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<tr>
<td>6.</td>
<td>Toxicity Grade: 1</td>
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<tr>
<td></td>
<td>End Date Time: Jan/29/2021 UNK:UNK</td>
</tr>
<tr>
<td>Question</td>
<td>Answer</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>--------</td>
</tr>
<tr>
<td>7. Is the adverse event serious?</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</td>
<td></td>
</tr>
<tr>
<td>existing hospitalization; Persistent or significant disability/incapacity;</td>
<td></td>
</tr>
<tr>
<td>Congenital anomaly/birth defect; Important medical event (i.e. may</td>
<td></td>
</tr>
<tr>
<td>jeopardize subject and may require medical/surgical intervention to</td>
<td></td>
</tr>
<tr>
<td>prevent above outcomes).</td>
<td></td>
</tr>
<tr>
<td>8. Is this adverse event the result of a study Medication Error?</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>9. Is this event related to study treatment:</td>
<td>RELATED</td>
</tr>
<tr>
<td>10. Latest Action Taken with Study Treatment:</td>
<td>NOT APPLICABLE</td>
</tr>
<tr>
<td>11. Was a Concomitant Medication given?</td>
<td>NO</td>
</tr>
<tr>
<td>12. Was a Non-Drug Treatment given?</td>
<td>NO</td>
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<tr>
<td>Question</td>
<td>Answer</td>
</tr>
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<td>-------------------------------------------------------------------------</td>
<td>-----------------</td>
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<tr>
<td>13. What was the outcome of this adverse event?:</td>
<td>RECOVERED/RESOLVED</td>
</tr>
<tr>
<td>14. Did the adverse event cause the subject to be discontinued from the study?</td>
<td>NO</td>
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<tr>
<td>15. Serious Adverse Event Number: For Pfizer Use Only</td>
<td>[ ]</td>
</tr>
<tr>
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<tr>
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</tr>
<tr>
<td>2. AE ID:</td>
<td>[2]</td>
</tr>
<tr>
<td>3. Adverse Event: (If possible specify diagnosis, not individual symptoms)</td>
<td>[Left axillary lymph node enlargement]</td>
</tr>
<tr>
<td>4. Start Date Time:</td>
<td>Jan/26/2021 UNK:UNK</td>
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<tr>
<td>5. Is the adverse event still ongoing?</td>
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</tr>
<tr>
<td></td>
<td>End Date Time:</td>
</tr>
<tr>
<td></td>
<td>Jan/29/2021 UNK:UNK</td>
</tr>
<tr>
<td>6. Toxicity Grade:</td>
<td>1</td>
</tr>
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<td></td>
<td></td>
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<td>---</td>
<td>---</td>
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<tr>
<td>7.</td>
<td>Is the adverse event serious?</td>
</tr>
<tr>
<td></td>
<td>NO</td>
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<tr>
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<td>If Yes, NOTIFY PFIZER IMMEDIATELY.</td>
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<tr>
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<td>Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).</td>
</tr>
<tr>
<td>8.</td>
<td>Is this adverse event the result of a study Medication Error?</td>
</tr>
<tr>
<td></td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td>If Yes, record the type of medication error on the Medication Error Log.</td>
</tr>
<tr>
<td>9.</td>
<td>Is this event related to study treatment:</td>
</tr>
<tr>
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<td>RELATED</td>
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<tr>
<td>10.</td>
<td>Latest Action Taken with Study Treatment:</td>
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<tr>
<td></td>
<td>NOT APPLICABLE</td>
</tr>
<tr>
<td>11.</td>
<td>Was a Concomitant Medication given?</td>
</tr>
<tr>
<td></td>
<td>NO</td>
</tr>
<tr>
<td>12.</td>
<td>Was a Non-Drug Treatment given?</td>
</tr>
<tr>
<td></td>
<td>NO</td>
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<td></td>
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<td>13.</td>
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<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>
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### Adverse Event Report

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<td>3.</td>
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<td>Start Date Time: Jan/25/2021 17:00</td>
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<td>Is the adverse event still ongoing? NO</td>
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The form has been marked as deleted.
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<tr>
<td></td>
<td><strong>NO</strong></td>
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<tr>
<td></td>
<td>If Yes, NOTIFY PFIZER IMMEDIATELY.</td>
</tr>
<tr>
<td></td>
<td>Fatal; Life-threatening;</td>
</tr>
<tr>
<td></td>
<td>Inpatient hospitalization or</td>
</tr>
<tr>
<td></td>
<td>prolongation of existing</td>
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<tr>
<td></td>
<td>hospitalization; Persistent or</td>
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<td></td>
<td>significant</td>
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<tr>
<td></td>
<td>disability/incapacity;</td>
</tr>
<tr>
<td></td>
<td>Congenital anomaly/birth</td>
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<tr>
<td></td>
<td>defect; Important medical</td>
</tr>
<tr>
<td></td>
<td>event (i.e. may jeopardize</td>
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<td></td>
<td>subject and may require</td>
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<td></td>
<td>medical/surgical</td>
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<td></td>
<td>intervention to prevent</td>
</tr>
<tr>
<td></td>
<td>above outcomes).</td>
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<td>8.</td>
<td>Is this adverse event the result of a study Medication Error?</td>
</tr>
<tr>
<td></td>
<td><strong>NO</strong></td>
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<tr>
<td></td>
<td>If Yes, record the type of</td>
</tr>
<tr>
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<td>medication error on the</td>
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<td>Medication Error Log.</td>
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<td>Is this event related to study treatment:</td>
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<tr>
<td></td>
<td>RELATED</td>
</tr>
<tr>
<td>10.</td>
<td>Latest Action Taken with Study Treatment:</td>
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<tr>
<td></td>
<td>NOT APPLICABLE</td>
</tr>
<tr>
<td>11.</td>
<td>Was a Concomitant Medication given?</td>
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<tr>
<td></td>
<td><strong>NO</strong></td>
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<td></td>
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</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>
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<td>14.</td>
<td>Did the adverse event cause the subject to be discontinued from the study?</td>
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<td>15.</td>
<td>Serious Adverse Event Number: For Pfizer Use Only</td>
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</tr>
<tr>
<td>1.</td>
<td>Category:</td>
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<tr>
<td>2.</td>
<td>AE ID:</td>
</tr>
<tr>
<td>3.</td>
<td>Adverse Event: (If possible specify diagnosis, not individual symptoms)</td>
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<tr>
<td>4.</td>
<td>Start Date Time:</td>
</tr>
<tr>
<td>5.</td>
<td>Is the adverse event still ongoing?</td>
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<tr>
<td></td>
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<tr>
<td>6.</td>
<td>Toxicity Grade:</td>
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<tr>
<td>Question</td>
<td>Answer</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>---------</td>
</tr>
<tr>
<td>7. Is the adverse event serious?</td>
<td>NO</td>
</tr>
<tr>
<td>If Yes, NOTIFY PFIZER IMMEDIATELY.</td>
<td></td>
</tr>
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<td>10. Latest Action Taken with Study Treatment:</td>
<td>NOT APPLICABLE</td>
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<td>YES</td>
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<td>12. Was a Non-Drug Treatment given?</td>
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<tr>
<td></td>
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### Adverse Event Report

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<td>Category: ADVERSE EVENT</td>
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<tr>
<td>2</td>
<td>AE ID: [5]</td>
</tr>
<tr>
<td>3</td>
<td>Adverse Event: Left axillary lymphadenopathy</td>
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<tr>
<td>4</td>
<td>Start Date Time: Jan/26/2021 UNK:UNK</td>
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<tr>
<td>5</td>
<td>Is the adverse event still ongoing? NO</td>
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<tr>
<td></td>
<td>End Date Time: Jan/27/2021 UNK:UNK</td>
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<td>Toxicity Grade: 1</td>
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**Site No:** 1241  
**Site Name:** (1241) Hospital Irma Dulce  
**Subject No:** 12411410  
**Subject Initials:** ---  
**Generated By:** [b] (4)  
**Generated Time (GMT):** 29-Mar-2021 19:09
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<td>Is the adverse event serious?</td>
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<tr>
<td></td>
<td>If Yes, NOTIFY PFIZER IMMEDIATELY.</td>
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</tr>
<tr>
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<td>Is this event related to study treatment:</td>
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<td></td>
<td>RELATED</td>
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<tr>
<td>10.</td>
<td>Latest Action Taken with Study Treatment:</td>
</tr>
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<td>NOT APPLICABLE</td>
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<tr>
<td>11.</td>
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<td></td>
<td>NO</td>
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<td>12.</td>
<td>Was a Non-Drug Treatment given?</td>
</tr>
<tr>
<td></td>
<td>YES</td>
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</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 [ ]
<table>
<thead>
<tr>
<th>#</th>
<th>Category</th>
<th>Medication Error</th>
<th>Start Date</th>
<th>Is the medication error Still Ongoing</th>
<th>Study Medication Errors Action</th>
<th>Form Instance</th>
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<tbody>
<tr>
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</table>
Medication Error

1. Category:

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

3. Start Date: //

4. Is the medication error still ongoing?

5. Latest Action Taken with Study Treatment:

6. Was a Concomitant Medication given?

7. Was a Non-Drug Treatment given?

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

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

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

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

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<tr>
<td>1.</td>
<td>What is the medication identifier? [ ]</td>
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<td>2.</td>
<td>Category:</td>
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<td>3.</td>
<td>Concomitant Medications Pre-specified:</td>
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| 4. | Medication: [ ]

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

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<table>
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<tr>
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<td>10.</td>
<td>Ongoing?</td>
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<tr>
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<td>Category</td>
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## Radiation Treatment

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<tr>
<td>2.</td>
<td>What is the treatment Identifier? [ ]</td>
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<td>Concomitant Non-drug Treatment Pre-specified:</td>
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<td>6.</td>
<td>Ongoing?</td>
</tr>
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<td>#</td>
<td>Transfusion Type</td>
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</tr>
<tr>
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</table>
1. Transfusion Type: 

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

**Header Text:** c4591001  
**Visit:** Unplanned Vaccination - Unscheduled  
**Form:** DATE OF VISIT  
**Form Version:** 22-Apr-2020 21:02  
**Form Status:** Not Started  
**Site No:** 1241  
**Site Name:** (1241) Hospital Irma Dulce  
**Subject No:** 12411410  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 19:09
## Vital Signs

1. **Date:** //

### Vital Signs Details

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

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**Header Text:** c4591001  
**Visit:** Unplanned Vaccination - Unscheduled  
**Form:** VITAL SIGNS - TEMP  
**Form Version:** 20-Feb-2021 02:16  
**Form Status:** Not Started  
**Site No:** 1241  
**Site Name:** (1241) Hospital Irma Dulce  
**Subject No:** 12411410  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 19:09
### Lab Urinalysis

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

### Lab Result

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

---

**Form: LAB URINALYSIS - PREGNANCY TEST**

**Visit:** Unplanned Vaccination - Unscheduled

**Form Version:** 20-Feb-2021 02:14

**Site No:** 1241

**Subject No:** 12411410

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

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09
### Vaccination

1. Was there a temporary delay of vaccination? 

2. Treatment Name  

3. Formulation:  

4. Dose Date Time:  

5. Anatomical Location:  

6. Body Side:  

7. Route:  

8. Actual Dose:  

9. Unit:  

10. Timeframe Subject Was Observed  

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

---
<table>
<thead>
<tr>
<th><strong>Contact Outcome</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Contact Type:</td>
</tr>
<tr>
<td>2. Was contact made?</td>
</tr>
<tr>
<td>3. Comments:</td>
</tr>
<tr>
<td>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>
**Header Text:** c4591001  
**Visit:** Potential ReVax Initial Contact - **Form:** DATE OF VISIT  
**Unscheduled**

**Form Version:** 22-Apr-2020 21:02  
**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241  
**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411410  
**Subject Initials:** ---

**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 19:09

### eCRF Audit Trail History

**Date of Visit**

<table>
<thead>
<tr>
<th></th>
<th>Date of Visit</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Date of Visit</td>
<td>Jan/21/2021</td>
</tr>
<tr>
<td>2</td>
<td>Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>
### Further Vaccination Confirmation

<table>
<thead>
<tr>
<th>1. Select appropriate response</th>
<th>Participant is willing to return for Vaccination 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Is participant willing to return for Vaccination 3?</td>
<td>Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2</td>
</tr>
</tbody>
</table>
**Header Text:** c4591001  
**Visit:** Disposition - Unscheduled  
**Form:** TREATMENT UNBLINDED  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1241  
**Site Name:** (1241) Hospital Irma Dulce  
**Subject No:** 12411410  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 19:09

### eCRF Audit Trail History

<table>
<thead>
<tr>
<th>Treatment Unblinded</th>
<th></th>
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<tbody>
<tr>
<td>1. Date Treatment Unblinded :</td>
<td>Jan/21/2021</td>
</tr>
<tr>
<td>2. Primary Reason for Unblinding:</td>
<td>ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION</td>
</tr>
</tbody>
</table>
**Withdrawal Of Consent**

<table>
<thead>
<tr>
<th></th>
<th>Withdrawal of Consent Date: //</th>
</tr>
</thead>
</table>

**Header Text:** c4591001  
**Visit:** Disposition - Unscheduled  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1241  
**Subject No:** 12411410  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 19:09  
**Site Name:** (1241) Hospital Irma Dulce  
**Subject Initials:** ---  
**Form:** WITHDRAWAL OF CONSENT  
**Form Status:** Not Started
**Death Details**

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

**Cause of Death**

2. Cause of Death Status:  

   Cause of Death: [ ]
### eCRF Audit Trail History

<table>
<thead>
<tr>
<th>Date of Visit</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Visit</td>
<td>Jan/25/2021</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
<tr>
<td>1. Consent Was:</td>
<td>OBTAINED</td>
</tr>
<tr>
<td>---------------</td>
<td>----------</td>
</tr>
<tr>
<td></td>
<td>Date Written Consent Obtained</td>
</tr>
<tr>
<td></td>
<td>Jan/25/2021</td>
</tr>
</tbody>
</table>
### Form Comments

#### Inclusion Criteria Not Met

<table>
<thead>
<tr>
<th></th>
<th>Description of Inclusion Criterion Not Met</th>
<th>Not Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Exclusion Criteria Met

<table>
<thead>
<tr>
<th></th>
<th>Description of Exclusion Criterion Met</th>
<th>Not Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>-----------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td><strong>Date of Completion/Discontinuation/Death:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Jan/25/2021</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td><strong>Phase of Disposition:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>REPEAT SCREENING 1</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td><strong>Status:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>COMPLETED</td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td><strong>Specify Status:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>[ ]</td>
<td></td>
</tr>
</tbody>
</table>
### 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: Jan/25/2021</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>
**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

| 5.a | Sample ID | [BRKBVH] |
| 5.b | Sample ID | [BSCZ0J] |
| 5.c | Sample ID | [BSCZ0K] |
### eCRF Audit Trail History

**Electronic Sample Tracking**

<table>
<thead>
<tr>
<th></th>
<th>Data Origin</th>
<th>Sample Type</th>
<th>Sample Collected?</th>
<th>If no sample was collected or sample was not collected according to protocol, please provide reason:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>SITE</td>
<td>NASAL_SWAB</td>
<td>YES</td>
<td>[ ]</td>
</tr>
<tr>
<td>2.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td></td>
<td></td>
<td>YES</td>
<td>Date of Collection: Jan/25/2021</td>
</tr>
<tr>
<td>4.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Aliquot

Please enter barcode for each aliquot.

<table>
<thead>
<tr>
<th>5.a</th>
<th>Sample ID</th>
<th>[BRKBVL]</th>
</tr>
</thead>
</table>

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**Form**: ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
**Form Version**: 22-Apr-2020 21:03  
**Form Status**: Data Complete, Frozen, Verified  
**Site No**: 1241  
**Site Name**: (1241) Hospital Irma Dulce  
**Subject No**: 12411410  
**Subject Initials**: ---  
**Generated By**: (b) (4)  
**Generated Time (GMT)**: 29-Mar-2021 19:09
## eCRF Audit Trail History

**Vaccination**

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

Date of Visit

1. Date of Visit | Feb/15/2021
2. Erroneous Visit |
### Lab Audit Trail History

#### Lab Urinalysis

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<td>Collection Date: Feb/15/2021</td>
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<td>Laboratory Name and Address (Derived): [STUDY SITE]</td>
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<tr>
<td>5.</td>
<td>Specimen Type: URINE</td>
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#### Lab Result

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<tr>
<td></td>
<td>Result: NEGATIVE</td>
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<tr>
<td></td>
<td>Not Done:</td>
</tr>
</tbody>
</table>
**Electronic Sample Tracking**

1. Data Origin | SITE  
2. Sample Type | NASAL_SWAB  
3. Sample Collected? | YES  
   Date of Collection:  
   Feb/15/2021  
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 | [BRKF4Y] |
### eCRF Audit Trail History

**Vaccination**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Was there a temporary delay of vaccination?</td>
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<td>Treatment Name</td>
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<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>
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<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>
### Date of Visit

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

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**Header Text:** c4591001  
**Visit:** V103_MONTH1  
**Form:** DATE OF VISIT  
**Form Version:** 22-Apr-2020 21:02  
**Form Status:** Not Started  
**Site No:** 1241  
**Site Name:** (1241) Hospital Irma Dulce  
**Subject No:** 12411410  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 19:09
### Contact Outcome

1. **Contact Type:**

2. **Was contact made?**

3. **Comments:** [ ]
### Date of Visit

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

1. **Contact Type:**
   
2. **Was contact made?**
   
3. **Comments:** [ ]
**Disposition - Treatment**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Completion/Discontinuation/Death:</td>
<td>//</td>
</tr>
<tr>
<td>2. Phase of Disposition:</td>
<td></td>
</tr>
<tr>
<td>3. Status:</td>
<td></td>
</tr>
<tr>
<td>4. Specify Status:</td>
<td>[ ]</td>
</tr>
</tbody>
</table>
**Header Text:** c4591001  
**Visit:** Subject Status - Unscheduled  
**Form:** SUBJECT STATUS  
**Form Version:** 22-Apr-2020 21:03  
**Form Status:** Data Complete, Verified  
**Site No:** 1241  
**Site Name:** (1241) Hospital Irma Dulce  
**Subject No:** 12411410  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 19:09

<table>
<thead>
<tr>
<th>eCRF Audit Trail History</th>
</tr>
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<tbody>
<tr>
<td><strong>Subject Status</strong></td>
</tr>
<tr>
<td>1. Subject Status</td>
</tr>
<tr>
<td>2. Subject Status Date</td>
</tr>
</tbody>
</table>
Header Text: c4591001
Visit: Investigator Signature - Unscheduled
Form: CASEBOOK SIGNATURE FORM
Form Version: 22-Apr-2020 21:04
Site No: 1241
Site Name: (1241) Hospital Irma Dulce
Subject No: 12411410
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 19:09

eCRF Audit Trail History

Casebook Signature Form

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

This form requires signing by a member of each of the following signature groups:
- CRF_Sign
- CRF_Sign_1

<table>
<thead>
<tr>
<th>Name</th>
<th>Signature Meaning</th>
<th>Date</th>
<th>Type</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(b) (4)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Item</td>
<td>Date</td>
<td>User</td>
<td>Comment</td>
<td></td>
</tr>
<tr>
<td>------</td>
<td>------</td>
<td>------</td>
<td>---------</td>
<td></td>
</tr>
<tr>
<td>Form</td>
<td>Jan-25-2021 17:33:32 (UTC-03:00) City of Buenos Aires</td>
<td>(b) (4), (b) (6)</td>
<td>Not Applicable</td>
<td></td>
</tr>
</tbody>
</table>
### Affidavit:

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

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

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

<table>
<thead>
<tr>
<th>Name</th>
<th>Signature Meaning</th>
<th>Date</th>
<th>Type</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>(b) (6)</td>
<td>N/A</td>
<td>Mar-12-2021 08:35:26 (UTC-03:00) City of Buenos Aires</td>
<td></td>
<td>Edit - All signatures invalidated</td>
</tr>
<tr>
<td>Edson Moreira</td>
<td>Approved</td>
<td>Feb-15-2021 15:57:00 (UTC-03:00) City of Buenos Aires</td>
<td>BOOK</td>
<td>Signed</td>
</tr>
<tr>
<td>(b) (6)</td>
<td>N/A</td>
<td>Feb-11-2021 11:15:56 (UTC-03:00) City of Buenos Aires</td>
<td></td>
<td>Edit - All signatures invalidated</td>
</tr>
</tbody>
</table>
Affidavit:
N/A

Edson Moreira | Approved | Jan-27-2021 13:59:59 (UTC-03:00) City of Buenos Aires | BOOK | Signed

Affidavit:
By my dated signature below, I, Edson Moreira, 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 | Jan-25-2021 17:31:13 (UTC-03:00) City of Buenos Aires | Edit - All signatures invalidated

Affidavit:
N/A

Edson Moreira | Approved | Jan-22-2021 05:27:12 (UTC-03:00) City of Buenos Aires | BOOK | Signed
Affidavit:
By my dated signature below, I, EdsonMoreira, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

Affidavit:
N/A

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.

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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>
</tr>
</thead>
<tbody>
<tr>
<td>Aug-24-2020</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>Data Entry: 30 JUN 2020</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>11:26:14</td>
<td></td>
<td>(b) (4), (b) (6)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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### 1. Subject ID

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

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<td>ve, 65 and 85 years, inclusive, 18 and 85 years, inclusive, at randomization (dependent on study stage)</td>
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**Form**: INCLUSION/EXCLUSION CRITERIA - eCRF

**Audit Trail History**

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

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

**Site No**: 1241

**Site Name**: (1241) Hospital Irma Dulce

**Subject No**: 12411410

**Subject Initials**: ---

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

**Generated Time (GMT)**: 29-Mar-2021 19:09
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Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)
### 1.a Criterion met?

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**Criteria IDs:**

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- (b) (6)
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plan, laborator 
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Crit  YES 
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Crit  IN02A00 
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<td>Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures</td>
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### 1.b Criterion met?

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**Data Entry:**

**Inclusion Number:**

- Initial Entry
- ACV0PFEINFP6000
- User: (b) (4), (b) (6)

**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.

**Critereon Met?:**

- Initial Entry
- YES

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**Inclusion/Exclusion Criteria - eCRF**

**Audit Trail History**

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

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

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411410

**Generated By:**

- (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09
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**Form**: INCLUSION/EXCLUSION CRITERIA - eCRF

**Audit Trail History**

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

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

**Site No**: 1241

**Site Name**: (1241) Hospital Irma Dulce

**Subject No**: 12411410

**Subject Initials**: ---

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

**Generated Time (GMT)**: 29-Mar-2021 19:09
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**1.c Criterion Description:**

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<td>participants who are</td>
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<td>history, physical</td>
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**1.c Criterion met?**

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### Inclusion Criteria

**Date:** Aug-24-2020 11:29:01  
**Location:** City of Buenos Aires  
**User:** ACV0PFEINFP6000  
**Value:** (b) (4)

**Reason:** Initial Entry

**Data Entry:**

- Incl 4  
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- n N  
- umb er:
- Crit: Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol
- Crit erio
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- et?:

**Form Version:** 21-Aug-2020 02:50  
**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241  
**Site Name:** (1241) Hospital Irma Dulce  
**Subject No:** 12411410  
**Subject Initials:** ---

**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 19:09
| Crit | erio | n ID | (F | or | Pfizer | use | only |): | IN04A00 |
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### 1.d Criterion met?

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**Audit Trail History**

**Form Version:** 21-Aug-2020 02:50  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1241  
**Site Name:** (1241) Hospital Irma Dulce  
**Subject No:** 12411410  
**Subject Initials:** ---  
**Generated By:**   
**Generated Time (GMT):** 29-Mar-2021 19:09
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<td>hepatitis C virus(HCV), or hepatitis B virus (HBV)</td>
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**Data Entry:**
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- er:
- Crit
- History of severe adverse reaction associated with a vaccine
- n: severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)
- Crit
- NO
- erio
- n
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- et?:

Initial Entry
| Crit ID: (For Pfizer use only): | EX03A00 |
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- **Criterion Met?:** NO

#### Data Entry: Exclusion Number ID:
- **For Pfizer use only:** EX04A00
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EX10A00

(For Pfizer use only):
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- Criterio (For Pfizer use only): EX12A00

**Criterio Description:**
- Previous vaccination with any coronavirus vaccine
- Criterio met?: NO
- Criterio ID: (For Pfizer use only): EX12A00
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**Reason:**
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**Site Name:** (1241) Hospital Irma Dulce

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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**Audit Trail History**

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

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**Site Name:** (1241) Hospital Irma Dulce

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**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
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**Form: INCLUSION/EXCLUSION CRITERIA - eCRF**

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

**Site No: 1241**

**Site Name: (1241) Hospital Irma Dulce**

**Subject No: 12411410**

**Subject Initials: ---**

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

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***Confidential***
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*Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: INCLUSION/EXCLUSION CRITERIA - eCRF
Audit Trail History
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**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History  
**Form Version:** 21-Aug-2020 02:50  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1241  
**Site Name:** (1241) Hospital Irma Dulce  
**Subject No:** 12411410  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 19:09

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**FDA-CBER-2021-5683-0994695**
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**Reason:** Initial Entry
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### 2. Sample Type

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### 3. Sample Collected?

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'Sample Collected?' is Yes, however no barcodes are entered. Please review.
### 5.a

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### 5.b

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5.c Sample ID

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<td>Data Entry: Sample ID BLCH0P</td>
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### 5.e Sample ID

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1. Data Origin

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<tr>
<td>Aug-24-2020 14:19:26</td>
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2. Sample Type

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3. Sample Collected?

<table>
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<td>auto query (autoquery)</td>
<td>Query 3: Closed</td>
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<td>auto query</td>
<td>Query 3: Opened</td>
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<td>Time</td>
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<td>Event Details</td>
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<tr>
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<td>(autoquery) more than 1 barcode present for sample collection. Please review and correct as appropriate.</td>
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### 5.a Sample ID

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<tbody>
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### 5.b

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<tbody>
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### 5.b Sample ID

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1. Was there a temporary delay of vaccination?

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

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3. Formulation:

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4. Dose Date Time:

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### 5. Anatomical Location:

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### 6. Body Side:

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### 7. Route:

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### 10. Timeframe Subject Was Observed

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<td>Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD</td>
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11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

<table>
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<th>Value</th>
<th>Reason</th>
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<tbody>
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### 1. Select appropriate response - Reactogenicity diary collection

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<th>Reason</th>
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<tbody>
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<td>(b) (6),</td>
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**Form: REACTOGENICITY DIARY - eCRF Audit Trail**

**History**

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

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411410

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

**Generated Time (GMT):** 29-Mar-2021 19:09
## 1. Date of Visit

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1. Date:

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<th>Reason</th>
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<tbody>
<tr>
<td>Sep-14-2020 14:36:40</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
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<td>Initial Entry</td>
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2.a

<table>
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<td></td>
<td></td>
<td>Temperature C</td>
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</tr>
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### 2.a Temperature Location:

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**1. Lab Panel:**

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<tr>
<td>Sep-14-2020</td>
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<td>Data Entry:</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>14:36:47</td>
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<td>(autocalc)</td>
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**2. Lab Sub-Panel:**

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<td>Initial Entry</td>
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**3. Collection Date:**

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

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

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<td>Initial Entry</td>
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<td>Date</td>
<td>Location</td>
<td>User</td>
<td>Value</td>
<td>Reason</td>
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### 2. Sample Type

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### 3. Sample Collected?

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<tbody>
<tr>
<td>Sep-14-2020</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>auto query</td>
<td>Query 1: Deleted</td>
<td>Close Auto Query</td>
</tr>
<tr>
<td>14:57:46</td>
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<table>
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<tbody>
<tr>
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<td>Query 1: Candidate</td>
<td>'Sample Collected?' is Yes, however no barcodes are entered. Please review</td>
</tr>
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### 5.a

<table>
<thead>
<tr>
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<td>Sep-14-2020</td>
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### 5.a Sample ID

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

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### 2. Treatment Name

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### 3. Formulation:

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### 4. Dose Date Time:

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5. **Anatomical Location:**

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6. **Body Side:**

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7. **Route:**

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10. **Timeframe Subject Was Observed**

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

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## 1. Date of Visit

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**Form:** DATE OF VISIT - eCRF Audit Trail History

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411410

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09
### 1. Data Origin

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### 2. Sample Type

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### 3. Sample Collected?

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<td>Close Auto Query</td>
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<th>Value</th>
<th>Reason</th>
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<td>Query 1: Candidate</td>
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Page 210 of 300
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<th>Reason</th>
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5.a Sample ID

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Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021
Form: DATE OF VISIT - ILLNESS ONSET - eCRF
Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Frozen, Verified
Site No: 1241
Site Name: (1241) Hospital Irma Dulce
Subject No: 12411410
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 19:09

are missing. Please review and update as appropriate.

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**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History  
**Form Version:** 14-Jan-2021 02:23  
**Site No:** 1241  
**Site Name:** (1241) Hospital Irma Dulce  
**Subject No:** 12411410  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 19:09

### 4.d Symptoms:

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### 4.h Symptoms:

<table>
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<tbody>
<tr>
<td>Jan-14-2021 15:37:58 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
<td><strong>Data Entry:</strong> DIARRHEA</td>
<td>Initial Entry</td>
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### 4.h Was symptom present?

<table>
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<th>Reason</th>
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<tbody>
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<td>Jan-14-2021 15:37:58 (UTC-03:00) City of Buenos Aires</td>
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<td><strong>Data Entry:</strong> NO</td>
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### 4.i

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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
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### 4.i Symptoms:

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<td>Data Entry: VOMITING</td>
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### 4.i Was symptom present?

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

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<td>Data Entry: Symptoms - Runny Other: nose</td>
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### 5.a Symptoms - Other Text:

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<td>Data Entry: Runny nose</td>
<td>Initial Entry</td>
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### Audit Trail

**Header Text:** c4591001

**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

**Form:** MICROBIOLOGY SPECIMEN - Audit Trail

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

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411410

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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<th>Reason</th>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Form Created</td>
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<td>15:11:50</td>
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**Form Created**
1. Actual Date of Collection:

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2. Specimen Type:

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3. Specimen Collection Location:

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<th>Reason</th>
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4. Assay Code and Description:

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<td>auto calc (autocalc)</td>
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Data Entry: SEVERE ACUTE RES P SYNDROME CORO
5. **Device Type:**

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<td><strong>Data Entry:</strong> SARS-COV-2 DIAGNOSTIC TEST</td>
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6. **Trade Name:**

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<td><strong>Data Entry:</strong> ABBOTT MOLECULAR REALTIME SA RS-COV-2 ASSAY</td>
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Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021
Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Frozen, Verified
Site No: 1241
Site Name: (1241) Hospital Irma Dulce
Subject No: 12411410
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 19:09

Back to Form

## 1. Data Origin

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<tbody>
<tr>
<td>Jan-14-2021</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>auto calc (autocalc)</td>
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## 2. Sample Type

<table>
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## 3. Sample Collected?

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<tr>
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<td>Query 1: Candidate</td>
<td>'Sample Collected?' is Yes, however no barcodes are entered. Please review</td>
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FDA-CBER-2021-5683-0994748
### Header Text
- **Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021
- **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History
- **Form Version:** 22-Apr-2020 21:03
- **Site No:** 1241
- **Subject No:** 12411410
- **Generated By:** (b) (4)
- **Generated Time (GMT):** 29-Mar-2021 19:09

### Data Entry
- **Date of Collection:** Jan/13/2021
- **Sample ID:** RW92876

#### 5.a
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### 2. Sample Type

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### 3. Sample Collected?

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

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| 15:38:56 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6) | Subject used self swab |

---

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### 1.a

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<th>Reason</th>
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<td>Initial Entry</td>
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<tr>
<td>15:39:22</td>
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<td>(6)</td>
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<td><strong>Occurrence of Visits or Contacts:</strong> NO</td>
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### 1.a Physician or Healthcare Professional:

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

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### 1.b
### 1.b Physician or Healthcare Professional:

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**Data Entry:**
- Type of Practitioner: EMERGENCY ROOM

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

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**Data Entry:**
- Occurrence of Visits or Contacts: NO

### 1.c

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**Data Entry:**
- Type of PRIMAR
### 1.c Physician or Healthcare Professional:

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

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### 1.d Physician or Healthcare Professional:

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

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

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### 1. Occurrence of Visits or Contacts:

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

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

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<th>Reason</th>
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| Jan-25-2021 17:32:12 | (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6)      | **Data Entry:** YES  
*Respiratory Illness Diagnosis:* Covid-19  
*Date of Diagnosis:* Jan/14/2021 | New Information |
| Jan-14-2021 15:39:36 | (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6)      | **Data Entry:** NO | Initial Entry   |

3. Toxicity Grade:

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Page 238 of 300
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<th>Form: ILLNESS DETAILS - eCRF Audit Trail History</th>
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<td>Site Name: (1241) Hospital Irma Dulce</td>
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<tr>
<td>Subject No: 12411410</td>
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<td>Generated By: (b) (4)</td>
<td>Generated Time (GMT): 29-Mar-2021 19:09</td>
</tr>
</tbody>
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| Jan-14-2021 15:39:36                                      | ACV0PFEINFP6000                                    |
| (UTC-03:00) City of Buenos Aires                          | (b) (4), (b)                                       |

| Data Entry: 1                                           | Initial Entry                                     |

**Confidential**
**Header Text:** c4591001

**Visit:** POT_COVID_CONV A 1 -
Unscheduled Visit on Feb/11/2021

**Form:** DATE OF VISIT - ILLNESS CONVALESCENT -
eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1241

**Subject No:** 12411410

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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### 3. COVID-19 Illness Visit:

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### 3. Sample Collected?

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**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
**Form Version:** 22-Apr-2020 21:03
**Form Status:** Data Complete, Frozen, Verified
**Site No:** 1241
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**Subject No:** 12411410
**Subject Initials:** ---
**Generated By:** (b) (4)
**Generated Time (GMT):** 29-Mar-2021 19:09

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**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1241  
**Subject No:** 12411410  
**Generated By:** (b) (4)  
**Site Name:** (1241) Hospital Irma Dulce  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 19:09

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**Form: ADVERSE EVENT REPORT - Audit Trail**  
**Site No:** 1241  
**Site Name:** (1241) Hospital Irma Dulce  
**Subject No:** 12411410  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 19:09

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**Back to Form**
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<td><strong>Data Entry:</strong></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-11-2021</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>(b) (4), (b)</td>
<td><strong>Injection site pain</strong></td>
<td>Initial Entry</td>
</tr>
<tr>
<td>11:17:29</td>
<td>ACV0PFEINFP6000</td>
<td>(6)</td>
<td><strong>Data Entry:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
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<td>UNK:U</td>
<td></td>
</tr>
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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>Feb-11-2021</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>(b) (4), (b)</td>
<td><strong>Jan/26/2021 UNK:U</strong></td>
<td>Initial Entry</td>
</tr>
<tr>
<td>11:17:29</td>
<td>ACV0PFEINFP6000</td>
<td>(6)</td>
<td><strong>Data Entry:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
</tr>
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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>Feb-11-2021</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>11:17:29</td>
<td></td>
<td></td>
<td></td>
<td>End Date Time:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Jan/29/2021 UNK:</td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td>UNK</td>
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</table>

6. Toxicity Grade:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-11-2021</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: 1</td>
</tr>
<tr>
<td>11:17:29</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-11-2021</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry:</td>
<td>Initial Entry</td>
</tr>
</tbody>
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Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete
Site No: 1241
Site Name: (1241) Hospital Irma Dulce
Subject No: 12411410
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 19:09

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-11-2021</td>
<td></td>
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<td>(b) (4), (b)</td>
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<tr>
<td>11:17:29</td>
<td></td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>NO</td>
<td></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>Feb-11-2021</td>
<td></td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
<td>Data Entry: Initial Entry</td>
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<tr>
<td>11:17:29</td>
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<td>(UTC-03:00) City of Buenos Aires</td>
<td>RELATED</td>
<td></td>
</tr>
</tbody>
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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>Feb-11-2021</td>
<td></td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
<td>Data Entry: Initial Entry</td>
</tr>
<tr>
<td>11:17:29</td>
<td></td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>NOT APPLICABLE</td>
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</tr>
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11. Was a Concomitant Medication given?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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</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>Feb-11-2021 11:17:29</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>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>Feb-11-2021 11:17:29</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>RECOVERED/RESOLVED</td>
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</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-11-2021 11:17:29</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>NO</td>
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</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>Feb-11-2021 11:19:58 (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>
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</table>

### 2. AE ID:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Feb-11-2021 11:19:58 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>2</td>
<td>Initial Entry</td>
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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>Feb-11-2021 11:19:58 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Left axillary lymph node enlargement</td>
<td>Initial Entry</td>
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### 4. Start Date Time:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-11-2021</td>
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<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong></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>Feb-11-2021</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
<td>Data Entry: NO</td>
</tr>
<tr>
<td>11:19:58</td>
<td>City of Buenos Aires</td>
<td></td>
<td></td>
<td>End Date Time:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<td>Jan/29/2021 UNK: UNK</td>
</tr>
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</table>

6. Toxicity Grade:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-11-2021</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
<td>Data Entry: 1</td>
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<tr>
<td>11:19:58</td>
<td>City of Buenos Aires</td>
<td></td>
<td></td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).
### 8. Is this adverse event the result of a study Medication Error?
**If Yes, record the type of medication error on the Medication Error Log.**

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-11-2021 11:19:58</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
<td>Data Entry: NO</td>
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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>Feb-11-2021 11:19:58</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</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>
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<tbody>
<tr>
<td>Feb-11-2021 11:19:58</td>
<td>(UTC-03:00) City of Buenos Aires</td>
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<td>(b) (4), (b)</td>
<td>Data Entry: NOT APPLICABLE</td>
</tr>
</tbody>
</table>

### 11. Was a Concomitant Medication given?
**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>
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</thead>
<tbody>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
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**13. What was the outcome of this adverse event?:**

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-11-2021 11:19:58</td>
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<td>(b) (4), (6)</td>
<td>Data Entry: RECOVERED/RESOLUTION</td>
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**14. Did the adverse event cause the subject to be discontinued from the study?**

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
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<tbody>
<tr>
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<td>ACV0PFEINFP6000</td>
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</table>
Back to Form

### 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>Feb-15-2021</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Initial Entry</td>
</tr>
<tr>
<td></td>
<td></td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> ADVERSE EVENT</td>
<td></td>
</tr>
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</table>

### 2. AE ID:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-15-2021</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>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>Mar-12-2021</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Closed</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Mar-12-2021</td>
<td>(UTC-03:00)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Answe red</td>
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<tr>
<td></td>
<td></td>
<td>(b) (4), (b) (6)</td>
<td></td>
<td>It was entered by mistake, it will be deleted</td>
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</table>
### ADVERSE EVENT REPORT - eCRF Audit Trail

**Visit:** Logs - Unscheduled  
**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail

**Form Version:** 22-Apr-2020 21:02  
**Form Status:** Data Complete, Deleted

**Site No:** 1241  
**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411410  
**Subject Initials:** ---

**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 19:09

---

### THIS REPEATING FORM HAS BEEN DELETED ***

<table>
<thead>
<tr>
<th>City of Buenos Aires</th>
<th>Mar-12-2021 03:40:06 (UTC-03:00)</th>
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<th>(b) (4), (b) (6)</th>
<th>Query 1: Opened</th>
<th>AE 3, Injection site pain, with a Start Date 2021-01-25T17:00 and End Date 26-Jan-2021 overlaps with AE 1, Injection site pain with a Start Date 26-Jan-2021 and End Date 29-Jan-2021, please consider updating AE records or else clarify.(SDQ)</th>
</tr>
</thead>
<tbody>
<tr>
<td>City of Buenos Aires</td>
<td>Feb-15-2021 14:55:30 (UTC-03:00)</td>
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<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Injection site pain</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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### 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>
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<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Jan/25/2021 17:00</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>
5. Is the adverse event still ongoing?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
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<tbody>
<tr>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
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<td></td>
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<td>(6)</td>
<td>End Date Time:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Jan/26/2021 UNK: UNK</td>
</tr>
</tbody>
</table>

6. Toxicity Grade:

<table>
<thead>
<tr>
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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
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<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
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<tr>
<td></td>
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<td>(6)</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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<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Feb-15-2021 14:55:30</td>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
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<tr>
<td></td>
<td></td>
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<td>(6)</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>
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<tbody>
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<td>Data Entry: NO</td>
</tr>
<tr>
<td>14:55:30</td>
<td></td>
<td>Initial Entry</td>
<td></td>
<td></td>
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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>Feb-15-2021</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PF6INFP6000</td>
<td>(b) (4), (b)</td>
<td>Data Entry: RELATED</td>
</tr>
<tr>
<td>14:55:30</td>
<td></td>
<td>Initial Entry</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

10. Latest Action Taken with Study Treatment:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-15-2021</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PF6INFP6000</td>
<td>(b) (4), (b)</td>
<td>Data Entry: NOT APPLICABLE</td>
</tr>
<tr>
<td>14:55:47</td>
<td></td>
<td>Initial Entry</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

11. Was a Concomitant Medication given?

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-15-2021</td>
<td>14:55:30 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>NO</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-15-2021</td>
<td>14:55:30 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>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>Feb-15-2021</td>
<td>14:55:30 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>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>Feb-15-2021</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: ADVERSE EVENT</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>Feb-15-2021</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>4</td>
<td>Data Entry: 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-15-2021</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Headache</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>Feb-15-2021</td>
<td></td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry:</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>Feb-15-2021</td>
<td>14:56:58 (UTC-03:00) City</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
</tr>
<tr>
<td></td>
<td>of Buenos Aires</td>
<td></td>
<td></td>
<td>End Date Time:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Jan/27/2021 UNK:UNK</td>
</tr>
</tbody>
</table>

6. Toxicity Grade:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-15-2021</td>
<td>14:56:58 (UTC-03:00) City</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: 1</td>
</tr>
<tr>
<td></td>
<td>of Buenos Aires</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
8. Is this adverse event the result of a study Medication Error? 
If Yes, record the type of medication error on the Medication Error Log.

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-15-2021</td>
<td>14:56:58 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
<td>Data Entry: NO</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

9. Is this event related to study treatment:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-15-2021</td>
<td>14:56:58 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
<td>Data Entry: RELATED</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></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>Feb-15-2021</td>
<td>14:56:58 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
<td>Data Entry: NOT APPLICABLE</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

11. Was a Concomitant Medication given?
**12. Was a Non-Drug Treatment given?**

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-15-2021</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>Feb-15-2021</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>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>Feb-15-2021</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>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>Feb-15-2021</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>Data Entry: ADVERSE EVENT</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>14:59:53</td>
<td></td>
<td>auto calc (autocalc)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 2. AE ID:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-15-2021</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>5</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>14:59:53</td>
<td></td>
<td>auto calc (autocalc)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-15-2021</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>Left axillary lymphadenopathy</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>14:59:53</td>
<td></td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry:</td>
<td></td>
</tr>
</tbody>
</table>

### 4. Start Date Time:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-15-2021</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry:</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>Feb-15-2021</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>14:59:53</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>Jan/26/2021 UNK:UNK</td>
<td>End Date Time: Jan/27/2021 UNK:UNK</td>
<td></td>
</tr>
</tbody>
</table>

6. Toxicity Grade:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-15-2021</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: 1</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>14:59:53</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).
8. Is this adverse event the result of a study Medication Error?  
If Yes, record the type of medication error on the Medication Error Log.

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-15-2021</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>

9. Is this event related to study treatment:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mar-09-2021</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Closed</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Mar-08-2021</td>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Answered</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>According to SI this event is rare but expected and is described in the Consent as &quot;Lymph gland enlargement&quot;.</td>
</tr>
<tr>
<td>Mar-05-2021</td>
<td>(UTC-03:00) City</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Opened</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>ClinQ: Please explain why the AE is related to</td>
</tr>
</tbody>
</table>
### 10. Latest Action Taken with Study Treatment:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-15-2021</td>
<td>ACV0PFEINFP6000</td>
<td>(b)</td>
<td>(4), (b) (6)</td>
<td>Data Entry: NOT APPLICABLE</td>
</tr>
<tr>
<td>14:59:53</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td></td>
<td></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>Feb-15-2021</td>
<td>ACV0PFEINFP6000</td>
<td>(b)</td>
<td>(4), (b) (6)</td>
<td>Data Entry: NO</td>
</tr>
<tr>
<td>14:59:53</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td></td>
<td></td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-15-2021</td>
<td>ACV0PFEINFP6000</td>
<td>(b)</td>
<td>(4), (b) (6)</td>
<td>Data Entry: RELATED</td>
</tr>
<tr>
<td>14:59:53</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td></td>
<td></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>Feb-15-2021</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>RECOVERED/RESOLVED</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb-15-2021</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>NO</td>
</tr>
</tbody>
</table>
### 1. Date of Visit

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-25-2021</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
<td><strong>Data Entry:</strong> Jan/21/2021</td>
</tr>
<tr>
<td>17:32:52</td>
<td></td>
<td></td>
<td>(6)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>
### 1. Select appropriate response - Is participant willing to return for Vaccination 3?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-25-2021 17:33:01 (UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFENFP6000</td>
<td>(b) (4) (b) (6)</td>
<td><strong>Data Entry:</strong>&lt;br&gt;Participant is willing to return for Vaccination 3&lt;br&gt;Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

**Value**
- **Data Entry:**
  - Participant is willing to return for Vaccination 3
  - Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
### 1. Date Treatment Unblinded:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-25-2021 17:32:42</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Jan/21/2021</td>
</tr>
</tbody>
</table>

### 2. Primary Reason for Unblinding:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-25-2021 17:32:42</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION</td>
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### 1. Date of Visit

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### Consent Was:

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<tbody>
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<td>Jan-25-2021</td>
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<td>(6)</td>
<td>Date Written Consent Obtained</td>
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### 1. Date of Completion/Discontinuation/Death:

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<td>(b) (4), (b) (6)</td>
<td>Data Entry: Jan/25/2021</td>
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### 2. Phase of Disposition:

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<td>auto calc (autocalc)</td>
<td>Data Entry: REPEAT SCREENING</td>
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### 3. Status:

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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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<td>Initial Entry</td>
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**4. Laboratory Name and Address (Derived)**

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### 6.a

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<td>Jan-25-2021</td>
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<td><strong>Data Entry:</strong> 113</td>
<td>Initial Entry</td>
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<td><strong>Sponsor-Defined Identifier:</strong></td>
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<td><strong>Test:</strong> Choriogon adotropin Beta_PX11</td>
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<td><strong>Result:</strong> NEGATIVE</td>
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### 6.a Sponsor ID:

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### 6.a Result:

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1. Data Origin

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2. Sample Type

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3. Sample Collected?

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<th>Reason</th>
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<tr>
<td>Jan-25-2021</td>
<td>ACV0PFEINFP6000</td>
<td>auto query</td>
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<td>Close Auto Query</td>
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<td>(autoquery)</td>
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<td>Jan-25-2021</td>
<td>ACV0PFEINFP6000</td>
<td>auto query</td>
<td>Query 1: Candidate</td>
<td>'Sample Collected?' is Yes, however no barcodes are entered. Please review</td>
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### 5.a

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<td>Sample ID: BSCZ0J</td>
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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. Data Origin

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

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<td>Initial Entry</td>
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### 3. Sample Collected?

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<td>Jan-25-2021 18:30:38</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Candidate</td>
<td>'Sample Collected?' is Yes, however no barcodes are entered. Please review</td>
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**Header Text:** c4591001  
**Visit:** V101_VAX3  
**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History  
**Form Version:** 22-Apr-2020 21:03  
**Form Status:** Data Complete, Frozen, Verified  
**Site No:** 1241  
**Site Name:** (1241) Hospital Irma Dulce  
**Subject No:** 12411410  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 19:09

Data Entry: YES  
Date of Collection: Jan/25/2021

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Data Entry: Sample ID  

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**b) (4)**
### 1. Was there a temporary delay of vaccination?

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### 2. Treatment Name

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### 3. Formulation:

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### 4. Dose Date Time:

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5. Anatomical Location:

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6. Body Side:

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8. Actual Dose:

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<td>Data Entry:</td>
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<td>17:34:30</td>
<td>(UTC-03:00) City of Buenos Aires</td>
<td>(autocalc)</td>
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### 10. Timeframe Subject Was Observed

<table>
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<tr>
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<th>Reason</th>
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<tbody>
<tr>
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<td>Data Entry:</td>
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<tr>
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### 11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

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### Date of Visit

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### 1. Lab Panel:

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<tbody>
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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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<tbody>
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## 5. Specimen Type:

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## 6.a

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<th>Reason</th>
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</table>
| Feb-15-2021 14:53:50 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000        | auto calc (autocalc) | **Data Entry:**  
  **Sponsor-Defined Identifier:** 113  
  **Test:** Choriogon adotropin Beta_PX11  
  **Result:** NEGATIVE  
  **Not Done:** | Initial Entry   |

## 6.a Sponsor ID:

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### 1. Data Origin

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### 2. Sample Type

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### 3. Sample Collected?

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<td>Query 1: Deleted</td>
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<td>'Sample Collected?' is Yes, however no barcodes are entered. Please review</td>
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### 5.a

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#### Data Entry:
- **Sample ID**: BRKF4
- **Y**

### 5.a Sample ID

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#### Data Entry:
- **BRKF4Y**
### 1. Was there a temporary delay of vaccination?

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### 3. Formulation:

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

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<th>Reason</th>
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<td>Data Entry: Feb/15/2021 13:49, Initial Entry</td>
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<tr>
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<td>User</td>
<td>Value</td>
<td>Reason</td>
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</tr>
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**5. Anatomical Location:**

**6. Body Side:**

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**7. Route:**

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**8. Actual Dose:**

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9. Unit:

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10. Timeframe Subject Was Observed

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

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<th>Reason</th>
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### 1. Subject Status

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<td>(autocalc)</td>
<td>FOLLOW-UP</td>
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### 2. Subject Status Date

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<td>(b) (4)</td>
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<tr>
<td><strong>Generated Time (GMT):</strong></td>
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11:29:28 (UTC-03:00) City of Buenos Aires  
(autocalc) Aug/24/2020
1. Casebook Signature

<table>
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Site No: 1241
Site Name: (1241) Hospital Irma Dulce
Subject No: 12411410
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 19:09