**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>
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<tbody>
<tr>
<td>1.</td>
<td>Select appropriate response</td>
<td>06 OCT 2020</td>
</tr>
<tr>
<td></td>
<td>- Protocol version</td>
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</tr>
<tr>
<td>2.</td>
<td>Select appropriate response</td>
<td>STAGE 3 COHORTS</td>
</tr>
<tr>
<td></td>
<td>- What cohort does the subject belong to?</td>
<td></td>
</tr>
</tbody>
</table>
### Informed Consent

1. Consent Was: OBTAINED
   - Date Written Consent Obtained
   - Oct/20/2020
### eCRF Audit Trail History

**Demography**

<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>1.</td>
<td>Subject ID</td>
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<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>
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</table>
**eCRF Audit Trail History**

**Date of Visit**

1. **Date of Visit**
   - Oct/20/2020

2. **Erroneous Visit**
   -
<table>
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<tr>
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<td>Description of Inclusion Criterion Not Met</td>
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<table>
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<th>Exclusion Criteria Met</th>
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<td>Description of Exclusion Criterion Met</td>
<td>Not Applicable</td>
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**Disposition - Screening**

1. **Date of Completion/Discontinuation/Death**: Oct/20/2020
2. **Phase of Disposition**: SCREENING
3. **Status**: COMPLETED
4. **Specify Status**: [ ]
## 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>
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</thead>
<tbody>
<tr>
<td>1.a</td>
<td>[Gout]</td>
<td>Jan/UNK/2019</td>
<td>YES</td>
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<td>1.b</td>
<td>[Gastroesophageal Reflux Disease]</td>
<td>UNK/UNK/2015</td>
<td>YES</td>
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<tr>
<td>1.c</td>
<td>[Tobacco Dependence 1/2 ppd]</td>
<td>UNK/UNK/1968</td>
<td>YES</td>
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<td>Line/MH Number:</td>
<td>4</td>
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<tr>
<td>----------------</td>
<td>---</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:</td>
<td>osteoarthritis right knee</td>
<td></td>
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<tr>
<td>Start Date:</td>
<td>UNK/UNK/2000</td>
<td></td>
<td></td>
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<tr>
<td>Ongoing:</td>
<td>YES</td>
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<tr>
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<tbody>
<tr>
<td>Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:</td>
<td>partial knee replacement</td>
</tr>
<tr>
<td>Start Date:</td>
<td>UNK/UNK/2009</td>
</tr>
<tr>
<td>Ongoing:</td>
<td>NO</td>
</tr>
<tr>
<td>End Date:</td>
<td>UNK/UNK/2009</td>
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</tbody>
</table>

<table>
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<tr>
<th>Line/MH Number:</th>
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<tbody>
<tr>
<td>Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:</td>
<td>knee arthroscopy right</td>
</tr>
<tr>
<td>Start Date:</td>
<td>UNK/UNK/2005</td>
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<tr>
<td>Ongoing:</td>
<td>NO</td>
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<tr>
<td>End Date:</td>
<td>UNK/UNK/2005</td>
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</table>
### eCRF Audit Trail History

**HIV Status**

<table>
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<tr>
<th>1.</th>
<th>Select appropriate response</th>
<th>The subject is NOT known to be HIV POSITIVE</th>
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<tbody>
<tr>
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<td>- What is the subject HIV status?</td>
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</table>
### Vital Signs

<p>| | |</p>
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>1.</td>
<td>Date: Oct/20/2020</td>
</tr>
<tr>
<td>2.</td>
<td>Weight: [226.0]</td>
</tr>
<tr>
<td>3.</td>
<td>Unit: LB</td>
</tr>
<tr>
<td>4.</td>
<td>Height: [70.0]</td>
</tr>
<tr>
<td>5.</td>
<td>Unit: in</td>
</tr>
<tr>
<td>6.</td>
<td>Body Mass Index: [32.4]</td>
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</table>

### Vital Signs Details

<p>| | |</p>
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<tr>
<th></th>
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<tbody>
<tr>
<td>7.a</td>
<td>Record Identifier: 1</td>
</tr>
<tr>
<td></td>
<td>Temperature: [98.3]</td>
</tr>
<tr>
<td></td>
<td>Unit: F</td>
</tr>
<tr>
<td></td>
<td>Temperature Location: ORAL CAVITY</td>
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**Header Text:** c4591001  
**Visit:** V1_DAY1_VAX1_L  
**Form Version:** 22-Apr-2020 21:03  
**Form:** RANDOMIZATION  
**Site No:** 1251  
**Site Name:** (1251) Achieve Clinical Research  
**Subject No:** 12511250  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 18:51

### eCRF Audit Trail History

#### Disposition

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<th>Oct/20/2020</th>
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<td>2.</td>
<td>Randomization Number:</td>
<td>[270319]</td>
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<tr>
<td>3.</td>
<td>Randomization Group:</td>
<td>[ ]</td>
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</table>

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---

---
### Electronic Sample Tracking

1. **Data Origin**: SITE
2. **Sample Type**: SERUM
3. **Sample Collected?**: YES  
   Date of Collection: Oct/20/2020
4. If no sample was collected or sample was not collected according to protocol, please provide reason: [ ]

### Aliquot

Please enter barcode for each aliquot.

<table>
<thead>
<tr>
<th></th>
<th>Sample ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.a</td>
<td>BR90V0</td>
</tr>
<tr>
<td>5.b</td>
<td>BR90WB</td>
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<tr>
<td>5.c</td>
<td>BR90WC</td>
</tr>
<tr>
<td>5.d</td>
<td>BNWBRR</td>
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<tr>
<td>5.e</td>
<td>BNWBRS</td>
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</table>
# Electronic Sample Tracking

<table>
<thead>
<tr>
<th>1. Data Origin</th>
<th>SITE</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Sample Type</td>
<td>NASAL_SWAB</td>
</tr>
<tr>
<td>3. Sample Collected?</td>
<td>YES</td>
</tr>
<tr>
<td>Date of Collection:</td>
<td>Oct/20/2020</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>
</tbody>
</table>

## Aliquot

Please enter barcode for each aliquot.

| 5.a Sample ID | [BR90T7] |
**eCRF Audit Trail History**

**Vaccination**

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

**Reactogenicity Diary**

<table>
<thead>
<tr>
<th>1. Select appropriate response for Reactogenicity diary collection</th>
<th>NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT</th>
</tr>
</thead>
</table>

---

---

---

---
<table>
<thead>
<tr>
<th>Date of Visit</th>
<th>Nov/11/2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
</tbody>
</table>
### Vital Signs

| 1. Date: | Nov/11/2020 |

### Vital Signs Details

<table>
<thead>
<tr>
<th>2.a</th>
<th>Record Identifier: 1</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Temperature: [97.9]</td>
</tr>
<tr>
<td></td>
<td>Unit: F</td>
</tr>
<tr>
<td></td>
<td>Temperature Location: ORAL CAVITY</td>
</tr>
</tbody>
</table>
### eCRF Audit Trail History

#### Electronic Sample Tracking

<p>| | |</p>
<table>
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<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>
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<tr>
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<td>Date of Collection:</td>
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<tr>
<td>4.</td>
<td>If no sample was collected or sample was not collected according to protocol, please provide reason:</td>
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</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: | Nov/11/2020 09:12
5. Anatomical Location: | DELTOID MUSCLE
6. Body Side: | RIGHT
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**

<table>
<thead>
<tr>
<th>No.</th>
<th>Date of Visit</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Dec/9/2020</td>
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</tr>
<tr>
<td>2.</td>
<td>Erroneous Visit</td>
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</tbody>
</table>
**eCRF Audit Trail History**

### Electronic Sample Tracking

<p>| | |</p>
<table>
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<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>
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<td>Date of Collection:</td>
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<tr>
<td>4.</td>
<td>If no sample was collected or sample was not collected according to protocol, please provide reason:</td>
</tr>
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### Aliquot

Please enter barcode for each aliquot.

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<table>
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<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>5.a</td>
<td>Sample ID</td>
</tr>
<tr>
<td>5.b</td>
<td>Sample ID</td>
</tr>
<tr>
<td>5.c</td>
<td>Sample ID</td>
</tr>
<tr>
<td>Date of Visit</td>
<td></td>
</tr>
<tr>
<td>-----------------------</td>
<td>-------</td>
</tr>
<tr>
<td>1. Date of Visit</td>
<td>//</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
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</table>

**Header Text:** c4591001  
**Visit:** V4_MONTH6_L  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1251  
**Subject No:** 12511250  
**Generated By:** (b) (4)  
**Form:** DATE OF VISIT  
**Form Status:** Not Started  
**Site Name:** (1251) Achieve Clinical Research  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 18:51
<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>
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<tr>
<td>4. If no sample was collected or sample was not collected according to protocol, please provide reason:</td>
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</tbody>
</table>

**Aliquot**

Please enter barcode for each aliquot.

| 5. Sample ID |
|--------------|------------|
| [ ]          |

**Header Text:** c4591001  
**Visit:** V4_MONTH6_L  
**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY  
**Form Version:** 22-Apr-2020 21:03  
**Form Status:** Not Started  
**Site No:** 1251  
**Site Name:** (1251) Achieve Clinical Research  
**Subject No:** 12511250  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 18:51
### Date of Visit

<table>
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<td>3. Sample Collected?</td>
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<td>1. Data Origin</td>
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<td>3. Sample Collected?</td>
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<td>4. If no sample was collected or sample was not collected according to protocol, please provide reason:</td>
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<tr>
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<tbody>
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<tr>
<td>5. Sample ID</td>
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<tr>
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<tr>
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<td>//</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
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</tbody>
</table>

**COVID-19 Illness Visit**

| 3. COVID-19 Illness Visit: | |

---

**Header Text:** c4591001  
**Visit:** POT_COVID_ILL - New Unscheduled Visit  
**Form:** DATE OF VISIT - ILLNESS ONSET  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1251  
**Site Name:** (1251) Achieve Clinical Research  
**Subject No:** 12511250  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 18:51  
**Form Status:** Not Started

---

---
### Signs and Symptoms

1. **Date of Assessment:** //

2. **Date of First Symptom Started:** //

3. **Symptoms Ongoing?**

### Symptoms

4. **Symptoms:**

   - **Was symptom present?**

### Symptoms - Other

5. **Symptoms - Other Text:** [ ]
### Electronic Sample Tracking

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

#### Aliquot

Please enter barcode for each aliquot.

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<table>
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<tr>
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<tbody>
<tr>
<td>5.</td>
<td>Sample ID [ ]</td>
</tr>
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**Header Text:** c4591001  
**Visit:** POT_COVID_ILL - New Unscheduled Visit  
**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1251  
**Site Name:** (1251) Achieve Clinical Research  
**Subject No:** 12511250  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 18:51
### Electronic Sample Tracking

<p>| | |</p>
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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>4.</td>
<td>If no sample was collected or sample was not collected according to protocol, please provide reason:</td>
</tr>
</tbody>
</table>

### Aliquot

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<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5.</td>
<td>Sample ID</td>
</tr>
<tr>
<td>Health Care Utilization</td>
<td></td>
</tr>
<tr>
<td>-------------------------</td>
<td></td>
</tr>
<tr>
<td>1. Physician or Healthcare Professional:</td>
<td></td>
</tr>
<tr>
<td>Occurrence of Visits or Contacts:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Health Care Utilization Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Other Type of Practitioner Specify: [ ]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Health Care Utilization</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. Has the subject been hospitalized due to potential COVID-19 illness?</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>2.</td>
</tr>
<tr>
<td>3.</td>
</tr>
<tr>
<td>Date of Visit</td>
</tr>
<tr>
<td>-----------------------</td>
</tr>
<tr>
<td>1. Date of Visit</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
</tr>
</tbody>
</table>

**COVID-19 Illness Visit**

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

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

**Aliquot**

Please enter barcode for each aliquot.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5.</td>
<td>Sample ID</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Date of Visit</td>
<td></td>
</tr>
<tr>
<td>--------------</td>
<td>--</td>
</tr>
<tr>
<td>1. Date of Visit</td>
<td>//</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td></td>
</tr>
<tr>
<td><strong>COVID-19 Repeat Swab</strong></td>
<td></td>
</tr>
<tr>
<td>3. COVID-19 Repeat Swab:</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**

   [ ]
<table>
<thead>
<tr>
<th>#</th>
<th>Category</th>
<th>AE Identifier</th>
<th>Adverse Event</th>
<th>Start Date</th>
<th>Is the Adverse Event Still Ongoing</th>
<th>Form Instance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>ADVERSE EVENT</td>
<td>1</td>
<td>increased pain with activities-right knee</td>
<td>Dec/2/2020</td>
<td>YES</td>
<td>Repeating Pages</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Adverse Event Report</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td>Category:</td>
<td>ADVERSE EVENT</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>AE ID:</td>
<td>[1]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Adverse Event:</td>
<td>[increased pain with activities-right knee]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(If possible specify diagnosis, not individual symptoms)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>Start Date Time:</td>
<td>Dec/2/2020 UNK:UNK</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>Is the adverse event still ongoing?</td>
<td>YES</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>Toxicity Grade:</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
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<td>---</td>
<td>---</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>7.</strong></td>
<td>Is the adverse event serious?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>If Yes, NOTIFY PFIZER IMMEDIATELY.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>YES Is this serious event associated with congenital anomaly or birth defect?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NO</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Did this serious event result in death?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NO</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Did this serious event require or prolong hospitalization?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>YES</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Did this serious event result in persistent or significant disability/incapacity?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NO</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Is this serious event life threatening?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NO</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Other medically important serious event</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NO</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>8.</strong></td>
<td>Is this adverse event the result of a study Medication Error?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>If Yes, record the type of medication error on the Medication Error Log.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NO</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>9.</strong></td>
<td>Is this event related to study treatment:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NOT RELATED</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>If Not Related to study treatment(s), this event is due to:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>OTHER</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>If Other, specify:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>[increased activities]</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>10.</strong></td>
<td>Latest Action Taken with Study Treatment:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NOT APPLICABLE</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
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<td>---</td>
<td>---</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11.</td>
<td>Was a Concomitant Medication given?</td>
<td>YES</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12.</td>
<td>Was a Non-Drug Treatment given?</td>
<td>YES</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13.</td>
<td>What was the outcome of this adverse event?:</td>
<td>RECOVERING/RESOLVING</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14.</td>
<td>Did the adverse event cause the subject to be discontinued from the study?</td>
<td>NO</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15.</td>
<td>Serious Adverse Event Number: For Pfizer Use Only</td>
<td>[2020488165]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>#</td>
<td>Category</td>
<td>Medication Error</td>
<td>Start Date</td>
<td>Is the medication error Still Ongoing</td>
<td>Study Medication Errors Action</td>
<td>Form Instance</td>
</tr>
<tr>
<td>----</td>
<td>----------</td>
<td>------------------</td>
<td>------------</td>
<td>--------------------------------------</td>
<td>--------------------------------</td>
<td>---------------</td>
</tr>
<tr>
<td>1.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Repeating Pages</td>
</tr>
</tbody>
</table>

---

FDA-CBER-2021-5683-0833096

***Confidential***
### Medication Error

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

---

**Note:** The medication error associated with any adverse events is marked as [ ].
<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></td>
<td></td>
<td></td>
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<td></td>
<td>Repeating Pages</td>
</tr>
</tbody>
</table>

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Site No: 1251
Subject No: 12511250
Generated By: (b) (4)

Site Name: (1251) Achieve Clinical Research
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 18:51
### Concomitant Medications

1. **What is the medication identifier?**
   
2. **Category:**
   
3. **Concomitant Medications Pre-specified:**
   
4. **Medication:**
   
   Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

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

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>What is the medication identifier?</td>
</tr>
<tr>
<td>2.</td>
<td>Category:</td>
</tr>
<tr>
<td>3.</td>
<td>Concomitant Medications 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 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).</td>
</tr>
<tr>
<td>5.</td>
<td>Dose:</td>
</tr>
<tr>
<td>6.</td>
<td>Dose Unit:</td>
</tr>
<tr>
<td>7.</td>
<td>Dose Frequency:</td>
</tr>
<tr>
<td>8.</td>
<td>Route:</td>
</tr>
<tr>
<td>9.</td>
<td>Start Date: //</td>
</tr>
<tr>
<td>10.</td>
<td>Ongoing?</td>
</tr>
</tbody>
</table>

---

***Confidential***
<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>
<td>1.</td>
<td></td>
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<td></td>
<td></td>
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<td>Repeating Pages</td>
</tr>
</tbody>
</table>

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Page 48 of 139
**Radiation Treatment**

1. **Category:**

2. **What is the treatment Identifier?**
   
3. **Concomitant Non-drug Treatment Pre-specified:**

4. **Treatment:**

5. **Start Date:**
   
6. **Ongoing?**
<table>
<thead>
<tr>
<th>#</th>
<th>Transfusion Type</th>
<th>Date of Transfusion</th>
<th>Form Instance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Repeating Pages</td>
<td></td>
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</tr>
<tr>
<td>Back to Form</td>
<td></td>
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</tr>
<tr>
<td>--------------</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Transfusion Type:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Date of Transfusion: //</td>
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</tbody>
</table>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Form Status:** Not Started

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511250

**Subject Initials:** ---

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

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

---

**FDA-CBER-2021-5683-0833105**

---
### Date of Visit

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

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

1. Was there a temporary delay of vaccination?

2. Treatment Name  
   
3. Formulation:

4. Dose Date Time:  
   //

5. Anatomical Location:

6. Body Side:

7. Route:

8. Actual Dose:  
   [ ]

9. Unit:

10. Timeframe Subject Was Observed

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

---

**Form: VACCINATION**

**Visit:** Unplanned Vaccination - Unscheduled

**Form Version:** 10-Dec-2020 02:26  
**Form Status:** Not Started

**Site No:** 1251  
**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511250  
**Subject Initials:** ---

**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 18:51
### Header Text:
- **c4591001**
- **Visit:** Unplanned Vaccination - Unscheduled
- **Form:** CONTACT OUTCOME - MONTH 1
- **Form Version:** 10-Oct-2020 15:57
- **Form Status:** Not Started
- **Site No:** 1251
- **Site Name:** (1251) Achieve Clinical Research
- **Subject No:** 12511250
- **Subject Initials:** ---
- **Generated By:** (b) (4)
- **Generated Time (GMT):** 29-Mar-2021 18:51

### Contact Outcome

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

---

***Confidential***
### Contact Outcome

1. Contact Type:  
2. Was contact made?  
3. Comments: [ ]
<table>
<thead>
<tr>
<th>Date of Visit</th>
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</thead>
<tbody>
<tr>
<td>1. Date of Visit //</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
</tr>
</tbody>
</table>
Informed Consent - Asymptomatic Surveillance

1. Consent Was:

Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 18:51
### 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><strong>Electronic Sample Tracking</strong></th>
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<tbody>
<tr>
<td><strong>1. Data Origin</strong></td>
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<tr>
<td><strong>2. Sample Type</strong></td>
</tr>
<tr>
<td><strong>3. Sample Collected?</strong></td>
</tr>
<tr>
<td><strong>4. If no sample was collected or sample was not collected according to protocol, please provide reason:</strong> [ ]</td>
</tr>
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<th><strong>Aliquot</strong></th>
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<tbody>
<tr>
<td>Please enter barcode for each aliquot.</td>
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<tr>
<td><strong>5. Sample ID</strong> [ ]</td>
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</table>
### eCRF Audit Trail History

#### Disposition - Treatment

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<tbody>
<tr>
<td><strong>1.</strong> Date of Completion/Discontinuation/Death:</td>
<td>Dec/9/2020</td>
</tr>
<tr>
<td><strong>2.</strong> Phase of Disposition:</td>
<td>VACCINATION</td>
</tr>
<tr>
<td><strong>3.</strong> Status:</td>
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</tr>
<tr>
<td><strong>4.</strong> Specify Status:</td>
<td>[ ]</td>
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*Header Text: c4591001
Visit: End of Treatment - Unscheduled
Form: DISPOSITION - TREATMENT
Form Version: 10-Dec-2020 02:29
Form Status: Data Complete, Frozen, Verified
Site No: 1251
Site Name: (1251) Achieve Clinical Research
Subject No: 12511250
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 18:51*
### eCRF Audit Trail History

#### Date of Visit

<table>
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<th>No.</th>
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<th>Date</th>
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<tbody>
<tr>
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<td>Feb/12/2021</td>
</tr>
<tr>
<td>2.</td>
<td>Erroneous Visit</td>
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**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - Unscheduled

**Form:** DATE OF VISIT

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

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511250

**Subject Initials:** ---

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

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

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

---

**FDA-CBER-2021-5683-0833118**

---

***Confidential***

FDA-CBER-2021-5683-0833118
**Further Vaccination Confirmation**

1. Select appropriate response - Is participant willing to return for Vaccination 3?  
   | Participant is NOT willing to return for Vaccination 3 OR otherwise not eligible |
**Disposition - Follow-Up**

1. **Date of Completion/Discontinuation/Death:** //
2. **Phase of Disposition:**
3. **Status:**
4. **Specify Status:** [ ]
### Treatment Unblinded

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<td>Primary Reason for Unblinding:</td>
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<td>Withdrawal Of Consent</td>
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<td>-----------------------</td>
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<td>1. Withdrawal of Consent Date</td>
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**Header Text:** c4591001  
**Visit:** Disposition - Unscheduled  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1251  
**Subject No:** 12511250  
**Generated By:** (b) (4)  
**Form:** WITHDRAWAL OF CONSENT  
**Form Status:** Not Started  
**Site Name:** (1251) Achieve Clinical Research  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 18:51
**Death Details**

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**Cause of Death**

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<td>2.</td>
<td>Cause of Death Status:</td>
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**eCRF Audit Trail History**

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<td>1. Subject Status</td>
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### Header Text:

**c4591001**

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1251

**Subject No:** 12511250

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

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

---

**Form:** CASEBOOK SIGNATURE FORM

**Form Status:** Data Complete, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

---

**eCRF Audit Trail History**

**Casebook Signature Form**

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<thead>
<tr>
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<th>Signature Meaning</th>
<th>Date</th>
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<th>Action</th>
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<tr>
<td>CRF_Sign</td>
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<td>CRF_Sign_1</td>
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</tr>
<tr>
<td>Item</td>
<td>Date</td>
<td>User</td>
<td>Comment</td>
<td></td>
</tr>
<tr>
<td>------</td>
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<td></td>
</tr>
<tr>
<td>Form</td>
<td>Oct-21-2020 09:35:48 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>(b) (4), (b) (6)</td>
<td>NA</td>
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Not Applicable
This form requires signing by a member of each of the following signature groups:
- CRF_Sign
- CRF_Sign_1

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

(b) (4)
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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
<tr>
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<td>Data Entry: 06 OCT 2020</td>
<td>Initial Entry</td>
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<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
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<td></td>
<td></td>
<td></td>
</tr>
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</table>

**Back to Form**

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

<table>
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<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>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: STAGE 3 COHORTS</td>
<td>Initial Entry</td>
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<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
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</table>
### 1. Consent Was:

<table>
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<tr>
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<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
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<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> OBTAINED Date Written Consent Obtained Oct/20/2020</td>
<td>Initial Entry</td>
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</table>
### 1. Subject ID

<table>
<thead>
<tr>
<th>Date</th>
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<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Oct-21-2020</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td><strong>Data Entry:</strong> 12511250</td>
<td>Item copied from previous form</td>
</tr>
<tr>
<td>09:34:37</td>
<td>(UTC-06:00)</td>
<td>(autocalc)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Central Time (US &amp; Canada)</td>
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</table>

### 2. Birth Date:

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<th>Reason</th>
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<tr>
<td>Oct-21-2020</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td><strong>Data Entry:</strong> (b) (6)/1953</td>
<td>Enrollment Entry</td>
</tr>
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<td>(UTC-06:00)</td>
<td>(autocalc)</td>
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<td>Central Time (US &amp; Canada)</td>
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### 3. Sex:

<table>
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<th>User</th>
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<th>Reason</th>
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<tbody>
<tr>
<td>Oct-23-2020</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Closed</td>
<td>Response satisfies query</td>
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<td>10:36:38</td>
<td>(UTC-06:00)</td>
<td>(4), (6)</td>
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<td>Central Time (US &amp; Canada)</td>
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<table>
<thead>
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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tr>
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<td>ACV0PFEINFP6000</td>
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<td>Query 1: Answered</td>
<td>Transcription Error</td>
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<td>07:49:29</td>
<td>(UTC-06:00)</td>
<td>(autoquery)</td>
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### 4. Ethnicity:

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<th>Reason</th>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN</td>
<td>Initial Entry</td>
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### 5. Race: (Check X all that apply):

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<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>(b) (4), (b) (6)</td>
<td>Data Entry: BLACK OR AFRICAN AMERICAN</td>
<td>Initial Entry</td>
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</table>
### 1. Date of Visit

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<td>Initial Entry</td>
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</table>
**Date of Completion/Discontinuation/Death**

<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>(b) (4), auto calc</td>
<td>Data Entry: Oct/20/2020</td>
<td>Initial Entry</td>
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<tr>
<td>09:36:17</td>
<td>(UTC-06:00)</td>
<td>(autocalc)</td>
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<td>Central Time</td>
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<td>(US &amp; Canada)</td>
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**Phase of Disposition:**

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<tr>
<td>Central Time</td>
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<td>(US &amp; Canada)</td>
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**Status:**

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<td>(b) (4), auto calc</td>
<td>Data Entry: COMPLETED</td>
<td>Initial Entry</td>
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<td>(UTC-06:00)</td>
<td>(autocalc)</td>
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<td>Central Time</td>
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**1.a**

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**1.a Line/MH Number:**

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

<table>
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<tr>
<th>Date</th>
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<th>User</th>
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1.a Start Date:

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<td>Initial Entry</td>
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<tr>
<td>(UTC-06:00)</td>
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<td>Central Time (US &amp; Canada)</td>
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1.a Ongoing:

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<th>Reason</th>
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<td>(UTC-06:00)</td>
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1.b

<table>
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**Location:** ACV0PFEINFP6000  
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**knee arthroscopy right**

**Start Date:** UNK/UNK/2005

**Ongoing:** NO

**End Date:** UNK/UNK/2009

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### 7.a

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### 3. Sample Collected?

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**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511250

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 18:51
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## 7. Route:

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<td>INTRAMUSCULAR</td>
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</table>

## 10. Timeframe Subject Was Observed

**Page 107 of 139**
### II. Was the subject observed for at least the protocol specified observation period after investigational product administration?

<table>
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### 1. Select appropriate response - Reactogenicity diary collection

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**Form Version:** 06-Jul-2020 21:53  
**Form Status:** Data Complete, Frozen, Verified  
**Site No:** 1251  
**Site Name:** (1251) Achieve Clinical Research  
**Subject No:** 12511250  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 18:51
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**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511250

**Subject Initials:** ---

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

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

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2.a

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## 2. Sample Type

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## 3. Sample Collected?

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5.a Sample ID

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2. Treatment Name

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3. Formulation:

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4. Dose Date Time:
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7. **Route:**

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10. **Timeframe Subject Was Observed**
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11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

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Page 117 of 139
### 1. Date of Visit

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# Sample Type

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# Sample Collected?

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<td>Jan-07-2021</td>
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<td>Query 1: Candidate</td>
<td>'Sample Collected?’ is Yes, however no barcodes</td>
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4. If no sample was collected or sample was not collected according to protocol, please provide reason:

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<th>User</th>
<th>Value</th>
<th>Reason</th>
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Date of Collection: Dec/9/2020 | Initial Entry |
|                           |                        |       |                              |                                             |
|                           |                        |       |                              |                                             |

5.a

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5.a Sample ID

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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Central Time (US &amp; Canada)</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

### 7. Is the adverse event serious?

*If Yes, NOTIFY PFIZER IMMEDIATELY.*

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec-11-2020</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 2: Deleted</td>
<td>Close Auto Query</td>
</tr>
<tr>
<td>04:56:32</td>
<td>(UTC-06:00)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Central Time (US &amp; Canada)</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec-10-2020</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Closed</td>
<td>Close Auto Query</td>
</tr>
<tr>
<td>11:56:11</td>
<td>(UTC-06:00)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Adverse Event Report - eCRF Audit Trail

**Header Text:** c4591001  
**Visit:** Logs - Unscheduled  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1251  
**Subject No:** 12511250  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 18:51

| Central Time (US & Canada) | ACV0PFEINFP6000 | Data Entry: YES  
|----------------------------|------------------|--------------------------------------------------|--------------------------------------------------|
| Dec-10-2020 11:56:11 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Is this serious event associated with congenital anomaly or birth defect?  
|                             |                  | NO                                                |
|                             |                  | Did this serious event result in death?  
|                             |                  | NO                                                |
|                             |                  | Did this serious event require or prolong hospitalization?  
|                             |                  | YES                                               |
|                             |                  | Did this serious event result in persistent or significant disability/incapacity?  
|                             |                  | NO                                                |
|                             |                  | Is this serious event life threatening?  
|                             |                  | NO                                                |

**Form Status:** Data Complete, Verified  
**Site Name:** (1251) Achieve Clinical Research  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 18:51

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**FDA-CBER-2021-5683-0833181**

---
<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Timezone</th>
<th>Event ID</th>
<th>Event Type</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec-10-2020</td>
<td>11:53:40</td>
<td>Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query</td>
<td>For AE increased pain with activities-right knee: Response to &quot;Is the adverse event serious?&quot; is 'Yes' but &quot;Serious Adverse Event Number&quot; is blank.</td>
</tr>
<tr>
<td>Dec-10-2020</td>
<td>11:53:40</td>
<td>Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query</td>
<td>'Is the adverse event serious?' is marked as YES, but responses to all of the seriousness criteria are NO. At least one seriousness criterion is expected to be YES for serious events. Please review and</td>
</tr>
</tbody>
</table>
### Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02
**Site No:** 1251
**Subject No:** 12511250
**Generated By:** (b) (4)

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

<table>
<thead>
<tr>
<th>Date/Time</th>
<th>Event ID</th>
<th>Data Entry</th>
<th>Initial Entry</th>
</tr>
</thead>
</table>
| Dec-10-2020 11:53:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 (b) (4), (b) (6) | YES | Initial Entry

#### Data Entry:
- **Is this serious event associated with congenital anomaly or birth defect?**
  - NO
- **Did this serious event result in death?**
  - NO
- **Did this serious event require or prolong hospitalization?**
  - NO
- **Did this serious event result in persistent or significant disability/incapacity?**
  - NO
- **Is this serious event life threatening?**
  - NO
8. Is this adverse event the result of a study Medication Error?  
If Yes, record the type of medication error on the Medication Error Log.

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec-10-2020</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

9. Is this event related to study treatment:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec-10-2020</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NOT RELATED</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

OTHER

If Other, specify:

increased activities

10. Latest Action Taken with Study Treatment:
### 11. Was a Concomitant Medication given?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec-10-2020</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
<td>Data Entry: NOT APPLICABLE</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>11:53:40 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
<td>Data Entry: YES</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec-10-2020</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
<td>Data Entry: YES</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>11:53:40 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
<td>Data Entry: YES</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec-17-2020</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
<td>Query 1: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>04:13:10 (UTC-06:00) Central Time</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
<td>Query 1: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Date</td>
<td>Time</td>
<td>User ID</td>
<td>Action</td>
<td>Event Description</td>
</tr>
<tr>
<td>----------</td>
<td>--------------------</td>
<td>-----------------</td>
<td>-----------------</td>
<td>-----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Dec-11-2020 09:34:51 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Answered</td>
<td></td>
</tr>
<tr>
<td>Dec-11-2020 09:34:51 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Recovering/Resolving to Safety DB however, recorded as NOT RECOVERED/NOT RESOLVED on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.</td>
<td></td>
</tr>
<tr>
<td>Dec-10-2020 11:53:40 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NOT RECEIVED/RESOLVED/UNKNOWN</td>
<td></td>
</tr>
</tbody>
</table>
14. **Did the adverse event cause the subject to be discontinued from the study?**

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec-10-2020 11:53:40</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
<td><strong>Data Entry:</strong></td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-06:00)</td>
<td>(6)</td>
<td>NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Central Time (US &amp; Canada)</td>
<td></td>
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</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec-11-2020 04:56:32</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
<td><strong>Data Entry:</strong></td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-06:00)</td>
<td>(6)</td>
<td>2020488165</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Central Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
### 1. Date of Completion/Discontinuation/Death:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-07-2021</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry:</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>08:31:32</td>
<td></td>
<td></td>
<td>Dec/9/2020</td>
<td></td>
</tr>
<tr>
<td>(UTC-06:00)</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Central Time (US &amp; Canada)</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

### 2. Phase of Disposition:

<table>
<thead>
<tr>
<th>Date</th>
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<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-07-2021</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry:</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>08:31:32</td>
<td></td>
<td></td>
<td>VACCINATION</td>
<td></td>
</tr>
<tr>
<td>(UTC-06:00)</td>
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</tr>
<tr>
<td>Central Time (US &amp; Canada)</td>
<td></td>
<td></td>
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</table>

### 3. Status:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-07-2021</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry:</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>08:31:32</td>
<td></td>
<td></td>
<td>COMPLETED</td>
<td></td>
</tr>
<tr>
<td>(UTC-06:00)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Central Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 1. Date of Visit

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mar-04-2021 09:36:31 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Feb/12/2021</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>
### 1. Select appropriate response - Is participant willing to return for Vaccination 3?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mar-04-2021</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Participant is NOT willing to return for Vaccination 3 OR otherwise not eligible</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>09:36:44</td>
<td>Central Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td>Location</td>
<td>User</td>
<td>Value</td>
<td>Reason</td>
</tr>
<tr>
<td>-----------------</td>
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<td>--------------------------------</td>
<td>---------------</td>
</tr>
<tr>
<td>Jan-07-2021</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td><strong>Data Entry:</strong> FOLLOW-UP</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>08:31:32 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td></td>
<td>(autocalc)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oct-21-2020</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td><strong>Data Entry:</strong> ENROLLED/RANDOMIZED</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>09:39:48 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td></td>
<td>(autocalc)</td>
<td></td>
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</tr>
<tr>
<td>Oct-21-2020</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td><strong>Data Entry:</strong> SCREENED</td>
<td>Initial Entry</td>
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<td>09:36:17 (UTC-06:00) Central Time (US &amp; Canada)</td>
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<td>(autocalc)</td>
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<table>
<thead>
<tr>
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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-07-2021</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td><strong>Data Entry:</strong> Dec/9/2020</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>08:31:32 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td></td>
<td>(autocalc)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oct-21-2020</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc</td>
<td><strong>Data Entry:</strong> Oct/20/2020</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>09:39:48 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td></td>
<td>(autocalc)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: Oct/20/2020</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>---------------------------</td>
<td>-----------------</td>
<td>---------------------</td>
<td>-------------------------</td>
<td>--------------</td>
</tr>
<tr>
<td>Oct-21-2020 09:36:17 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
### 1. Casebook Signature

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mar-10-2021 13:07:19</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b)</td>
<td><strong>Data Entry:</strong> Click Here to Enable</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td></td>
<td>(6)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>