### eCRF Audit Trail History

**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.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Select appropriate response - Protocol version</td>
</tr>
<tr>
<td>2.</td>
<td>Select appropriate response - What cohort does the subject belong to?</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>1.</td>
<td>Consent Was: OBTAINED</td>
</tr>
<tr>
<td></td>
<td>Date Written Consent Obtained</td>
</tr>
<tr>
<td></td>
<td>Oct/8/2020</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>1.</td>
<td>Subject ID</td>
</tr>
<tr>
<td>2.</td>
<td>Birth Date:</td>
</tr>
<tr>
<td>3.</td>
<td>Sex:</td>
</tr>
<tr>
<td>4.</td>
<td>Ethnicity:</td>
</tr>
<tr>
<td>5.</td>
<td>Race: (Check X all that apply):</td>
</tr>
<tr>
<td>6.</td>
<td>Racial Designation:</td>
</tr>
</tbody>
</table>
eCRF Audit Trail History

Date of Visit

1. Date of Visit | Oct/8/2020
2. Erroneous Visit |
**Form Comments**

Inclusion Criteria Not Met

1. Description of Inclusion Criterion Not Met
   - Not Applicable

Exclusion Criteria Met

2. Description of Exclusion Criterion Met
   - Not Applicable
## eCRF Audit Trail History

### Disposition - Screening

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

<table>
<thead>
<tr>
<th>Line/MH Number</th>
<th>Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies</th>
<th>Start Date</th>
<th>Ongoing</th>
<th>End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>[1]</td>
<td>[Temporal lobe Epilepsy]</td>
<td>UNK/UNK/2001</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>[2]</td>
<td>[Bilateral tubal ligation Sterilized]</td>
<td>UNK/UNK/2018</td>
<td>NO</td>
<td>UNK/UNK/2018</td>
</tr>
</tbody>
</table>
1. Select appropriate response - What is the subject HIV status?

The subject is NOT known to be HIV POSITIVE
### Vital Signs

1. **Date:** Oct/8/2020
2. **Weight:** [109.0]
3. **Unit:** kg
4. **Height:** [164.0]
5. **Unit:** cm
6. **Body Mass Index:** [40.5]

### Vital Signs Details

<table>
<thead>
<tr>
<th>7.a</th>
<th>Record Identifier:</th>
<th>1</th>
</tr>
</thead>
<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>
**Header Text:** c4591001  
**Visit:** V1_DAY1_VAX1_L  
**Form Version:** 15-Sep-2020 21:51  
**Site No:** 1247  
**Subject No:** 12471220  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 18:51

### eCRF Audit Trail History

#### Lab Urinalysis

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Lab Panel: <strong>URINALYSIS</strong></td>
</tr>
<tr>
<td>2.</td>
<td>Lab Sub-Panel: <strong>PREGNANCY</strong></td>
</tr>
<tr>
<td>3.</td>
<td>Collection Date: Oct/8/2020</td>
</tr>
<tr>
<td>4.</td>
<td>Laboratory Name and Address (Derived): [STUDY SITE]</td>
</tr>
<tr>
<td>5.</td>
<td>Specimen Type: <strong>URINE</strong></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 BetaPX113</td>
</tr>
<tr>
<td></td>
<td>Result: NOT DONE</td>
</tr>
<tr>
<td></td>
<td>Not Done: NOT DONE</td>
</tr>
</tbody>
</table>
### eCRF Audit Trail History

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

**Electronic Sample Tracking**

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

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<tbody>
<tr>
<td>5.a</td>
<td>Sample ID</td>
</tr>
<tr>
<td>5.b</td>
<td>Sample ID</td>
</tr>
<tr>
<td>5.c</td>
<td>Sample ID</td>
</tr>
</tbody>
</table>
**eCRF Audit Trail History**

### Electronic Sample Tracking

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

### Aliquot

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<p>| | |</p>
<table>
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</thead>
<tbody>
<tr>
<td>5.a</td>
<td>Sample ID</td>
</tr>
<tr>
<td></td>
<td>[BM9CV2]</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:**  
   Oct/8/2020 09:38

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
### Reactogenicity Diary

<p>| 1. | Select appropriate response - Reactogenicity diary collection | NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT |</p>
<table>
<thead>
<tr>
<th><strong>eCRF Audit Trail History</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Date of Visit</strong></td>
</tr>
<tr>
<td>1. Date of Visit</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
</tr>
<tr>
<td>Vital Signs Details</td>
</tr>
<tr>
<td>--------------------</td>
</tr>
<tr>
<td>2.a</td>
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<tr>
<td>eCRF Audit Trail History</td>
</tr>
<tr>
<td>-------------------------</td>
</tr>
<tr>
<td><strong>Lab Urinalysis</strong></td>
</tr>
<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): [STUDY SITE]</td>
</tr>
<tr>
<td>5. Specimen Type:</td>
</tr>
<tr>
<td><strong>Lab Result</strong></td>
</tr>
<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>
**eCRF Audit Trail History**

**Electronic Sample Tracking**

<p>| | |</p>
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<thead>
<tr>
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<tbody>
<tr>
<td>1.</td>
<td>Data Origin</td>
</tr>
<tr>
<td>2.</td>
<td>Sample Type</td>
</tr>
<tr>
<td>3.</td>
<td>Sample Collected?</td>
</tr>
<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:  
   Oct/28/2020 11:09

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
Date of Visit

1. Date of Visit: Nov/30/2020
2. Erroneous Visit
**Electronic Sample Tracking**

1. **Data Origin**: SITE
2. **Sample Type**: SERUM
3. **Sample Collected?**: YES  
   Date of Collection:  
   Nov/30/2020
4. **If no sample was collected or sample was not collected according to protocol, please provide reason:** [ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a **Sample ID**: [BR7MSB]
5.b **Sample ID**: [BRY9S5]
5.c **Sample ID**: [BRY9S6]
### Date of Visit

<table>
<thead>
<tr>
<th></th>
<th>Date of Visit</th>
<th>Erroneous Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Electronic Sample Tracking

1. **Data Origin**

2. **Sample Type**

3. **Sample Collected?**

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

   [ ]

## Aliquot

Please enter barcode for each aliquot.

5. **Sample ID**

   [ ]
### Date of Visit

<table>
<thead>
<tr>
<th></th>
<th>Date of Visit</th>
<th>//</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.</td>
<td>Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>
### Electronic Sample Tracking

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

### Aliquot

Please enter barcode for each aliquot.

5. Sample ID [ ]
**Date of Visit**

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

**Form Information**

- **Header Text:** c4591001
- **Visit:** V6_MONTH24_L
- **Form Version:** 22-Apr-2020 21:02
- **Site No:** 1247
- **Subject No:** 12471220
- **Generated By:** (b) (4)
- **Form:** DATE OF VISIT
- **Form Status:** Not Started
- **Site Name:** (1247) Tievlei Trial Centre-Karl Bremer Hospital
- **Subject Initials:** ---
- **Generated Time (GMT):** 29-Mar-2021 18:51
<table>
<thead>
<tr>
<th>Electronic Sample Tracking</th>
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</thead>
<tbody>
<tr>
<td>1. Data Origin</td>
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<tr>
<td>2. Sample Type</td>
</tr>
<tr>
<td>3. Sample Collected?</td>
</tr>
<tr>
<td>4. If no sample was collected or sample was not collected according to protocol, please provide reason:</td>
</tr>
</tbody>
</table>

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<tr>
<th>Aliquot</th>
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</thead>
<tbody>
<tr>
<td>Please enter barcode for each aliquot.</td>
</tr>
<tr>
<td>5. Sample ID</td>
</tr>
</tbody>
</table>
**Header Text:** c4591001  
**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/24/2020  
**Form:** DATE OF VISIT - ILLNESS ONSET  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1247  
**Subject No:** 12471220  
**Generated By:** (b) (4)  
**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 18:51

### eCRF Audit Trail History

<table>
<thead>
<tr>
<th>Date of Visit</th>
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</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Visit</td>
<td>Dec/24/2020</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>

### COVID-19 Illness Visit

| 3. COVID-19 Illness Visit: | COVID_A |
### Signs and Symptoms

1. Date of Assessment: **Dec/24/2020**

2. Date of First Symptom Started: **Dec/22/2020**

3. Symptoms Ongoing? **NO**
   - Date of Last Symptom Resolved: **Dec/26/2020**

### Symptoms

<table>
<thead>
<tr>
<th>4.a</th>
<th>Symptoms:</th>
<th>FEVER</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Was symptom present?</td>
<td>NO</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4.b</th>
<th>Symptoms:</th>
<th>NEW OR INCREASED COUGH</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Was symptom present?</td>
<td>NO</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4.c</th>
<th>Symptoms:</th>
<th>NEW OR INCREASED SHORTNESS OF BREATH</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Was symptom present?</td>
<td>NO</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4.d</th>
<th>Symptoms:</th>
<th>CHILLS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Was symptom present?</td>
<td>NO</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4.e</th>
<th>Symptoms:</th>
<th>NEW OR INCREASED MUSCLE PAIN</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Was symptom present?</td>
<td>NO</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4.f</th>
<th>Symptoms:</th>
<th>NEW LOSS OF TASTE OR SMELL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Was symptom present?</td>
<td>NO</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4.g</th>
<th>Symptoms:</th>
<th>NEW OR INCREASED SORE THROAT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Was symptom present?</td>
<td>YES</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4.h</th>
<th>Symptoms:</th>
<th>DIARRHEA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Was symptom present?</td>
<td>NO</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4.i</th>
<th>Symptoms:</th>
<th>VOMITING</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Was symptom present?</td>
<td>NO</td>
</tr>
<tr>
<td>Symptoms - Other</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Symptoms - Other Text: [ ]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Header Text:** c4591001  
**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/24/2020  
**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19  
**Form Version:** 10-Dec-2020 02:29  
**Site No:** 1247  
**Subject No:** 12471220  
**Generated By:** [b] (4)  
**Generated Time (GMT):** 29-Mar-2021 18:51
<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>Not Done</td>
<td>Not Done</td>
<td>Not Done</td>
<td>Not Done</td>
<td>Not Done</td>
<td>repeating Pages</td>
</tr>
</tbody>
</table>
Microbiology Specimen

1. **Actual Date of Collection:** Not Done
   
2. **Specimen Type:** Not Done
   
3. **Specimen Collection Location:** Not Done
   
4. **Assay Code and Description:** Not Done
   
5. **Device Type:** Not Done
   
6. **Trade Name:** Not Done
   
7. **Test Result:** Not Done
   
8. **Comments/Findings/Details:** Not Done
   
9. **Trade Name Other, Specify:** Not Done

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## eCRF Audit Trail History

### Electronic Sample Tracking

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

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### Aliquot

Please enter barcode for each aliquot.

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### Health Care Utilization

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### Health Care Utilization Other

2. Other Type of Practitioner Specify: [ ]

### Health Care Utilization

3. Has the subject been hospitalized due to potential COVID-19 illness? NO
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<th>Con Non-Drug Treatments Pre-specified</th>
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**Visit:** POT_COVID_ILL 1  
**Form:** RESPIRATORY TREATMENT  
**Form Version:** 06-Jul-2020 21:53  
**Site No:** 1247  
**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital  
**Subject No:** 12471220  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 18:51

***Confidential***
### Respiratory Treatment

1. **What is the treatment Identifier?**
   - Not Applicable
   - [ ]

2. **Concomitant Non-drug Treatment Pre-specified:**
   - Not Applicable

3. **Treatment:**
   - Not Applicable

4. **Treatment:**
   - Not Applicable
   - [ ]

5. **Start Date:**
   - Not Applicable
   - //

6. **Ongoing?**
   - Not Applicable
## eCRF Audit Trail History

### Illness Details

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**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 18:51
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Not Done | Not Done | Not Done | Not Done | Not Done | Not Done | Not Done
Not Done | Not Done | Not Done | Not Done | Not Done | Not Done | Not Done
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Site No: 1247
Subject No: 12471220
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 18:51
### Laboratory Data Hematology

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**Comments**

**Low**

**High**

**Unit**

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**Comments**

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**High**

**Unit**
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</tr>
<tr>
<td>Vital Signs Details</td>
</tr>
<tr>
<td>---------------------</td>
</tr>
<tr>
<td>Date: Not Done</td>
</tr>
<tr>
<td>Systolic: Not Done</td>
</tr>
<tr>
<td>Diastolic: Not Done</td>
</tr>
<tr>
<td>Respiratory Rate in respirations/minute: Not Done</td>
</tr>
<tr>
<td>Heart Rate in beats/minute: Not Done</td>
</tr>
<tr>
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</tr>
<tr>
<td>----</td>
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<td>Vital Signs</td>
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### Oxygenation Parameters

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<table>
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<tr>
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<tbody>
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<table>
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<tbody>
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<td>#</td>
<td>Sponsor-Defined Identifier</td>
<td>Category for Medication</td>
</tr>
<tr>
<td>----</td>
<td>-----------------------------</td>
<td>--------------------------</td>
</tr>
<tr>
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**Header Text:** c4591001

**Visit:** POT_COVID_ILL 1

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1247

**Subject No:** 12471220

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51
**Concomitant Medications**

1. **What is the medication identifier?** Not Applicable  
   [ ]

2. **Category:** Not Applicable

3. **Concomitant Medications Pre-specified:** Not Applicable

4. **Medication:** Not Applicable  
   [ ]

5. **Start Date:** Not Applicable
   //

6. **Ongoing?** Not Applicable
<table>
<thead>
<tr>
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<th>Date of Assessment</th>
<th>Location of Assessment</th>
<th>Imaging Method</th>
<th>Overall Assessment</th>
<th>Form Instance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Not Done</td>
<td>Not Done</td>
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<td>Repeating Pages</td>
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### Imaging

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<th>Comments</th>
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<tbody>
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<th>Not Done</th>
<th>Comments</th>
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<th>Comments</th>
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<table>
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</table>
# eCRF Audit Trail History

## Date of Visit

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

## COVID-19 Illness Visit

<table>
<thead>
<tr>
<th></th>
<th>COVID-19 Illness Visit:</th>
<th>COVID_A1</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Electronic Sample Tracking**

1. Data Origin | SITE  
2. Sample Type | SERUM  
3. Sample Collected? | YES  
   Date of Collection:  
   Jan/21/2021  
4. If no sample was collected or sample was not collected according to protocol, please provide reason:  
   [ ]

**Aliquot**

Please enter barcode for each aliquot.

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

<table>
<thead>
<tr>
<th>Aliquot</th>
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<tbody>
<tr>
<td>Please enter barcode for each aliquot.</td>
</tr>
<tr>
<td>5. Sample ID</td>
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Header Text: c4591001
Visit: Unplanned 1 - Unscheduled Visit on Oct/30/2020
Form: DATE OF VISIT
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1247
Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital
Subject No: 12471220
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 18:51

eCRF Audit Trail History

Date of Visit

1. Date of Visit Oct/30/2020
2. Erroneous Visit
## Unplanned Assessments

<table>
<thead>
<tr>
<th>Assessments</th>
<th>CONTACT OUTCOME</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(b) (4)</td>
</tr>
</tbody>
</table>

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**eCRF Audit Trail History**

**Unplanned Assessments**

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<thead>
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<th>1</th>
<th>Assessments</th>
<th>CONTACT OUTCOME</th>
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</table>
**Header Text:** c4591001  
**Visit:** Unplanned 1 - Unscheduled Visit on Oct/30/2020  
**Form Version:** 22-Apr-2020 21:04  
**Site No:** 1247  
**Subject No:** 12471220  
**Generated By:** (b) (4)  

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**eCRF Audit Trail History**

**Contact Outcome**

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<tbody>
<tr>
<td>1.</td>
<td>Contact Type:</td>
<td>TELEPHONE VISIT</td>
</tr>
<tr>
<td>2.</td>
<td>Was contact made?</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td>Date of Contact:</td>
<td>Oct/30/2020</td>
</tr>
<tr>
<td></td>
<td>Contact Outcome:</td>
<td>VISIT NOT REQUIRED, DATA ENTRY ERROR IN E-DIARY</td>
</tr>
<tr>
<td>3.</td>
<td>Comments:</td>
<td>[ ]</td>
</tr>
<tr>
<td>#</td>
<td>Category</td>
<td>AE Identifier</td>
</tr>
<tr>
<td>---</td>
<td>------------------</td>
<td>---------------</td>
</tr>
<tr>
<td>1</td>
<td>ADVERSE EVENT</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>ADVERSE EVENT</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>ADVERSE EVENT</td>
<td>3</td>
</tr>
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<td>---------------</td>
<td></td>
</tr>
<tr>
<td>AE ID</td>
<td>[1]</td>
<td></td>
</tr>
<tr>
<td>Adverse Event:</td>
<td>[Diarrhea]</td>
<td></td>
</tr>
<tr>
<td>Start Date Time:</td>
<td>Oct/9/2020 UNK:UNK</td>
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</tr>
<tr>
<td>Is the adverse event still ongoing?</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>Toxicity Grade:</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Is the adverse event serious?</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>If Yes, NOTIFY PFIZER IMMEDIATELY.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is this adverse event the result of a study Medication Error?</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>Is this event related to study treatment:</td>
<td>RELATED</td>
<td></td>
</tr>
<tr>
<td>Latest Action Taken with Study Treatment:</td>
<td>NOT APPLICABLE</td>
<td></td>
</tr>
<tr>
<td>Was a Concomitant Medication given?</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>Was a Non-Drug Treatment given?</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>13. What was the outcome of this adverse event?</td>
<td>RECOVERED/RESOLVED</td>
<td></td>
</tr>
<tr>
<td>14. Did the adverse event cause the subject to be discontinued from the study?</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>15. Serious Adverse Event Number: For Pfizer Use Only</td>
<td>[ ]</td>
<td></td>
</tr>
</tbody>
</table>
### Adverse Event Report

1. **Category:** ADVERSE EVENT

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

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

4. **Start Date Time:** Oct/29/2020 UNK:UNK

5. **Is the adverse event still ongoing?** NO
   
   **End Date Time:**
   Oct/29/2020 UNK:UNK

6. **Toxicity Grade:** 2

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

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

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

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

11. **Was a Concomitant Medication given?** YES

12. **Was a Non-Drug Treatment given?** NO
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>13.</td>
<td>What was the outcome of this adverse event?</td>
</tr>
<tr>
<td>14.</td>
<td>Did the adverse event cause the subject to be discontinued from the study?</td>
</tr>
<tr>
<td>15.</td>
<td>Serious Adverse Event Number: For Pfizer Use Only</td>
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</table>
### Adverse Event Report

<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td><strong>1. Category:</strong></td>
<td>ADVERSE EVENT</td>
</tr>
<tr>
<td><strong>2. AE ID:</strong></td>
<td>[3]</td>
</tr>
<tr>
<td><strong>3. Adverse Event:</strong> (If possible specify diagnosis, not individual symptoms)</td>
<td>[Generalized Joint pain]</td>
</tr>
<tr>
<td><strong>4. Start Date Time:</strong></td>
<td>Oct/29/2020 UNK:UNK</td>
</tr>
<tr>
<td><strong>5. Is the adverse event still ongoing?</strong></td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td>End Date Time: Oct/29/2020 UNK:UNK</td>
</tr>
<tr>
<td><strong>6. Toxicity Grade:</strong></td>
<td>2</td>
</tr>
<tr>
<td><strong>7. Is the adverse event serious?</strong></td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td>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).</td>
</tr>
<tr>
<td><strong>8. Is this adverse event the result of a study Medication Error?</strong></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><strong>9. Is this event related to study treatment:</strong></td>
<td>RELATED</td>
</tr>
<tr>
<td><strong>10. Latest Action Taken with Study Treatment:</strong></td>
<td>NOT APPLICABLE</td>
</tr>
<tr>
<td><strong>11. Was a Concomitant Medication given?</strong></td>
<td>NO</td>
</tr>
<tr>
<td><strong>12. Was a Non-Drug Treatment given?</strong></td>
<td>NO</td>
</tr>
<tr>
<td>Question</td>
<td>Answer</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------</td>
</tr>
<tr>
<td>13. What was the outcome of this adverse event?</td>
<td>RECOVERED/RESOLVED</td>
</tr>
<tr>
<td>14. Did the adverse event cause the subject to be discontinued from the study?</td>
<td>NO</td>
</tr>
<tr>
<td>15. Serious Adverse Event Number: For Pfizer Use Only</td>
<td>[ ]</td>
</tr>
</tbody>
</table>
**Adverse Event Report**

1. **Category:** ADVERSE EVENT
2. **AE ID:** [4]
3. **Adverse Event:** [Left axillary lymphadenopathy]
4. **Start Date Time:** Oct/29/2020 UNK:UNK
5. **Is the adverse event still ongoing?** NO
   - **End Date Time:** Nov/2/2020 UNK:UNK
6. **Toxicity Grade:** 1
7. **Is the adverse event serious?** NO
   - **If Yes, NOTIFY PFIZER IMMEDIATELY.**
     - Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).
8. **Is this adverse event the result of a study Medication Error?** NO
   - **If Yes, record the type of medication error on the Medication Error Log.**
9. **Is this event related to study treatment:** RELATED
10. **Latest Action Taken with Study Treatment:** NOT APPLICABLE
11. **Was a Concomitant Medication given?** NO
12. **Was a Non-Drug Treatment given?** NO
### ADVERSE EVENT REPORT

**Visit:** Logs - Unscheduled  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1247  
**Subject No:** 12471220  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 18:51

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

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**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital  
**Subject Initials:** ---  
**Form Status:** Data Complete, Frozen

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**Serious Adverse Event Number:** For Pfizer Use Only

---

**Final On: 01-Apr-2021 03:51 (GMT)**
### Adverse Event Report

1. **Category:** ADVERSE EVENT

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

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

4. **Start Date Time:** Oct/30/2020 UNK:UNK

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

6. **Toxicity Grade:** 2

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

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

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

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

11. **Was a Concomitant Medication given?** YES

12. **Was a Non-Drug Treatment given?** NO
13. What was the outcome of this adverse event?: | RECOVERING/RESOLVING  

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 Error's Action</th>
<th>Form Instance</th>
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</thead>
<tbody>
<tr>
<td>1.</td>
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**Header Text:** c4591001  
**Visit:** Logs  
**Form Version:** 17-Jul-2020 21:54  
**Site No:** 1247  
**Subject No:** 12471220  
**Generated By:** (b) (4)  
**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 18:51
### Medication Error

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</thead>
<tbody>
<tr>
<td>1. Category:</td>
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<td>Comments</td>
</tr>
<tr>
<td>2. Medication Error (Type of Medication Error):</td>
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<td>Comments</td>
</tr>
<tr>
<td>3. Start Date:</td>
<td>Not Applicable</td>
<td>Comments</td>
</tr>
<tr>
<td>4. Is the medication error still ongoing?</td>
<td>Not Applicable</td>
<td>Comments</td>
</tr>
<tr>
<td>5. Latest Action Taken with Study Treatment:</td>
<td>Not Applicable</td>
<td>Comments</td>
</tr>
<tr>
<td>6. Was a Concomitant Medication given?</td>
<td>Not Applicable</td>
<td>Comments</td>
</tr>
<tr>
<td>7. Was a Non-Drug Treatment given?</td>
<td>Not Applicable</td>
<td>Comments</td>
</tr>
<tr>
<td>8. Did the Medication Error cause the subject to be discontinued from the study?</td>
<td>Not Applicable</td>
<td>Comments</td>
</tr>
<tr>
<td>9. Was this medication error associated with any adverse events?</td>
<td>Not Applicable</td>
<td>Comments</td>
</tr>
<tr>
<td>10. Serious Adverse Event Number: For Pfizer Use Only</td>
<td>Not Applicable</td>
<td>Comments</td>
</tr>
</tbody>
</table>

Note: All fields marked with Not Applicable have been filled in with the same text.
<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>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Repeating Pages</td>
</tr>
</tbody>
</table>

**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

**Site Name:** (1247) Tievlei Trial Centre-Karl Bremer Hospital

**Generated Time (GMT):** 29-Mar-2021 18:51
<table>
<thead>
<tr>
<th></th>
<th>Concomitant Medications</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>What is the medication identifier?</td>
</tr>
<tr>
<td></td>
<td>[ ]</td>
</tr>
<tr>
<td>2</td>
<td>Category:</td>
</tr>
<tr>
<td></td>
<td>[ ]</td>
</tr>
<tr>
<td>3</td>
<td>Concomitant Medications</td>
</tr>
<tr>
<td></td>
<td>Pre-specified:</td>
</tr>
<tr>
<td>4</td>
<td>Medication:</td>
</tr>
<tr>
<td></td>
<td>Provide the complete generic drug name (including salt form, where applicable). Where</td>
</tr>
<tr>
<td></td>
<td>generic name is unknown, enter the full trade or proprietary name. Include clarifying</td>
</tr>
<tr>
<td></td>
<td>information in the Medication text (e.g., Ingredient(s), route, use, formulation).</td>
</tr>
<tr>
<td>5</td>
<td>Date:</td>
</tr>
<tr>
<td></td>
<td>//</td>
</tr>
<tr>
<td>#</td>
<td>Sponsor-Defined Identifier</td>
</tr>
<tr>
<td>---</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>1.</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>
### Concomitant Medications

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

2. **Category:**
   - Not Applicable

3. **Concomitant Medications Pre-specified:**
   - Not Applicable

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).
   - Not Applicable
   - [ ]

5. **Dose:**
   - Not Applicable
   - [ ]

6. **Dose Unit:**
   - Not Applicable

7. **Dose Frequency:**
   - Not Applicable

8. **Route:**
   - Not Applicable

9. **Start Date:**
   - Not Applicable
   - //

10. **Ongoing?**
    - Not Applicable
<table>
<thead>
<tr>
<th>#</th>
<th>Category</th>
<th>Treatment Identifier</th>
<th>Con Non-Drug Treatments Pre-specified</th>
<th>Treatment</th>
<th>Start Date</th>
<th>Form Instance</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Repeating Pages</td>
</tr>
</tbody>
</table>
### Radiation Treatment

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<th>Comments</th>
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</thead>
<tbody>
<tr>
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<td>Comments</td>
</tr>
<tr>
<td>2. What is the treatment Identifier?</td>
<td>Not Applicable</td>
<td>Comments</td>
</tr>
<tr>
<td>3. Concomitant Non-drug Treatment Pre-specified:</td>
<td>Not Applicable</td>
<td>Comments</td>
</tr>
<tr>
<td>4. Treatment:</td>
<td>Not Applicable</td>
<td>Comments</td>
</tr>
<tr>
<td>5. Start Date:</td>
<td>Not Applicable</td>
<td>Comments</td>
</tr>
<tr>
<td>6. Ongoing?</td>
<td>Not Applicable</td>
<td>Comments</td>
</tr>
<tr>
<td>#</td>
<td>Transfusion Type</td>
<td>Date of Transfusion</td>
</tr>
<tr>
<td>---</td>
<td>-----------------</td>
<td>---------------------</td>
</tr>
<tr>
<td>1.</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<tr>
<td>---</td>
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<td>Transfusion Type:</td>
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<td>2.</td>
<td>Date of Transfusion:</td>
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Comments

//

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90177e196ae2fc2 Final Final On: 01-Apr-2021 03:51 (GMT)
**Disposition - Treatment**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>1. Date of Completion/Discontinuation /Death:</td>
<td>Nov/30/2020</td>
</tr>
<tr>
<td>2. Phase of Disposition:</td>
<td>VACCINATION</td>
</tr>
<tr>
<td>3. Status:</td>
<td>COMPLETED</td>
</tr>
<tr>
<td>4. Specify Status:</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

**eCRF Audit Trail History**

- **Disposition - Treatment**
  - Date of Completion/Discontinuation /Death: Nov/30/2020
  - Phase of Disposition: VACCINATION
  - Status: COMPLETED
  - Specify Status: [ ]
**Date of Visit**

1. Date of Visit
   
2. Erroneous Visit
## Vital Signs

1. Date: //

## Vital Signs Details

2. Record Identifier:
   - Temperature: [ ]
   - Unit:
   - Temperature Location:
### Lab Urinalysis

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

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

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>1.</td>
<td>Contact Type:</td>
</tr>
<tr>
<td>2.</td>
<td>Was contact made?</td>
</tr>
<tr>
<td>3.</td>
<td>Comments:</td>
</tr>
<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>
Informed Consent - Asymptomatic Surveillance

1. Consent Was:
### Electronic Sample Tracking

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

### Aliquot

Please enter barcode for each aliquot.

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

<table>
<thead>
<tr>
<th>Aliquot</th>
</tr>
</thead>
<tbody>
<tr>
<td>Please enter barcode for each aliquot.</td>
</tr>
</tbody>
</table>

| 5. Sample ID | [ ] |
### Disposition - Follow-Up

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

**Form:** DISPOSITION - FOLLOW-UP  
**Form Version:** 15-Sep-2020 21:53  
**Form Status:** Not Started  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 18:51
Header Text: c4591001
Visit: Potential ReVax Initial Contact - Unscheduled
Form Version: 22-Apr-2020 21:02
Site No: 1247
Subject No: 12471220
Generated By: (b) (4)

Form: DATE OF VISIT
Form Status: Data Complete, Frozen, Verified
Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 18:51

eCRF Audit Trail History

<table>
<thead>
<tr>
<th>Date of Visit</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Visit</td>
<td>Jan/27/2021</td>
</tr>
<tr>
<td>Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>
### eCRF Audit Trail History

**Further Vaccination Confirmation**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Select appropriate response - Is participant willing to return for Vaccination 3?</td>
</tr>
<tr>
<td></td>
<td>Participant is willing to return for Vaccination 3</td>
</tr>
<tr>
<td></td>
<td>Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2</td>
</tr>
<tr>
<td><strong>eCRF Audit Trail History</strong></td>
<td></td>
</tr>
<tr>
<td>-----------------------------</td>
<td></td>
</tr>
<tr>
<td><strong>Treatment Unblinded</strong></td>
<td></td>
</tr>
</tbody>
</table>

1. Date Treatment Unblinded : Jan/27/2021
2. Primary Reason for Unblinding: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION
<table>
<thead>
<tr>
<th><strong>Withdrawal Of Consent</strong></th>
<th><strong>Comments</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Withdrawal of Consent Date :</td>
<td>Not Applicable</td>
</tr>
<tr>
<td></td>
<td>//</td>
</tr>
</tbody>
</table>

**Form Comments**

eCRF Audit Trail History

Withdrawal Of Consent

- 1. Withdrawal of Consent Date: Not Applicable

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

**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials:** ---
### Death Details

<table>
<thead>
<tr>
<th>1. Date of Collection / Notification of Death:</th>
<th>Not Applicable</th>
<th>Comments</th>
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<tbody>
<tr>
<td>//</td>
<td></td>
<td></td>
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</tbody>
</table>

### Cause of Death

<table>
<thead>
<tr>
<th>2. Cause of Death Status:</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Cause of Death:</td>
<td>Not Applicable</td>
</tr>
<tr>
<td></td>
<td>[ ]</td>
</tr>
</tbody>
</table>
eCRF Audit Trail History

Subject Status

1. Subject Status | FOLLOW-UP
2. Subject Status Date | Nov/30/2020
### eCRF Audit Trail History

<table>
<thead>
<tr>
<th>Casebook Signature Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Casebook Signature</td>
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</table>
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>
</table>

(b) (4)

FDA-CBER-2021-5683-0894121
<table>
<thead>
<tr>
<th>Item</th>
<th>Date</th>
<th>User</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form</td>
<td>Oct-08-2020 12:51:40 (UTC+02:00) Harare, Pretoria</td>
<td>(b) (4), (b) (6)</td>
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(b) (4), (b) (6)
### Back to Form

<table>
<thead>
<tr>
<th>Item</th>
<th>Date</th>
<th>User</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form</td>
<td>Dec-24-2020 13:57:33 (UTC+02:00) Harare, Pretoria</td>
<td>(b) (4), (b) (6)</td>
<td>Not Done</td>
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</tbody>
</table>
**Header Text:**  c4591001  
**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/24/2020  
**Form Version:** 06-Jul-2020 21:54  
**Form Status:** Data Complete  
**Site No:** 1247  
**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital  
**Subject No:** 12471220  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 18:51

<table>
<thead>
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<th>Item</th>
<th>Date</th>
<th>User</th>
<th>Comment</th>
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<tr>
<td>1</td>
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<td>(b) (4), (b) (6)</td>
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</table>
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/24/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Site No: 1247
Subject No: 12471220
Generated By: (b) (4)

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Item | Date | User | Comment
--- | --- | --- | ---
2 | Dec-24-2020 13:57:33 (UTC+02:00) Harare, Pretoria | (b) (4), (b) (6) | Not Done
Back to Form

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

<table>
<thead>
<tr>
<th>Item</th>
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<th>User</th>
<th>Comment</th>
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</thead>
<tbody>
<tr>
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<tr>
<td>Item</td>
<td>Date</td>
<td>User</td>
<td>Comment</td>
</tr>
<tr>
<td>------</td>
<td>-----------------------------</td>
<td>--------------</td>
<td>-----------</td>
</tr>
<tr>
<td>5</td>
<td>Dec-24-2020 13:57:33 (UTC+2)</td>
<td>(b) (4), (b) (6)</td>
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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/24/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54
Form Status: Data Complete

Site No: 1247
Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471220
Subject Initials: ---

Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 18:51

<table>
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<th>Item</th>
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<th>User</th>
<th>Comment</th>
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<tbody>
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<td>6</td>
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<tr>
<td>Item</td>
<td>Date</td>
<td>User</td>
<td>Comment</td>
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<tr>
<td>------</td>
<td>------</td>
<td>------</td>
<td>---------</td>
</tr>
<tr>
<td>7</td>
<td>Dec-24-2020 13:57:33 (UTC+02:00) Harare, Pretoria</td>
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</table>
### Header Text:
- **c4591001**
- **Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/24/2020
- **Form Version:** 06-Jul-2020 21:54
- **Site No:** 1247
- **Subject No:** 12471220
- **Generated By:** (b) (4)
- **Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital
- **Subject Initials:** ---
- **Form:** MICROBIOLOGY SPECIMEN - Comments
- **Form Status:** Data Complete
- **Generated Time (GMT):** 29-Mar-2021 18:51

### Back to Form

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</table>
### Visit Details

**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/24/2020

**Site No:** 1247  
**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject No:** 12471220  
**Subject Initials:** ---

**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 18:51

### Item Details

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<tr>
<td>9</td>
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</table>
**Back to Form**

<table>
<thead>
<tr>
<th>Item</th>
<th>Date</th>
<th>User</th>
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**Subject No**: 12471220
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POT_COVID_ILL 1 - Unscheduled Visit on Dec/24/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

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Subject No: 12471220
Subject Initials: ---

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**Form Version:** 15-Sep-2020 21:55

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**Subject No:** 12471220  
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**Generated Time (GMT):** 29-Mar-2021 18:51

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**Form Version:** 06-Jul-2020 21:55

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**Generated Time (GMT):** 29-Mar-2021 18:51

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**Form Status:** Data Complete, Frozen, Verified  
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- CRF_Sign_1

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**Affidavit:**

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<td>Signed</td>
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**Affidavit:**

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

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

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

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**Affidavit:**

N/A

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**Affidavit:**

By my dated signature below, I, Haylene Nell, 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.
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<td>Data Entry: Line/MH Number: Temporal lobe Epilepsy, Start Date: UNK/UNK/2001, Ongoing: YES</td>
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#### 1.a Line/MH Number:

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

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<td>Svitlana Tonkovydy (b) (4) Query 1: Closed Response satisfies query</td>
<td>Query 1: Closed</td>
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***Confidential***

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FDA-CBER-2021-5683-0894297
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<td>GPD Clin: Please specify type of Epilepsy, if known. Thanks</td>
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**1.b**

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| Dec-01-2020 09:20:17 (UTC+02:00) Harare, Pretoria | ACV0PFEINFP6000  | (b) (4), (b) (6)          | Data Entry: Line/MH Nu 2 mber:  
Medical History: Bilateral tubal ligation Sterilized  
Start Date: UNK/UNK/2018  
Ongoing: NO  
End Date: UNK/UNK/2018 | Transcription Error |

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<th>Value</th>
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</table>
| Oct-12-2020 10:34:23 (UTC+02:00) Harare, Pretoria | ACV0PFEINFP6000  | (b) (4), (b) (6)          | Data Entry: Line/MH Nu 2 mber:  
Medical History: Bilateral tubal ligation Sterilized  
Start Date: UNK/UNK/2018 | Transcription Error |
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**Data Entry:**
- **Line/MH Number:** 2
- **Medical History Term:** Steralized
- **Start Date:** UNK/UNK/2018
- **Ongoing:** YES

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

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<td>Query 2: Reissued:Opened GPD CLIN: Please clarify what information is to be updated. Thank you.</td>
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<tr>
<td>Oct-29-2020 22:35:52</td>
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<td>Query 2: Candidate CLINQUERY: Since bilateral tubal ligation is not sufficient to confirm subject was not of childbearing potential, please clarify if there is any other information that may be added to the MH to confirm childbearing status (no preg test at visit 1).</td>
</tr>
<tr>
<td>Date</td>
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<td>User</td>
<td>Reason</td>
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<td>Bilateral tubal ligation Sterilized</td>
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<td>(UTC+02:00) Pretoria</td>
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<tr>
<td>Date</td>
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<tr>
<td>Oct-09-2020 07:52:27</td>
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</table>

This page contains information about the medical history of a participant, including details on past medical procedures such as bilateral tubal ligation and possible next steps to clarify childbearing status.
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<tr>
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<th>Site/Time Zone</th>
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<tbody>
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<td>Query 1: Reissued:Opened  GPD CLIN: Procedure should not be marked as ongoing, please update if appropriate. Thank you.</td>
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<td>Query 1: Answered  Procedure is not ongoing, however the result after the procedure is ongoing. Please clarify whether the procedure should be marked as ongoing or not.</td>
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<td>Query 1: Opened  GPD CLIN: Subject is noted to have had a surgical procedure of 'bilateral tubal ligation' which is noted as ongoing since 2018. Please confirm if event should be noted as ongoing. If not, please add stop date.</td>
</tr>
<tr>
<td>Oct-09-2020 07:52:27 (UTC+02:00) Harare, Pretoria</td>
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### 1. Select appropriate response - What is the subject HIV status?

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### Vital Signs Baseline - eCRF Audit Trail History

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<td><strong>4. Height:</strong></td>
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### 2. Lab Sub-Panel:

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<td><strong>Data Entry:</strong> Oct/8/2020</td>
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### 4. Laboratory Name and Address (Derived)

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### 5. Specimen Type:

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### 6.a

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

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**6.a Test:**

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**6.a Not Done:**

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<th>Reason</th>
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<tr>
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<td>(b) (4), (b) (6)</td>
<td>Query 1: Answered</td>
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<tr>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Opened</td>
</tr>
<tr>
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<td>Data Entry: NOT DONE</td>
<td>Initial Entry</td>
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**Form**: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

**Site Name**: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Subject Initials**: ---

**Generated Time (GMT)**: 29-Mar-2021 18:51
### Back to Form

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<th>Reason</th>
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### 2. Randomization Number:

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### 2. Sample Type

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<th>Location</th>
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<td>Oct-08-2020 12:54:21 (UTC+02:00)</td>
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<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
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### 3. Sample Collected?

<table>
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<tr>
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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-08-2020 20:03:58 (UTC+02:00)</td>
<td>Harare, Pretoria</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Closed, Close Auto Query</td>
</tr>
<tr>
<td>Oct-08-2020 16:09:48 (UTC+02:00)</td>
<td>Harare, Pretoria</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Opened, 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.</td>
</tr>
<tr>
<td>Oct-08-2020 12:54:21 (UTC+02:00)</td>
<td>Harare, Pretoria</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Candidate, 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.</td>
</tr>
<tr>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: YES, Date of Collection: Oct/8/2020, Initial Entry</td>
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### 5.a Sample ID

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### 5.b Sample ID

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### 5.c Sample ID

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<td>Initial Entry</td>
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<table>
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<tbody>
<tr>
<td>Oct-08-2020 12:54:34</td>
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<td>Initial Entry</td>
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2. **Sample Type**

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

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<th>Reason</th>
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<td>Close Auto Query</td>
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<table>
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<th>Reason</th>
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<tbody>
<tr>
<td>Oct-08-2020 16:09:48</td>
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<td>Query 1: Opened</td>
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<table>
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<th>Value</th>
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<th>Reason</th>
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**5.a**
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### 5.a Sample ID

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

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### 2. Treatment Name

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### 3. Formulation:

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<td>Initial Entry</td>
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### 4. Dose Date Time:

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<td>Initial Entry</td>
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<td>(UTC+02:00) Harare, Pretoria</td>
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### 5. Anatomical Location:

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### 6. Body Side:

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<td>(UTC+02:00) Harare, Pretoria</td>
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### 7. Route:

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

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<th>Reason</th>
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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?

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<th>User</th>
<th>Value</th>
<th>Reason</th>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: YES</td>
<td>Initial Entry</td>
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</table>
### 1. Select appropriate response - Reactogenicity diary collection

<table>
<thead>
<tr>
<th>Date</th>
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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Oct-19-2020 11:25:46</td>
<td>(UTC+02:00) Harare, Pretoria</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Closed Issue resolved. Subject is not subset of 'Reactogenicity Diary collection' now.</td>
</tr>
<tr>
<td>Oct-16-2020 14:25:03</td>
<td>(UTC+02:00) Harare, Pretoria</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Reissued:Candidate Email to be sent for CRA/Signant notification</td>
</tr>
<tr>
<td>Oct-15-2020 10:23:37</td>
<td>(UTC+02:00) Harare, Pretoria</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Answered Data clarification sent.</td>
</tr>
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<td>Oct-14-2020 14:22:33</td>
<td>(UTC+02:00) Harare, Pretoria</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Opened eDiary: Per Trial Max, Subject is the subset of 'Reactogenicity Diary collection'. Please review and consider to update response for 'Reactogenicity diary collection' as 'Yes', else clarify in query response. Thanks.</td>
</tr>
<tr>
<td>Oct-08-2020 12:55:08</td>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT Initial Entry</td>
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### 1. Date of Visit

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**User Details:**
- (b) (4)
- (b) (6)
## 1. Date:

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<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
</table>
| Oct-28-2020 14:00:54 (UTC+02:00) Harare, Pretoria | ACV0PFEINFP6000 | (b) (4), (b) (6) | **Data Entry:**  
Oct/28/2020 | Initial Entry |

## 2.a

### 2.a Record Identifier:

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| Oct-28-2020 14:00:54 (UTC+02:00) Harare, Pretoria | ACV0PFEINFP6000 | (b) (4), (b) (6) | **Data Entry:**  
1 | Initial Entry |

### 2.a Temperature:

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37.0 | Initial Entry |

### 2.a Unit:

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| Oct-28-2020 14:00:54 (UTC+02:00) Harare, Pretoria | ACV0PFEINFP6000 | (b) (4), (b) (6) | **Data Entry:**  
C | Initial Entry |

### 2.a Temperature Location:

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<td>(b) (4)</td>
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<td>Initial Entry</td>
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<tr>
<td>-------------------------------------------------</td>
<td>------------</td>
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**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Site No:** 1247

**Subject No:** 12471220

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

**Generated Time (GMT):** 29-Mar-2021 18:51

**Data Entry:** ORAL CAVITY
### 1. Lab Panel:

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<td>Oct-28-2020 14:01:13</td>
<td>(UTC+02:00) Harare, Pretoria</td>
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### 2. Lab Sub-Panel:

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### 3. Collection Date:

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

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### 5. Specimen Type:

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### 6.a

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<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: Sponsor-Defin 113</td>
</tr>
<tr>
<td>Date</td>
<td>Location</td>
<td>User</td>
<td>Value</td>
<td>Reason</td>
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<td>Oct-28-2020 14:01:13 (UTC+02:00) Harare, Pretoria</td>
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### 6.a Result:

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

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### 2. Sample Type

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<td>ACV0PFEINFP6000</td>
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<td><strong>Data Entry:</strong> NASAL_SWAB</td>
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### 3. Sample Collected?

<table>
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<th>Location</th>
<th>User</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
<td>Oct-29-2020 10:06:31 (UTC+02:00) Harare, Pretoria</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Deleted</td>
<td>Close Auto Query</td>
</tr>
<tr>
<td>Oct-28-2020 14:01:33 (UTC+02:00) Harare, Pretoria</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Candidate</td>
<td>'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.</td>
</tr>
<tr>
<td>Oct-28-2020 14:01:33 (UTC+02:00) Harare, Pretoria</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> YES Date of Collection:</td>
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### 5.a

<table>
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<td><strong>Data Entry:</strong> Sample ID: BM9FKT</td>
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</table>
### 5.a Sample ID

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

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2. Treatment Name

<table>
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<td>Harare, Pretoria</td>
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<td>auto calc (autocalc) Data Entry: BLINDED THERAPY</td>
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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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<td>Initial Entry</td>
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<td>(UTC+02:00) Harare,</td>
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<td>INTRAMUSCULAR</td>
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10. Timeframe Subject Was Observed

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

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<td>Initial Entry</td>
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### 1. Date of Visit

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**Data Entry:** Nov/30/2020
### 1. Data Origin

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### 2. Sample Type

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### 3. Sample Collected?

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<td>Response satisfies query</td>
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<tr>
<td>Nov-30-2020 21:07:32</td>
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<td>auto query</td>
<td>Query 1 : Closed</td>
<td>Close Auto Query</td>
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<td>Reason</td>
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**5.a Sample ID**

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<td><strong>Data Entry:</strong> BR7MSB</td>
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<tr>
<td>(UTC+02:00) Harare,</td>
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## 5.b

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<td>Data Entry: Sample ID: BRY9S5</td>
<td>Initial Entry</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. Date of Visit

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### 3. COVID-19 Illness Visit

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### Back to Form

#### 1. Date of Assessment:

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#### 2. Date of First Symptom Started:

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#### 3. Symptoms Ongoing?

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#### 4.a

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**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF

**Audit Trail History**

**Form Status:** Data Complete
**4.c Symptoms:**

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**4.c Was symptom present?**

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**4.d Symptoms:**

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**4.d Was symptom present?**

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### 4.e Was symptom present?

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### 4.f Symptoms:

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### 4.f Was symptom present?

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### 4.g
### 4.g Symptoms:

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Symptom NEW OR INCREASED SORE THROAT  
Symptom Present: YES | Initial Entry |

### 4.g Was symptom present?

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### 4.h

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Symptoms: DIARRHEA  
Symptom Present: NO | Initial Entry |

### 4.h Symptoms:

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### 4.h Was symptom present?

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- **4.i Symptoms:**

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- **4.i Was symptom present?**

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2. **Specimen Type:**

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4. **Assay Code and Description:**

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### 8. Comments/Findings/Details:

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### 9. Trade Name Other, Specify:

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### Data Origin

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### Sample Type

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### Sample Collected?

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### 5.a

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(b) (4)
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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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<tr>
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<td>Date</td>
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***Confidential***
### 1.d Physician or Healthcare Professional:

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### 1.e

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Data Entry: Type of Practitioner: URGENT CARE
Occurrence of Visits or Contacts: NO
Initial Entry
### 1.e Physician or Healthcare Professional:

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

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### 1.f Physician or Healthcare Professional:

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### 1.f 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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<td><strong>Form:</strong> HEALTH CARE UTILIZATION - eCRF Audit Trail History</td>
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<td><strong>Visit:</strong> POT_COVID_ILL 1 - Unscheduled Visit on Dec/24/2020</td>
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<td><strong>Site No:</strong> 1247</td>
<td><strong>Site Name:</strong> (1247) Tiervlei Trial Centre-Karl Bremer Hospital</td>
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<td><strong>Generated Time (GMT):</strong> 29-Mar-2021 18:51</td>
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| Pretoria | (b) (4), (b) (6) |
### 1. What is the treatment Identifier?

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### 2. Concomitant Non-drug Treatment Pre-specified:

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### 3. Treatment:

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### 4. Treatment:

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### 5. Start Date:

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### 6. Ongoing?

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Pretoria
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**3. Collection Date:**

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**Form Version:** 15-Sep-2020 21:51  
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**Subject No:** 12471220  
**Generated By:** [redacted]  
**Generated Time (GMT):** 29-Mar-2021 18:51
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**Generated By:** (b) (4)  
**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History  
**Form Status:** Data Complete  
**Site Name:** (1247) Tiervei Trial Centre-Karl Bremer Hospital  
**Subject Initials:** ---  
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***Confidential***
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Subject No: 12471220
Generated By: (b) (4)

Lab Normal Range: Not Done

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Subject No: 12471220
Generated By: (b) (4)
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Form Status: Data Complete
Site Name: (1247) Tievlei Trial Centre-Karl Bremer Hospital
Subject Initials: ---
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Form Version: 15-Sep-2020 21:55
Site No: 1247
Subject No: 12471220
Generated By: (b) (4)

Test:: Not Done
Result:: Not Done
Not Done:: Not Done
Lab Normal Range: Not Done

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History
Form Status: Data Complete
Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 18:51
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## Test

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***Confidential***

FDA-CBER-2021-5683-0894380
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**Form Version:** 15-Sep-2020 21:55  
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**Subject No:** 12471220  
**Generated By:** (b) (4)  
**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History  
**Form Status:** Data Complete  
**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 18:51
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**Form:** VITAL SIGNS - COVID - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:52  
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**Subject Initials:** ---

**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 18:51

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### 2.a SPO2 Pulse Oximetry %

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

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

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

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4. **Medication:**

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

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6. **Ongoing?**

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**Back to Form**
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**Form Version:** 06-Jul-2020 21:55  
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**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Date of Assessment:**

**2. Location of Assessment:**

**3. Type of Imaging Exam:**

**4. Assessment:**
### 1. Date of Visit

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<td>Initial Entry</td>
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1. Data Origin

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<th>Reason</th>
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<tbody>
<tr>
<td>Jan-22-2021 14:07:30 (UTC+02:00) Harare, Pretoria</td>
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<td>auto calc (autocalc)</td>
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2. Sample Type

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

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

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### 5.b Sample ID

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Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1247

Site Name: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

Subject No: 12471220

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51
### 1. Assessments

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<td>auto query (autoquery)</td>
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<td>(UTC+02:00) Harare, Pretoria</td>
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<td>auto query (autoquery)</td>
<td>Query 1: Candidate</td>
<td>'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.</td>
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<tr>
<td>Nov-02-2020 13:37:37</td>
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2. **Was contact made?**

<table>
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| Nov-02-2020 13:38:28 (UTC+02:00) Harare, Pretoria | ACV0PFEINFP6000 | (b) (4), (b) (6) | **Data Entry:** YES | Date of Contact:
Oct/30/2020
Contact Outcome:
VISIT NOT REQUIRED, DATA ENTRY ERROR IN E-DIARY | Initial Entry |
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**Visit:** Logs - Unscheduled  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1247  
**Subject No:** 12471220  
**Generated By:** (b) (4)  
**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 18:51

### Back to Form

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<p>| FDA-CBER-2021-5683-0894400 |</p>
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**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1247  
**Subject No:** 12471220  
**Generated By:** [b] (4)  
**Site Name:** (1247) Tiervlei Trial Centre-Karl Bremer Hospital  
**Generated Time (GMT):** 29-Mar-2021 18:51

Back to Form
### 1. Category:

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<th>Reason</th>
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### 2. AE ID:

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<td>Harare, Pretoria</td>
<td>auto calc</td>
<td>1</td>
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### 3. Adverse Event:
*(If possible specify diagnosis, not individual symptoms)*

<table>
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<th>Date</th>
<th>Location</th>
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<th>Value</th>
<th>Reason</th>
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### 4. Start Date Time:

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

<table>
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<tbody>
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<td>NO</td>
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### 6. Toxicity Grade:

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7. Is the adverse event serious?

*If Yes, NOTIFY PFIZER IMMEDIATELY.*

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

<table>
<thead>
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<th>Location</th>
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<th>Value</th>
<th>Reason</th>
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<td>(b) (4) (6)</td>
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8. Is this adverse event the result of a study Medication Error?

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

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

<table>
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<th>Reason</th>
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10. Latest Action Taken with Study Treatment:

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11. Was a Concomitant Medication given?

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12. Was a Non-Drug Treatment given?

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13. What was the outcome of this adverse event?

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

<table>
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<th>Reason</th>
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1. **Category:**

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2. **AE ID:**

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3. **Adverse Event:**

(If possible specify diagnosis, not individual symptoms)

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<th>Reason</th>
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<tbody>
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5. **Is the adverse event still ongoing?**

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<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Nov-30-2020 10:44:40</td>
<td>(UTC+02:00) Harare, Pretoria</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
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</table>

6. **Toxicity Grade:**

<table>
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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
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<td>(UTC+02:00) Harare, Pretoria</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: End Date Time: Oct/29/2020 UNK:UNK</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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8. Is this adverse event the result of a study Medication Error?

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

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9. Is this event related to study treatment:

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<th>Reason</th>
</tr>
</thead>
<tbody>
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10. Latest Action Taken with Study Treatment:

<table>
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<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
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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>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-30-2020 10:44:40</td>
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### 12. Was a Non-Drug Treatment given?

<table>
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<th>Reason</th>
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<td>Initial Entry</td>
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### 13. What was the outcome of this adverse event?

<table>
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<tr>
<th>Date</th>
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<th>Value</th>
<th>Reason</th>
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<tbody>
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<td>Nov-30-2020 10:44:40 (UTC+02:00) Harare, Pretoria</td>
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<td><strong>Data Entry:</strong> RECOVERED/RESOLVED</td>
<td>Initial Entry</td>
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### 14. Did the adverse event cause the subject to be discontinued from the study?

<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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1. **Category:**

<table>
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<th>Reason</th>
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2. **AE ID:**

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<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
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3. **Adverse Event:**

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

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<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tr>
<td>Dec-01-2020 18:20:23</td>
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<tr>
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<td>Dec-01-2020 10:18:00</td>
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4. **Start Date Time:**
5. Is the adverse event still ongoing?

<table>
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<th>Reason</th>
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<tbody>
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<td>Initial Entry</td>
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<td>(b) (6)</td>
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6. Toxicity Grade:

<table>
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<th>Reason</th>
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<td>(b) (6)</td>
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</tr>
<tr>
<td>Pretoria</td>
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7. Is the adverse event serious?

*If Yes, NOTIFY PFIZER IMMEDIATELY.*

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

<table>
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<tr>
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<tbody>
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<tr>
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<td>(b) (6)</td>
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<tr>
<td>Pretoria</td>
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</table>

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

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

<table>
<thead>
<tr>
<th>Date</th>
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<tbody>
<tr>
<td>Nov-30-2020 10:45:24</td>
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<td>Initial Entry</td>
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<tr>
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<td>(b) (6)</td>
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<td></td>
</tr>
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</table>

9. Is this event related to study treatment:
### 10. Latest Action Taken with Study Treatment:

<table>
<thead>
<tr>
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<td>(UTC+02:00) Harare, Pretoria</td>
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<td><strong>Data Entry:</strong> RELATED</td>
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### 11. Was a Concomitant Medication given?

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

<table>
<thead>
<tr>
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### 13. What was the outcome of this adverse event?

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<td><strong>Data Entry:</strong> RECOVERED/RESOLVED</td>
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</table>

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

<table>
<thead>
<tr>
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### 1. Category:

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<th>Reason</th>
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### 2. AE ID:

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### 3. Adverse Event:

*If possible specify diagnosis, not individual symptoms*

<table>
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<tr>
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### 4. Start Date Time:

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

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### 6. Toxicity Grade:

<table>
<thead>
<tr>
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7. Is the adverse event serious?

*If Yes, NOTIFY PFIZER IMMEDIATELY.*

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

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

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

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9. Is this event related to study treatment:

<table>
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10. Latest Action Taken with Study Treatment:

<table>
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<tr>
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11. Was a Concomitant Medication given?

<table>
<thead>
<tr>
<th>Date</th>
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12. **Was a Non-Drug Treatment given?**

<table>
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<th>Reason</th>
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13. **What was the outcome of this adverse event?**

<table>
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<tr>
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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
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<td>(b) (4) (6)</td>
<td>Data Entry: RECOVERED/RESOLVED Initial Entry</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>
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<tbody>
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<td>Date</td>
<td>Location</td>
<td>User</td>
<td>Value</td>
<td>Reason</td>
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<td>-----------</td>
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**1. Category:**

**2. AE ID:**

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<th>Value</th>
<th>Reason</th>
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<td>Initial Entry</td>
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**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>Dec-02-2020 20:47:23 (UTC+02:00) Harare, Pretoria</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Dec-02-2020 08:16:46 (UTC+02:00) Harare, Pretoria</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Answered</td>
<td>No- related to vaccine</td>
</tr>
<tr>
<td>Dec-01-2020 18:22:37 (UTC+02:00) Harare, Pretoria</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Reissued:Opened</td>
<td>GPD CLIN: Please confirm if AE of ongoing Grade 2 'joint pain' could be related to COVID-19. If confirmed, please conduct a COVID illness visit and swab collection as soon as possible and capture term on SOD form only. Please review and update.</td>
</tr>
<tr>
<td>Dec-01-2020 18:21:23 (UTC+02:00) Harare, Pretoria</td>
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<td>(b) (4), (b) (6)</td>
<td>Query 1: Closed</td>
<td>Response satisfies query</td>
</tr>
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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:
1247

### Site Name:
(1247) Tiervlei Trial Centre-Karl Bremer Hospital

### Subject No:
12471220

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

### Generated Time (GMT):
29-Mar-2021 18:51

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<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Nov-30-2020 10:47:33 (UTC+02:00) Harare, Pretoria</td>
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<td>Joint pain</td>
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</tr>
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<td>Query 2: Opened</td>
</tr>
<tr>
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<td>Data Entry: Generalized Joint pain</td>
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<tr>
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<td></td>
<td>Query 1: Answered</td>
</tr>
<tr>
<td>Dec-01-2020 10:18:34 (UTC+02:00) Harare, Pretoria</td>
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<td>auto query (autoquery)</td>
<td></td>
<td>Query 2: Answered</td>
</tr>
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<td>Nov-30-2020 20:23:54 (UTC+02:00) Harare, Pretoria</td>
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<td>(b) (4), (b) (6)</td>
<td></td>
<td>Query 1: Opened</td>
</tr>
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**4. Start Date Time:**

<table>
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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-30-2020 10:47:33 (UTC+02:00) Harare, Pretoria</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Oct/30/2020 UNK:UNK</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

---

**GPD CLIN:** Please confirm if AE of ongoing Grade 2 'joint pain' could be related to COVID-19. If confirmed, please conduct a COVID illness visit and swab collection as soon as possible and capture term on SOD form only. Please review and update.

**CLINQUERY:** Please update the CRF to specify anatomical site in the event term. If generalized, please state as such. Thank you.
### 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>(UTC+02:00)</td>
<td></td>
<td>(b) (4)</td>
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</tr>
<tr>
<td>Jan-27-2021 11:19:20</td>
<td>Harare, Pretoria</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Answered</td>
<td>Confirmed still ongoing</td>
</tr>
<tr>
<td>(UTC+02:00)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jan-25-2021 17:25:17</td>
<td>Harare, Pretoria</td>
<td>Hayley Wyper</td>
<td>Query 2: Opened</td>
<td>CLINQUERY: Please review if event remains ongoing. Else, report end date and update event outcome status</td>
</tr>
<tr>
<td>(UTC+02:00)</td>
<td></td>
<td>(b) (4)</td>
<td></td>
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<td>(UTC+02:00)</td>
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<td>(b) (4)</td>
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<td></td>
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<tr>
<td>Dec-03-2020 07:49:55</td>
<td>Harare, Pretoria</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Answered</td>
<td>Ongoing at this stage - patient is being follow up by GP and will forward results as soon as they are available</td>
</tr>
<tr>
<td>(UTC+02:00)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Dec-02-2020 14:43:06</td>
<td>Harare, Pretoria</td>
<td>Juleen Gayed</td>
<td>Query 1: Opened</td>
<td>Clin: Please confirm if this AE is still ongoing?</td>
</tr>
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<td>(b) (4)</td>
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<tr>
<td>Nov-30-2020 10:47:33</td>
<td>Harare, Pretoria</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: YES</td>
<td>Initial Entry</td>
</tr>
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### 6. Toxicity Grade:

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<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Harare, Pretoria</td>
<td>(b) (4)</td>
<td>Data Entry:</td>
<td>Initial Entry</td>
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<td>(UTC+02:00)</td>
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<td>(b) (6)</td>
<td>2</td>
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### 7. Is the adverse event serious?
If Yes, NOTIFY PFIZER IMMEDIATELY.

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

<table>
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<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-30-2020 10:47:33</td>
<td>(UTC+02:00)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
<td>Data Entry: NO</td>
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<tr>
<td></td>
<td>Harare, Pretoria</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>
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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-30-2020 10:47:33</td>
<td>(UTC+02:00)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
<td>Data Entry: NO</td>
</tr>
<tr>
<td></td>
<td>Harare, Pretoria</td>
<td></td>
<td></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>Nov-30-2020 10:47:33</td>
<td>(UTC+02:00)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
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<td>Harare, Pretoria</td>
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</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>
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<tbody>
<tr>
<td>Nov-30-2020 10:47:33</td>
<td>(UTC+02:00)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
<td>Data Entry: NOT APPLICABLE</td>
</tr>
<tr>
<td></td>
<td>Harare, Pretoria</td>
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<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>
<tbody>
<tr>
<td>Nov-30-2020 10:47:33</td>
<td>(UTC+02:00)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (6)</td>
<td>Data Entry: YES</td>
</tr>
<tr>
<td></td>
<td>Harare, Pretoria</td>
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12. Was a Non-Drug Treatment given?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
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</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>Nov-30-2020 10:47:33</td>
<td>Harare, Pretoria</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</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>
</thead>
<tbody>
<tr>
<td>Nov-30-2020 10:47:33</td>
<td>Harare, Pretoria</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>Dec-01-2020 13:17:24 (UTC+02:00)</td>
<td>Harare, Pretoria</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
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### 2. Medication Error (Type of Medication Error):

<table>
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<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec-01-2020 13:17:24 (UTC+02:00)</td>
<td>Harare, Pretoria</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Not Applicable</td>
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</table>

### 3. Start Date:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec-01-2020 13:17:24 (UTC+02:00)</td>
<td>Harare, Pretoria</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Not Applicable</td>
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</table>

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

<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>Dec-01-2020 13:17:24 (UTC+02:00)</td>
<td>Harare, Pretoria</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Not Applicable</td>
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</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec-01-2020 13:17:24 (UTC+02:00)</td>
<td>Harare, Pretoria</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
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### 6. Was a Concomitant Medication given?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec-01-2020 13:17:24 (UTC+02:00)</td>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Not Applicable</td>
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7. Was a Non-Drug Treatment given?

<table>
<thead>
<tr>
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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: Not Applicable</td>
<td>Initial Entry</td>
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8. Did the Medication Error cause the subject to be discontinued from the study?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
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<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec-01-2020 13:17:24</td>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: Not Applicable</td>
<td>Initial Entry</td>
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</table>

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

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

10. Serious Adverse Event Number: For Pfizer Use Only

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec-01-2020 13:17:24</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Not Applicable</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>
1. What is the medication identifier?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec-01-2020 13:17:55</td>
<td>(UTC+02:00) Harare, Pretoria</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Not Applicable</td>
<td>Initial Entry</td>
</tr>
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</table>

2. Category:

<table>
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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec-01-2020 13:17:55</td>
<td>(UTC+02:00) Harare, Pretoria</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Not Applicable</td>
<td>Initial Entry</td>
</tr>
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</table>

3. Concomitant Medications Pre-specified:

<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>Dec-01-2020 13:17:55</td>
<td>(UTC+02:00) Harare, Pretoria</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Not Applicable</td>
<td>Initial Entry</td>
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</tbody>
</table>

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).

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec-01-2020 13:17:55</td>
<td>(UTC+02:00) Harare, Pretoria</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Not Applicable</td>
<td>Initial Entry</td>
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5. Date:

<table>
<thead>
<tr>
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<th>Location</th>
<th>User</th>
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<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Dec-01-2020 13:17:55</td>
<td>(UTC+02:00) Harare, Pretoria</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Not Applicable</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>
### 1. What is the medication identifier?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec-01-2020 13:18:26 (UTC+02:00) Harare, Pretoria</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Not Applicable</td>
<td>Initial Entry</td>
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</table>

### 2. Category:

<table>
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<tr>
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<th>Location</th>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Not Applicable</td>
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### 3. Concomitant Medications Pre-specified:

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<tr>
<td>Dec-01-2020 13:18:26 (UTC+02:00) Harare, Pretoria</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Not Applicable</td>
<td>Initial Entry</td>
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</tbody>
</table>

### 4. Medication:

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<tbody>
<tr>
<td>Dec-01-2020 13:18:26 (UTC+02:00) Harare, Pretoria</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
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</table>

### 5. Dose:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Dec-01-2020 13:18:26 (UTC+02:00) Harare, Pretoria</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Not Applicable</td>
<td>Initial Entry</td>
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### 6. Dose Unit:
### 7. Dose Frequency:

<table>
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<tbody>
<tr>
<td>Dec-01-2020 13:18:26</td>
<td>Harare, Pretoria</td>
<td>(b) (4) (6)</td>
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### 8. Route:

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<tbody>
<tr>
<td>Dec-01-2020 13:18:26</td>
<td>Harare, Pretoria</td>
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<td><strong>Data Entry:</strong></td>
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### 9. Start Date:

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<th>Reason</th>
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<tbody>
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<td>Dec-01-2020 13:18:26</td>
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### 10. Ongoing?

<table>
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<tr>
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<th>Reason</th>
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<tbody>
<tr>
<td>Dec-01-2020 13:18:26</td>
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<td>(b) (4) (6)</td>
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**1. Category:**

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<td>(UTC+02:00) Harare, Pretoria</td>
<td>(b) (4), (b) (6)</td>
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<td>Initial Entry</td>
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**2. What is the treatment Identifier?**

<table>
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<tr>
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<th>Location</th>
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<th>Value</th>
<th>Reason</th>
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<tbody>
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<td>(b) (4), (b) (6)</td>
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<td>Initial Entry</td>
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**3. Concomitant Non-drug Treatment Pre-specified:**

<table>
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<th>Reason</th>
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<td>Initial Entry</td>
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**4. Treatment:**

<table>
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<tbody>
<tr>
<td>Dec-01-2020 13:18:44</td>
<td>(UTC+02:00) Harare, Pretoria</td>
<td>(b) (4), (b) (6)</td>
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</table>

**5. Start Date:**

<table>
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<tr>
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<th>Reason</th>
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<tbody>
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<td>(b) (4), (b) (6)</td>
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**6. Ongoing?**

<table>
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<tbody>
<tr>
<td>Dec-01-2020 13:18:44</td>
<td>(UTC+02:00) Harare, Pretoria</td>
<td>(b) (4), (b) (6)</td>
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### 1. Transfusion Type:

<table>
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<tbody>
<tr>
<td>Dec-01-2020 13:19:01</td>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: Not Applicable</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC+02:00) Harare, Pretoria</td>
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### 2. Date of Transfusion:

<table>
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<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
<tr>
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<td>Data Entry: Not Applicable</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC+02:00) Harare, Pretoria</td>
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</table>
**1. Date of Completion/Discontinuation/Death:**

<table>
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<th>Reason</th>
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<tbody>
<tr>
<td>Nov-30-2020 10:41:32</td>
<td>(UTC+02:00) Harare, Pretoria</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4)</td>
<td>Data Entry: Nov/30/2020</td>
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**2. Phase of Disposition:**

<table>
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<th>Reason</th>
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<tbody>
<tr>
<td>Nov-30-2020 10:41:32</td>
<td>(UTC+02:00) Harare, Pretoria</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: VACCINATION</td>
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**3. Status:**

<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>
<tr>
<td>Nov-30-2020 10:41:32</td>
<td>(UTC+02:00) Harare, Pretoria</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4) (b) (6)</td>
<td>Data Entry: COMPLETED</td>
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</table>
1. Date of Visit

<table>
<thead>
<tr>
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<th>Location</th>
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<tbody>
<tr>
<td>Feb-23-2021 13:32:14</td>
<td>(UTC+02:00) Harare, Pretoria</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4)</td>
<td>Data Entry: Jan/27/2021</td>
</tr>
</tbody>
</table>

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

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

**Site Name**: (1247) Tiervlei Trial Centre-Karl Bremer Hospital

**Generated Time (GMT)**: 29-Mar-2021 18:51
### 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>
</table>
| Feb-24-2021 16:55:04  | (UTC+02:00) Harare, Pretoria      | ACV0PFEINFP6000 | (b) (4), (b) (6)                                                     | **Data Entry:** Participant is willing to return for Vaccination 3  
|                       |                                   |               |                                                                      | Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2 |
| (b) (4)               |                                   |               |                                                                       | Changed Information            |
| Feb-23-2021 13:32:23   | (UTC+02:00) Harare, Pretoria      | ACV0PFEINFP6000 | (b) (4), (3) (6)                                                     | **Data Entry:** Participant is NOT willing to return for Vaccination 3 OR otherwise not eligible |
|                       |                                   |               |                                                                       | Initial Entry                  |
### 1. Date Treatment Unblinded:

<table>
<thead>
<tr>
<th>Date</th>
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<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Feb-23-2021 13:33:30 (UTC+02:00) Harare, Pretoria</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Jan/27/2021</td>
<td>Initial Entry</td>
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</table>

### 2. Primary Reason for Unblinding:

<table>
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<th>Date</th>
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<th>Reason</th>
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<tbody>
<tr>
<td>Feb-24-2021 21:45:07 (UTC+02:00) Harare, Pretoria</td>
<td>ACV0PFEINFP6000</td>
<td>Rivkah Rosen (b) (4)</td>
<td>Query 1: Closed</td>
<td>Response satisfies query</td>
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<tr>
<td>Feb-24-2021 16:55:58 (UTC+02:00) Harare, Pretoria</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Answered</td>
<td>&quot;Participant is willing to return&quot; is selected</td>
</tr>
<tr>
<td>Feb-24-2021 12:34:19 (UTC+02:00) Harare, Pretoria</td>
<td>ACV0PFEINFP6000,InFormAdapter.Discrepancy</td>
<td>DMW QUERY (b) (4)</td>
<td>Query 1: Opened</td>
<td>DMW7399252;Primary Reason for Unblinding is &quot;ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION&quot;, but &quot;Participant is willing to return for Vaccination 3&quot; is not selected in the Further Vaccination Confirmation CRF. Please review and update as appropriate.</td>
</tr>
<tr>
<td>Feb-23-2021 13:33:30 (UTC+02:00) Harare, Pretoria</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry:  ASSESS ELIGIBILITY</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>Header Text: c4591001</td>
<td>Form: TREATMENT UNBLINDED - eCRF Audit Trail History</td>
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<tr>
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<td>---------------------------------------------------</td>
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<td>Visit: Disposition - Unscheduled</td>
<td>Form Status: Data Complete, Frozen, Verified</td>
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<tr>
<td>Form Version: 22-Apr-2020 21:03</td>
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<tr>
<td>Site No: 1247</td>
<td>Subject No: 12471220</td>
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<td>Subject Initials: ---</td>
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<td>Generated Time (GMT): 29-Mar-2021 18:51</td>
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</table>

**FOR ADDITION AL V ACCIDENT**
### 1. Withdrawal of Consent Date :

<table>
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<tr>
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<td>(b) (4); (b) (6)</td>
<td>Data Entry: Not Applicable</td>
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Back to Form

# Date of Collection / Notification of Death:

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<th>Value</th>
<th>Reason</th>
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<td>(b) (4), (b) (6)</td>
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</table>

**Data Entry:** Not Applicable

**Initial Entry**
### 1. Subject Status

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<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Nov-30-2020 10:41:32 (UTC+02:00) Harare, Pretoria</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> FOLLOW-UP</td>
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<tr>
<td>Oct-08-2020 12:54:09 (UTC+02:00) Harare, Pretoria</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> ENROLLED/RANDOMIZED</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>Oct-08-2020 12:51:55 (UTC+02:00) Harare, Pretoria</td>
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<td><strong>Data Entry:</strong> SCREENED</td>
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### 2. Subject Status Date

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<th>Reason</th>
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### 1. Casebook Signature

<table>
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<td>Nov-11-2020 11:35:11</td>
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