**Header Text:** c4591001

**Visit:** COHORT_SELECTION  
**Form:** COHORT SELECTION

**Form Version:** 30-Jul-2020 21:29  
**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1019  
**Site Name:** (1019) Diagnostics Research Group

**Subject No:** 10191010  
**Subject Initials:** ---

**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 04:44

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**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>
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</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>
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</table>
## Informed Consent

<table>
<thead>
<tr>
<th></th>
<th>Consent Was:</th>
<th>OBTAINED</th>
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<tbody>
<tr>
<td>1</td>
<td>Date Written Consent Obtained</td>
<td>Aug/11/2020</td>
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### Demography

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<tr>
<th></th>
<th>Subject ID</th>
<th>Birth Date</th>
<th>Sex</th>
<th>Ethnicity</th>
<th>Race: (Check X all that apply)</th>
<th>Racial Designation</th>
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<tr>
<td>1</td>
<td>[10191010]</td>
<td>(b) (6) /1940</td>
<td>FEMALE</td>
<td>NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN</td>
<td>WHITE</td>
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Date of Visit

1. Date of Visit Aug/11/2020
2. Erroneous Visit
**Form Comments**  
**eCRF Audit Trail History**

### Inclusion Criteria Not Met

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<tr>
<th>1.a</th>
<th>Description of Inclusion Criterion</th>
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### Exclusion Criteria Met

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### eCRF Audit Trail History

#### Disposition - Screening

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### 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>
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<tbody>
<tr>
<td>1.a</td>
<td>[Cataracts - bilateral]</td>
<td>UNK/UNK/2016</td>
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<td>1.b</td>
<td>[Myopia - bilateral]</td>
<td>UNK/UNK/1984</td>
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<td>1.c</td>
<td>[Presbyopia]</td>
<td>UNK/UNK/1984</td>
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<td>1.d</td>
<td>[Tonsillitis]</td>
<td>UNK/UNK/1961</td>
<td>NO</td>
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### Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:

<table>
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<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>
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<tr>
<td>1.e</td>
<td>[nasal polyps]</td>
<td>May/UNK/2018</td>
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<td>1.f</td>
<td>[Dry mouth]</td>
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<td>1.h</td>
<td>[Chronic Obstructive Pulmonary Disease]</td>
<td>UNK/UNK/1984</td>
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<td>[Sleep apnea]</td>
<td>UNK/UNK/1989</td>
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<td>Start Date:</td>
<td>Ongoing:</td>
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<td>[14]</td>
<td>Heart murmur</td>
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<td>[15]</td>
<td>Peripheral Vascular Disease</td>
<td>May/UNK/2018</td>
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<td>[16]</td>
<td>External hemorrhoids</td>
<td>UNK/UNK/2010</td>
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<td>[18]</td>
<td>Obesity</td>
<td>UNK/UNK/1985</td>
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<td>Line/MH Number</td>
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<td>Start Date</td>
<td>Ongoing</td>
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<td>[20]</td>
<td>[Chronic kidney disease stage III]</td>
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<td>[21]</td>
<td>[Endometriosis]</td>
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<td>[22]</td>
<td>[Uterine lesion - benign]</td>
<td>UNK/UNK/2005</td>
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<td>[23]</td>
<td>[Insomnia]</td>
<td>UNK/UNK/2014</td>
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<td>[24]</td>
<td>[Tension headaches]</td>
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<td>Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:</td>
<td>[Carpal tunnel syndrome, bilateral]</td>
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<tbody>
<tr>
<td>Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:</td>
<td>[Familial tremors]</td>
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<td>Start Date:</td>
<td>UNK/UNK/1974</td>
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<td>Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:</td>
<td>[Diabetic neuropathy bilateral hands]</td>
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<tr>
<td>Start Date:</td>
<td>UNK/UNK/2000</td>
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<td>Ongoing:</td>
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<tr>
<td>Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:</td>
<td>[Diabetic neuropathy, bilateral lower extremities]</td>
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<tr>
<td>Start Date:</td>
<td>UNK/UNK/2000</td>
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<tr>
<td>Ongoing:</td>
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<tbody>
<tr>
<td>Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:</td>
<td>[Osteoarthritis, bilateral hands and knees]</td>
</tr>
<tr>
<td>Start Date:</td>
<td>UNK/UNK/1997</td>
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<tr>
<td>Ongoing:</td>
<td>YES</td>
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</table>
### Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:

#### 1.ad
- **Line/MH Number:** [30]
- **Disease/Syndrome/Surgery:** Gout
  - **Start Date:** UNK/UNK/1998
  - **Ongoing:** YES

#### 1.ae
- **Line/MH Number:** [31]
- **Disease/Syndrome/Surgery:** Osteopenia
  - **Start Date:** UNK/UNK/2012
  - **Ongoing:** YES

#### 1.af
- **Line/MH Number:** [32]
- **Disease/Syndrome/Surgery:** Osteoporosis
  - **Start Date:** UNK/UNK/2016
  - **Ongoing:** YES

#### 1.ag
- **Line/MH Number:** [33]
- **Disease/Syndrome/Surgery:** Fibromyalgia
  - **Start Date:** Apr/UNK/2014
  - **Ongoing:** YES

#### 1.ah
- **Line/MH Number:** [34]
- **Disease/Syndrome/Surgery:** Fracture L. 5th toe
  - **Start Date:** UNK/UNK/2003
  - **Ongoing:** NO
  - **End Date:** UNK/UNK/2003
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<td>Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:</td>
<td>Fracture, right foot</td>
</tr>
<tr>
<td>Start Date:</td>
<td>UNK/UNK/2010</td>
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<tr>
<td>Ongoing:</td>
<td>NO</td>
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<tbody>
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<td>Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:</td>
<td>Bilateral leg cramps</td>
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<td>Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:</td>
<td>Recurrent joint pain, neck, shoulders, ankles, elbows, hips, knees, wrists</td>
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<td>Start Date:</td>
<td>UNK/UNK/1980</td>
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<td>Recurrent back pain - lumbar</td>
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<td>Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:</td>
<td>Fracture, right shoulder</td>
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<td>Start Date:</td>
<td>Jul/UNK/2010</td>
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End Date: Jul/UNK/2010
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<td>1.an [40]</td>
<td>[Shoulder implant, right - insertion]</td>
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<td>[Shoulder implant removal, right]</td>
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<td>[Shoulder implant infection, right]</td>
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<td>cyst, right ankle, benign</td>
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<td>Stress fracture, right ankle</td>
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<td>Aug/UNK/2010</td>
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<td>Depression</td>
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<td>Start Date:</td>
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<td>Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:</td>
<td>Anxiety</td>
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<td>Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:</td>
<td>Diabetes mellitus type 2</td>
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<td>Start Date:</td>
<td>UNK/UNK/2002</td>
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<td>Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:</td>
<td>Hypothyroidism</td>
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<td>Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:</td>
<td>Iron deficiency anemia</td>
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<td>Start Date:</td>
<td>Sep/UNK/2010</td>
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<td>Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:</td>
<td>Psoriasis</td>
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<td>Start Date:</td>
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<td>1.ba [53]</td>
<td>Rosacea</td>
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<td>1.bb [54]</td>
<td>Left rotator cuff tear</td>
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<td>1.bc [55]</td>
<td>Left fourth trigger finger</td>
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<tr>
<td>1.bd [56]</td>
<td>Allergic rhinitis</td>
</tr>
<tr>
<td>1.be [57]</td>
<td>Drug allergy - penicillin</td>
</tr>
<tr>
<td>Line/MH Number: [58]</td>
<td>Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: [Drug allergy - macrodantin]</td>
</tr>
<tr>
<td>---------------------</td>
<td>-------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Start Date: UNK/UNK/1950</td>
<td>Ongoing: YES</td>
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<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>Start Date: UNK/UNK/1961</td>
<td>Ongoing: NO</td>
</tr>
<tr>
<td>End Date: UNK/UNK/1961</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Start Date: UNK/UNK/1981</td>
<td>Ongoing: NO</td>
</tr>
<tr>
<td>End Date: UNK/UNK/1981</td>
<td></td>
</tr>
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<tbody>
<tr>
<td>Start Date: UNK/UNK/1980</td>
<td>Ongoing: NO</td>
</tr>
<tr>
<td>End Date: UNK/UNK/1980</td>
<td></td>
</tr>
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</table>
### Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies

<table>
<thead>
<tr>
<th>Line/MH Number</th>
<th>Start Date</th>
<th>Ongoing</th>
<th>End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 bk</td>
<td>UNK/UNK/1996</td>
<td>NO</td>
<td>UNK/UNK/1996</td>
</tr>
<tr>
<td>1.bl</td>
<td>UNK/UNK/1999</td>
<td>NO</td>
<td>UNK/UNK/1999</td>
</tr>
<tr>
<td>1 bm</td>
<td>UNK/UNK/2006</td>
<td>NO</td>
<td>UNK/UNK/2006</td>
</tr>
<tr>
<td>Line/MH Number:</td>
<td>[66]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>----------------</td>
<td>------</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:</strong></td>
<td>Left wrist tendonitis repair</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Start Date:</td>
<td>Jan/UNK/2006</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ongoing:</td>
<td>NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>End Date:</td>
<td>Jan/UNK/2006</td>
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<table>
<thead>
<tr>
<th>Line/MH Number:</th>
<th>[67]</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:</strong></td>
<td>Left knee arthroplasty</td>
</tr>
<tr>
<td>Start Date:</td>
<td>UNK/UNK/2007</td>
</tr>
<tr>
<td>Ongoing:</td>
<td>NO</td>
</tr>
<tr>
<td>End Date:</td>
<td>UNK/UNK/2007</td>
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<table>
<thead>
<tr>
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<th>[68]</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:</strong></td>
<td>Cyst excision, right ankle</td>
</tr>
<tr>
<td>Start Date:</td>
<td>Jul/UNK/2010</td>
</tr>
<tr>
<td>Ongoing:</td>
<td>NO</td>
</tr>
<tr>
<td>End Date:</td>
<td>Jul/UNK/2010</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Line/MH Number:</th>
<th>[69]</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:</strong></td>
<td>Left rotator cuff repair surgery</td>
</tr>
<tr>
<td>Start Date:</td>
<td>Mar/1/2018</td>
</tr>
<tr>
<td>Ongoing:</td>
<td>NO</td>
</tr>
<tr>
<td>End Date:</td>
<td>Mar/1/2018</td>
</tr>
<tr>
<td>Line/MH Number:</td>
<td>70</td>
</tr>
<tr>
<td>----------------</td>
<td>----</td>
</tr>
<tr>
<td>Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:</td>
<td>[Chest Pain]</td>
</tr>
<tr>
<td>Start Date:</td>
<td>UNK/UNK/2018</td>
</tr>
<tr>
<td>Ongoing:</td>
<td>YES</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Line/MH Number:</th>
<th>71</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:</td>
<td>[atrial fibrillation]</td>
</tr>
<tr>
<td>Start Date:</td>
<td>Nov/1/2017</td>
</tr>
<tr>
<td>Ongoing:</td>
<td>YES</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Line/MH Number:</th>
<th>72</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:</td>
<td>[implantable loop recorder]</td>
</tr>
<tr>
<td>Start Date:</td>
<td>Nov/1/2017</td>
</tr>
<tr>
<td>Ongoing:</td>
<td>YES</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Line/MH Number:</th>
<th>73</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:</td>
<td>[mitral valve regurgitation]</td>
</tr>
<tr>
<td>Start Date:</td>
<td>UNK/UNK/2005</td>
</tr>
<tr>
<td>Ongoing:</td>
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<table>
<thead>
<tr>
<th>Line/MH Number:</th>
<th>74</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:</td>
<td>[edema- bilateral lower extremities]</td>
</tr>
<tr>
<td>Start Date:</td>
<td>Apr/25/2018</td>
</tr>
<tr>
<td>Ongoing:</td>
<td>YES</td>
</tr>
<tr>
<td>Line/MH Number</td>
<td>Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:</td>
</tr>
<tr>
<td>---------------</td>
<td>------------------------------------------------------------</td>
</tr>
<tr>
<td>1.bw</td>
<td>[cholelithiasis]</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>1.bx</td>
<td>[heartburn]</td>
</tr>
<tr>
<td>Line/MH Number:</td>
<td>79</td>
</tr>
<tr>
<td>Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:</td>
<td>[chronic constipation]</td>
</tr>
<tr>
<td>Start Date:</td>
<td>Apr/UNK/2010</td>
</tr>
<tr>
<td>Ongoing:</td>
<td>YES</td>
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</table>
### Vital Signs Details

<table>
<thead>
<tr>
<th>No.</th>
<th>Record Identifier</th>
<th>Temperature</th>
<th>Unit</th>
<th>Temperature Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.a</td>
<td>1</td>
<td>[97.8]</td>
<td>F</td>
<td>EAR</td>
</tr>
</tbody>
</table>

### Vital Signs

1. **Date:** Aug/11/2020
2. **Weight:** [189.7]
3. **Unit:** LB
4. **Height:** [62.5]
5. **Unit:** in
6. **Body Mass Index:** [34.1]
<table>
<thead>
<tr>
<th>eCRF Audit Trail History</th>
</tr>
</thead>
<tbody>
<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)</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>
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</table>

**Form:** LAB URINALYSIS - PREGNANCY TEST  
**Site No:** 1019  
**Subject No:** 10191010  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 04:44  

**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site Name:** (1019) Diagnostics Research Group  
**Subject Initials:** ---  

**Visit:** V1_DAY1_VAX1_L  
**Form Version:** 30-Jul-2020 21:27  
**Generated Time (GMT):** 2021-03-29 04:44
### eCRF Audit Trail History

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<th>Disposition</th>
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<td>1. Randomization Date :</td>
<td>Aug/11/2020</td>
</tr>
<tr>
<td>2. Randomization Number:</td>
<td>[225292]</td>
</tr>
<tr>
<td>3. Randomization Group:</td>
<td>[ ]</td>
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</table>
## eCRF Audit Trail History

### Electronic Sample Tracking

<p>| | |</p>
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Data Origin</td>
</tr>
<tr>
<td>2</td>
<td>Sample Type</td>
</tr>
<tr>
<td>3</td>
<td>Sample Collected?</td>
</tr>
<tr>
<td></td>
<td>Date of Collection:</td>
</tr>
<tr>
<td></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.

<table>
<thead>
<tr>
<th></th>
<th>Sample ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.a</td>
<td>BM86C1</td>
</tr>
<tr>
<td>5.b</td>
<td>BM86C2</td>
</tr>
<tr>
<td>5.c</td>
<td>BM86C3</td>
</tr>
<tr>
<td>5.d</td>
<td>BPRM37</td>
</tr>
<tr>
<td>5.e</td>
<td>BPRM38</td>
</tr>
</tbody>
</table>
### eCRF Audit Trail History

**Electronic Sample Tracking**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Data Origin</td>
</tr>
<tr>
<td>2.</td>
<td>Sample Type</td>
</tr>
</tbody>
</table>
| 3. | Sample Collected? | YES  
   | Date of Collection: | Aug/11/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ] |

**Aliquot**

Please enter barcode for each aliquot.

<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:**
   - Aug/11/2020 10:15

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
eCRF Audit Trail History

Reactogenicity Diary

1. Select appropriate response - Reactogenicity diary collection
   YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
### eCRF Audit Trail History

**Date of Visit**

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

**Vaccination Symptoms Diary - Symptom Resolved Dates**

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Were medications to treat fever/pain given on the last day the Subject Diary was completed?</td>
<td>NO</td>
</tr>
<tr>
<td>2.a</td>
<td>Symptom:</td>
<td>FEVER</td>
</tr>
<tr>
<td></td>
<td>Were fever or systemic symptoms present on the last day the Subject Diary was completed?</td>
<td>NO</td>
</tr>
<tr>
<td>2.b</td>
<td>Symptom:</td>
<td>FATIGUE</td>
</tr>
<tr>
<td></td>
<td>Were fever or systemic symptoms present on the last day the Subject Diary was completed?</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ongoing?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Stop Date:</td>
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<tr>
<td></td>
<td></td>
<td>Aug/12/2020</td>
</tr>
<tr>
<td>2.c</td>
<td>Symptom:</td>
<td>HEADACHE</td>
</tr>
<tr>
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<td>Were fever or systemic symptoms present on the last day the Subject Diary was completed?</td>
<td>NO</td>
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<tr>
<td>2.d</td>
<td>Symptom:</td>
<td>CHILLS</td>
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<tr>
<td></td>
<td>Were fever or systemic symptoms present on the last day the Subject Diary was completed?</td>
<td>NO</td>
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<td>2.e</td>
<td>Symptom:</td>
<td>VOMITING</td>
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<td></td>
<td>Were fever or systemic symptoms present on the last day the Subject Diary was completed?</td>
<td>NO</td>
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<tr>
<td>2.f</td>
<td>Symptom:</td>
<td>DIARRHEA</td>
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<tr>
<td></td>
<td>Were fever or systemic symptoms present on the last day the Subject Diary was completed?</td>
<td>NO</td>
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</table>
### 2.g Symptom: NEW OR WORSENED MUSCLE PAIN

Were fever or systemic symptoms present on the last day the Subject Diary was completed?

<table>
<thead>
<tr>
<th>Answer</th>
<th>Ongoing?</th>
</tr>
</thead>
<tbody>
<tr>
<td>NO</td>
<td>NO</td>
</tr>
</tbody>
</table>

### 2.h Symptom: NEW OR WORSENED JOINT PAIN

Were fever or systemic symptoms present on the last day the Subject Diary was completed?

<table>
<thead>
<tr>
<th>Answer</th>
<th>Ongoing?</th>
</tr>
</thead>
<tbody>
<tr>
<td>NO</td>
<td>NO</td>
</tr>
</tbody>
</table>

### 3. Injection Site Location: DELTOID MUSCLE

### 4. Injection Site Body Side: LEFT

### 5.a Injection Site Reaction: REDNESS

Were injection site reactions present on the last day the Subject Diary was completed?

<table>
<thead>
<tr>
<th>Answer</th>
<th>Ongoing?</th>
<th>Stop Date</th>
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</thead>
<tbody>
<tr>
<td>NO</td>
<td>NO</td>
<td>Aug/12/2020</td>
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</tbody>
</table>

### 5.b Injection Site Reaction: SWELLING

Were injection site reactions present on the last day the Subject Diary was completed?

<table>
<thead>
<tr>
<th>Answer</th>
<th>Ongoing?</th>
</tr>
</thead>
<tbody>
<tr>
<td>NO</td>
<td>NO</td>
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</tbody>
</table>

### 5.c Injection Site Reaction: PAIN AT INJECTION SITE

Were injection site reactions present on the last day the Subject Diary was completed?

<table>
<thead>
<tr>
<th>Answer</th>
<th>Ongoing?</th>
<th>Stop Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
<td>NO</td>
<td>Aug/12/2020</td>
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<tr>
<td>Vital Signs Details</td>
<td></td>
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<tr>
<td>---------------------</td>
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</tr>
<tr>
<td><strong>2.a</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Record Identifier:</td>
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<tr>
<td>Temperature:</td>
<td>[98.1]</td>
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</tr>
<tr>
<td>Unit:</td>
<td>F</td>
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<tr>
<td>Temperature Location:</td>
<td>EAR</td>
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</tbody>
</table>

**eCRF Audit Trail History**

**Vital Signs**

1. Date: Sep/1/2020

---

*FDA-CBER-2021-5683-0895087*
### eCRF Audit Trail History

#### Lab Urinalysis

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

#### Lab Result

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>6.a</td>
<td>Sponsor ID: [113]</td>
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<tr>
<td></td>
<td>Test: Choriogonadotropin Beta_PX113</td>
</tr>
<tr>
<td></td>
<td>Result:</td>
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<tr>
<td></td>
<td>Not Done: NOT DONE</td>
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### eCRF Audit Trail History

#### Electronic Sample Tracking

1. Data Origin | SITE
2. Sample Type | NASAL_SWAB
3. Sample Collected? | YES
   Date of Collection: | Sep/1/2020
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 | [BM8649]
<table>
<thead>
<tr>
<th></th>
<th>Vaccination</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Was there a temporary delay of vaccination?</td>
</tr>
<tr>
<td>2.</td>
<td>Treatment Name</td>
</tr>
<tr>
<td>3.</td>
<td>Formulation:</td>
</tr>
<tr>
<td>4.</td>
<td>Dose Date Time:</td>
</tr>
<tr>
<td>5.</td>
<td>Anatomical Location:</td>
</tr>
<tr>
<td>6.</td>
<td>Body Side:</td>
</tr>
<tr>
<td>7.</td>
<td>Route:</td>
</tr>
<tr>
<td>8.</td>
<td>Actual Dose:</td>
</tr>
<tr>
<td>9.</td>
<td>Unit:</td>
</tr>
<tr>
<td>10.</td>
<td>Timeframe Subject Was Observed</td>
</tr>
<tr>
<td>11.</td>
<td>Was the subject observed for at least the protocol specified observation period after investigational product administration?</td>
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</table>
eCRF Audit Trail History

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Visit</td>
<td>Oct/6/2020</td>
</tr>
<tr>
<td>2. Erroneous Visit</td>
<td>---</td>
</tr>
</tbody>
</table>
### eCRF Audit Trail History

#### Vaccination Symptoms Diary - Symptom Resolved Dates

1. **Were medications to treat fever/pain given on the last day the Subject Diary was completed?**
   - **NO**

2.a **Symptom:** FEVER
   - **Were fever or systemic symptoms present on the last day the Subject Diary was completed?**
     - **NO**

2.b **Symptom:** FATIGUE
   - **Were fever or systemic symptoms present on the last day the Subject Diary was completed?**
     - **NO**

2.c **Symptom:** HEADACHE
   - **Were fever or systemic symptoms present on the last day the Subject Diary was completed?**
     - **NO**

2.d **Symptom:** CHILLS
   - **Were fever or systemic symptoms present on the last day the Subject Diary was completed?**
     - **NO**

2.e **Symptom:** VOMITING
   - **Were fever or systemic symptoms present on the last day the Subject Diary was completed?**
     - **NO**

2.f **Symptom:** DIARRHEA
   - **Were fever or systemic symptoms present on the last day the Subject Diary was completed?**
     - **NO**
2.g Symptom: NEW OR WORSENCED MUSCLE PAIN
   Were fever or systemic symptoms present on the last day the Subject Diary was completed? NO

2.h Symptom: NEW OR WORSENCED JOINT PAIN
   Were fever or systemic symptoms present on the last day the Subject Diary was completed? NO

3. Injection Site Location: DELTOID MUSCLE

4. Injection Site Body Side: LEFT

5.a Injection Site Reaction: REDNESS
   Were injection site reactions present on the last day the Subject Diary was completed? NO

5.b Injection Site Reaction: SWELLING
   Were injection site reactions present on the last day the Subject Diary was completed? NO

5.c Injection Site Reaction: PAIN AT INJECTION SITE
   Were injection site reactions present on the last day the Subject Diary was completed? NO
### eCRF Audit Trail History

**Electronic Sample Tracking**

1. **Data Origin**  
   SITE

2. **Sample Type**  
   SERUM

3. **Sample Collected?**  
   YES  
   **Date of Collection:**  
   Oct/6/2020

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

### Aliquot

Please enter barcode for each aliquot.

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<td>5.b</td>
<td>[BRTLKK]</td>
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<tr>
<td>5.c</td>
<td>[BRTLKL]</td>
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<tr>
<td>5.d</td>
<td>[BRTLKM]</td>
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<td>Date of Visit</td>
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<td>-------------------</td>
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<tr>
<td>1. Date of Visit</td>
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<td>2. Erroneous Visit</td>
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</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**  

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<tr>
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(b) (4)

FDA-CBER-2021-5683-0895097
**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: Date of Visit

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**Visitor Information**

- **Visit:** V6_MONTH24_L
- **Form:** DATE OF VISIT
- **Form Version:** 22-Apr-2020 21:02
- **Form Status:** Not Started
- **Site No:** 1019
- **Site Name:** (1019) Diagnostics Research Group
- **Subject No:** 10191010
- **Subject Initials:** ---
- **Generated By:** (b) (4)
- **Generated Time (GMT):** 29-Mar-2021 04:44

---

**Note:** This page contains confidential information.
**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5. Sample ID [ ]
**Header Text:** c4591001  
**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020  
**Form:** DATE OF VISIT - ILLNESS ONSET  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1019  
**Subject No:** 10191010  
**Generated By:** (b) (4)  
**Site Name:** (1019) Diagnostics Research Group  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 04:44  

### eCRF Audit Trail History

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### COVID-19 Illness Visit

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<td>3. COVID-19 Illness Visit:</td>
<td>COVID_A</td>
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</table>
### Signs and Symptoms

#### 1. Date of Assessment:
- **Not Applicable**

#### 2. Date of First Symptom Started:
- **Not Applicable**

#### 3. Symptoms Ongoing?
- **Not Applicable**

### Symptoms

#### 4.a Symptoms:
- **FEVER**
  - Was symptom present? **Not Applicable**

#### 4.b Symptoms:
- **NEW OR INCREASED COUGH**
  - Was symptom present? **Not Applicable**

#### 4.c Symptoms:
- **NEW OR INCREASED SHORTNESS OF BREATH**
  - Was symptom present? **Not Applicable**

#### 4.d Symptoms:
- **CHILLS**
  - Was symptom present? **Not Applicable**

#### 4.e Symptoms:
- **NEW OR INCREASED MUSCLE PAIN**
  - Was symptom present? **Not Applicable**

#### 4.f Symptoms:
- **NEW LOSS OF TASTE OR SMELL**
  - Was symptom present? **Not Applicable**
**Symptoms - Other**

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[ ]
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<th>Specimen Collection Location</th>
<th>Assay Code and Description</th>
<th>Device Type</th>
<th>Form Instance</th>
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<td>Assay Code and Description:</td>
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<td>5</td>
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<td>6</td>
<td>Test Result:</td>
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<td>7</td>
<td>Comments/Findings/Details:</td>
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<td>8</td>
<td>Trade Name Other, Specify:</td>
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**Comments**

- Not Applicable
- [ ]
### Electronic Sample Tracking

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<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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**Aliquot**

Please enter barcode for each aliquot.

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**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020  
**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
**Form Version:** 22-Apr-2020 21:03  
**Form Status:** Data Complete, Frozen, Verified  
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**Site Name:** (1019) Diagnostics Research Group  
**Subject No:** 10191010  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 04:44

### Form Comments

#### eCRF Audit Trail History

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#### Aliquot

Please enter barcode for each aliquot.

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<tr>
<td>Health Care Utilization</td>
<td></td>
</tr>
<tr>
<td>------------------------</td>
<td>--</td>
</tr>
<tr>
<td>1.a</td>
<td>Physician or Healthcare Professional: <strong>SPECIALIST</strong></td>
</tr>
<tr>
<td>1.b</td>
<td>Physician or Healthcare Professional: <strong>EMERGENCY ROOM</strong></td>
</tr>
<tr>
<td>1.c</td>
<td>Physician or Healthcare Professional: <strong>PRIMARY CARE PHYSICIAN</strong></td>
</tr>
<tr>
<td>1.d</td>
<td>Physician or Healthcare Professional: <strong>URGENT CARE</strong></td>
</tr>
<tr>
<td>1.e</td>
<td>Physician or Healthcare Professional: <strong>TELEPHONE CONSULTATION</strong></td>
</tr>
<tr>
<td>1.f</td>
<td>Physician or Healthcare Professional: <strong>OTHER</strong></td>
</tr>
</tbody>
</table>

### Health Care Utilization Other

| 2. | Other Type of Practitioner Specify: **[ ]** |

### Health Care Utilization

<p>| 3. | Has the subject been hospitalized due to potential COVID-19 illness? <strong>YES</strong> |
| Has the subject been in intensive care due to potential COVID-19 illness? <strong>NO</strong> |</p>
<table>
<thead>
<tr>
<th>#</th>
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<th>Hospitalization Term</th>
<th>Admission Date</th>
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Discharge Date: Aug/29/2020
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**Lab Chemistry Details**

1. Lab Panel: CLINICAL CHEMISTRY
2. Laboratory Name and Address: [Methodist and Children's Hospital, 7700 Floyd Curl Dr., San Antonio, Texas 78229]
3. Collection Date: Aug/27/2020
4. Specimen Type: BLOOD

**Lab Result**

5.a Sponsor ID: [329]  
Test: C Reactive Protein_PX329  
Result: [ ]  
Not Done: NOT DONE  
LNMT Low [ ]  
High [ ]  
Unit

5.b Sponsor ID: [30]  
Test: Alanine Aminotransferase_PX30  
Result: [23]  
Not Done:  
LNMT Low [13]  
High [61]  
Unit U/L
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<tr>
<td>Not Done:</td>
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<tr>
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<td>Result: [0.6]</td>
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<tr>
<td>Not Done:</td>
<td>Comments</td>
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<td>LNMT Low [0.2] High [1.0] Unit mg/dL</td>
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### 5.f

| Sponsor ID: | [47] | Comments |
| Test: | Blood Urea Nitrogen_PX47 |  |
| Result: | [10] | Comments |
| Not Done: | | Comments |
| LNMT | Low [7] | Comments |
| High | [18] | |
| Unit | mg/dL | |

### 5.g

<p>| Sponsor ID: | [48] | Comments |
| Test: | Creatinine_PX48 |  |
| Result: | [1.01] | Comments |
| Not Done: | | Comments |
| LNMT | Low [0.6] | Comments |
| High | [1.3] | |
| Unit | mg/dL | |</p>
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1. Date: Aug/27/2020

Vital Signs Details

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1. **Date:** Aug/28/2020

**Vital Signs Details**

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1. Date: Aug/28/2020

**Vital Signs Details**

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Vital Signs

1. Date: Aug/29/2020

Vital Signs Details

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1 | **Oxygen Saturation**  
93.0 | Repeating Pages |
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**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020  
**Form:** VITAL SIGNS - PULSE OX ROOM AIR  
**Form Version:** 30-Jul-2020 21:28  
**Site No:** 1019  
**Subject No:** 10191010  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 04:44  

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**Back to Form**  
**Form Comments**  
**eCRF Audit Trail History**  
**Form Audit Trail**

### Vital Signs

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**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020  
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**Generated By:** (b) (4)  
**Site Name:** (1019) Diagnostics Research Group  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 04:44  

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**Form Audit Trail**

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Form: VITAL SIGNS - PULSE OX ROOM AIR
Form Version: 10-Oct-2020 16:04
Form Status: Data Complete, Deleted, Frozen
Site No: 1019
Site Name: (1019) Diagnostics Research Group
Subject No: 10191010
Subject Initials: ---
Generated By: [b] (4)
Generated Time (GMT): 29-Mar-2021 04:44

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1. **Date:** Aug/28/2020

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1. Date: Aug/28/2020

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**Form Audit Trail**
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**Oxygenation Parameters**

1. Date Time of Assessment: Not Applicable
   
2. Arterial Blood Gases PaO2 (mmHg): Not Applicable
   
3. FiO2 (Fraction of Inhaled Oxygen): Not Applicable

Comments
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<th>Name of Medication</th>
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   Not Applicable  
   
   Comments

2. Category:  
   Not Applicable  
   
   Comments

3. Concomitant Medications Pre-specified:  
   Not Applicable  
   
   Comments

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  
   
   Comments

5. Start Date:  
   Not Applicable  
   
   Comments

6. Ongoing?  
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<th>Imaging Method</th>
<th>Overall Assessment</th>
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2. **Location of Assessment:** Not Applicable
   
3. **Type of Imaging Exam:** Not Applicable
   
4. **Assessment:** Not Applicable

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### Back to Form

### Form Comments

### eCRF Audit Trail History
### Date of Visit

1. Date of Visit
   
2. Erroneous Visit

### COVID-19 Illness Visit

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

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<td>4.</td>
<td>If no sample was collected or sample was not collected according to protocol, please provide reason:</td>
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### Aliquot

Please enter barcode for each aliquot.

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**Header Text:** c4591001  
**Visit:** Unplanned - New Unscheduled Visit  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1019  
**Subject No:** 10191010  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 04:44
<table>
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<th>Unplanned Assessments</th>
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<tbody>
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<td>1. Assessments</td>
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**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

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

**Site No:** 1019

**Subject No:** 10191010

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

**Form:** UNPLANNED VISIT

**Form Status:** Not Started

**Site Name:** (1019) Diagnostics Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

---

**Assessments**

- [F] (b) (4) Fina On: 01-Apr-2021 04:47 (GMT)

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**FDA-CBER-2021-5683-0895170**

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**Page 118 of 707**
**Disposition - Treatment**

<p>| | | |</p>
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<thead>
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<tbody>
<tr>
<td>1.</td>
<td>Date of Completion/Discontinuation/Death:</td>
<td>Oct/6/2020</td>
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<tr>
<td>2.</td>
<td>Phase of Disposition:</td>
<td>VACCINATION</td>
</tr>
<tr>
<td>3.</td>
<td>Status:</td>
<td>COMPLETED</td>
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<tr>
<td>4.</td>
<td>Specify Status:</td>
<td>[ ]</td>
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</table>

**eCRF Audit Trail History**

- **Disposition - Treatment**

- **Date of Completion/Discontinuation/Death**: Oct/6/2020
- **Phase of Disposition**: VACCINATION
- **Status**: COMPLETED
- **Specify Status**: [ ]
### Disposition - Follow-Up

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<td>Date of Completion/Discontinuation/Death : Dec/2/2020</td>
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<tr>
<td>2.</td>
<td>Phase of Disposition: FOLLOW-UP</td>
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<tr>
<td>3.</td>
<td>Status: LOST TO FOLLOW-UP</td>
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<tr>
<td>4.</td>
<td>Specify Status: [lost to follow up]</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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</tbody>
</table>

**COVID-19 Repeat Swab**

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<td>3. COVID-19 Repeat Swab:</td>
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**Header Text:** c4591001  
**Visit:** POT_COVID_REPEAT_SWAB - New Unscheduled Visit  
**Form:** DATE OF VISIT - REPEAT SWAB  
**Form Status:** Not Started  
**Site No:** 1019  
**Site Name:** (1019) Diagnostics Research Group  
**Subject No:** 10191010  
**Subject Initials:** ---  
**Generated By:** [redacted]  
**Generated Time (GMT):** 29-Mar-2021 04:44
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:  
5. Sample ID

Aliquot

Please enter barcode for each aliquot.

[ ]
<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>End Date Time</th>
<th>Form Instance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>ADVERSE EVENT</td>
<td>1</td>
<td>Diarrhea</td>
<td>Aug/17/2020 00:00</td>
<td>NO</td>
<td>End Date Time: Aug/27/2020 00:00</td>
<td>Repeating Pages</td>
</tr>
<tr>
<td>2</td>
<td>ADVERSE EVENT</td>
<td>2</td>
<td>Diarrhea</td>
<td>Aug/27/2020 UNK:UNK</td>
<td>NO</td>
<td>End Date Time: Aug/29/2020 UNK:UNK</td>
<td>Repeating Pages</td>
</tr>
<tr>
<td>3</td>
<td>ADVERSE EVENT</td>
<td>3</td>
<td>Mental State Status Change</td>
<td>Oct/2/2020 UNK:UNK</td>
<td>NO</td>
<td>End Date Time: Oct/2/2020 UNK:UNK</td>
<td>Repeating Pages</td>
</tr>
</tbody>
</table>
## Adverse Event Report

1. **Category:** ADVERSE EVENT  
2. **AE ID:** [1]  
3. **Adverse Event:**  
   (If possible specify diagnosis, not individual symptoms) [Diarrhea]  
4. **Start Date Time:** Aug/17/2020 00:00  
5. **Is the adverse event still ongoing?** NO  
   **End Date Time:** Aug/27/2020 00:00  
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:** NOT RELATED  
   **If Not Related to study treatment(s), this event is due to:** OTHER  
   **If Other, specify:** [Pre-Existing conditions]  
10. **Latest Action Taken with Study Treatment:** NOT APPLICABLE
<p>| | |</p>
<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>11.</td>
<td>Was a Concomitant Medication given?</td>
</tr>
<tr>
<td>12.</td>
<td>Was a Non-Drug Treatment given?</td>
</tr>
<tr>
<td>13.</td>
<td>What was the outcome of this adverse event?:</td>
</tr>
<tr>
<td>14.</td>
<td>Did the adverse event cause the subject to be discontinued from the study?</td>
</tr>
<tr>
<td>15.</td>
<td>Serious Adverse Event Number: For Pfizer Use Only</td>
</tr>
</tbody>
</table>
**Adverse Event Report**

1. Category: ADVERSE EVENT

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

3. Adverse Event: [Diarrhea]  
   **Comments**

4. Start Date Time: Aug/27/2020 UNK:UNK

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

6. Toxicity Grade: 4

7. Is the adverse event serious? YES  
   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? YES

   Other medically important serious event YES

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?: | NOT RELATED  
If Not Related to study treatment(s), this event is due to:  
OTHER  
If Other, specify:  
[Unknown] |
| 10. | Latest Action Taken with Study Treatment: | NOT APPLICABLE |
| 11. | Was a Concomitant Medication given? | YES |
| 12. | Was a Non-Drug Treatment given? | NO |
| 13. | What was the outcome of this adverse event?: | RECOVERED/RESOLVED |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO |
| 15. | Serious Adverse Event Number: For Pfizer Use Only | [2020339743] |
Adverse Event Report

1. Category: ADVERSE EVENT
2. AE ID: [3]
3. Adverse Event: [Mental State Status Change]
4. Start Date Time: Oct/2/2020 UNK:UNK
5. Is the adverse event still ongoing? NO
   End Date Time: Oct/2/2020 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: NOT RELATED
   If Not Related to study treatment(s), this event is due to:
   OTHER
   If Other, specify:
   [unknown]
<p>| 10. Latest Action Taken with Study Treatment: | NOT APPLICABLE |
| 11. Was a Concomitant Medication given? | NO |
| 12. Was a Non-Drug Treatment given? | NO |
| 13. What was the outcome of this adverse event?: | RECOVERED/RESOLVED |
| 14. Did the adverse event cause the subject to be discontinued from the study? | NO |
| 15. Serious Adverse Event Number: For Pfizer Use Only | [ ] |</p>
<table>
<thead>
<tr>
<th>#</th>
<th>Category</th>
<th>Medication Error</th>
<th>Start Date</th>
<th>Is the medication error Still Ongoing</th>
<th>Study Medication Errors Action</th>
<th>Form Instance</th>
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<tbody>
<tr>
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<td>Repeating Pages</td>
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```
## Medication Error

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

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<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>Date:</td>
</tr>
<tr>
<td>#</td>
<td>Sponsor-Defined Identifier</td>
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<tr>
<td>---</td>
<td>-----------------------------</td>
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<td>1.</td>
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</tbody>
</table>
### Concomitant Medications

1. What is the medication identifier?  
   
2. Category:  
   
3. Concomitant Medications  
   Pre-specified:  
   
4. Medication:  
   Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).  
   
5. Dose:  
   
6. Dose Unit:  
   
7. Dose Frequency:  
   
8. Route:  
   
9. Start Date: //  
   
10. Ongoing?
<table>
<thead>
<tr>
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<th>Con Non-Drug Treatments Pre-specified</th>
<th>Treatment</th>
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<th>Form Instance</th>
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<td>Concomitant Non-drug Treatment Pre-specified:</td>
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<td>6.</td>
<td>Ongoing?</td>
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<td>Transfusion Type</td>
<td>Date of Transfusion</td>
<td>Form Instance</td>
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<td>1. Date of Visit //</td>
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<td>2. Erroneous Visit</td>
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**Header Text:** c4591001  
**Visit:** Unplanned Vaccination - Unscheduled  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1019  
**Subject No:** 10191010  
**Generated By:** (b) (4)

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

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**Form:** DATE OF VISIT  
**Form Status:** Not Started  
**Site Name:** (1019) Diagnostics Research Group  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 04:44
### Vital Signs Details

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

---

**Vital Signs**

1. **Date:** //
## Lab Urinalysis

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

## Lab Result

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

---

**Header Text:** c4591001  
**Visit:** Unplanned Vaccination - Unscheduled  
**Form Version:** 20-Feb-2021 02:14  
**Site No:** 1019  
**Subject No:** 10191010  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 04:44  

**Form:** LAB URINALYSIS - PREGNANCY TEST  
**Form Status:** Not Started  
**Site Name:** (1019) Diagnostics Research Group  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 04:44  

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**FDA-CBER-2021-5683-0895194**
<table>
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<tbody>
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<td>1. Was there a temporary delay of vaccination?</td>
</tr>
<tr>
<td>2. Treatment Name</td>
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<tr>
<td>3. Formulation:</td>
</tr>
<tr>
<td>4. Dose Date Time:</td>
</tr>
<tr>
<td>5. Anatomical Location:</td>
</tr>
<tr>
<td>6. Body Side:</td>
</tr>
<tr>
<td>7. Route:</td>
</tr>
<tr>
<td>8. Actual Dose:</td>
</tr>
<tr>
<td>9. Unit:</td>
</tr>
<tr>
<td>10. Timeframe Subject Was Observed</td>
</tr>
<tr>
<td>11. Was the subject observed for at least the protocol specified observation period after investigational product administration?</td>
</tr>
<tr>
<td>Contact Outcome</td>
</tr>
<tr>
<td>-----------------</td>
</tr>
<tr>
<td>1. Contact Type:</td>
</tr>
<tr>
<td>2. Was contact made?</td>
</tr>
<tr>
<td>3. Comments:</td>
</tr>
<tr>
<td>Contact Outcome</td>
</tr>
<tr>
<td>------------------------</td>
</tr>
<tr>
<td>1. Contact Type:</td>
</tr>
<tr>
<td>2. Was contact made?</td>
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<tr>
<td>3. Comments:</td>
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</tbody>
</table>

[ ]
**Date of Visit**

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

<p>| | |</p>
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<tbody>
<tr>
<td>1.</td>
<td>Consent Was:</td>
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<tr>
<td>Electronic Sample Tracking</td>
<td></td>
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<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>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Aliquot</th>
</tr>
</thead>
<tbody>
<tr>
<td>Please enter barcode for each aliquot.</td>
</tr>
<tr>
<td>5. Sample ID</td>
</tr>
</tbody>
</table>
## Electronic Sample Tracking

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

## Aliquot

Please enter barcode for each aliquot.

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

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<thead>
<tr>
<th></th>
<th>Date of Visit</th>
<th>//</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.</td>
<td>Erroneous Visit</td>
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</tr>
</tbody>
</table>
## Further Vaccination Confirmation

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Select appropriate response - Is participant willing to return for Vaccination 3?</td>
</tr>
</tbody>
</table>
### Treatment Unblinded

<p>| | |</p>
<table>
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Withdrawal Of Consent

1. Withdrawal of Consent Date : //
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| 1. Date of Collection / Notification of Death: | // |

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eCRF Audit Trail History
Casebook Signature Form

1. Casebook Signature  | Click Here to Enable
Audit Trail

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

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FDA-CBER-2021-5683-0895209

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**Form:** ILLNESS DETAILS - Comments

**Form Version:** 06-Jul-2020 21:52  
**Form Status:** Data Complete, Frozen, Verified  
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**Subject No:** 10191010  
**Subject Initials:** ---  
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**Generated Time (GMT):** 29-Mar-2021 04:44

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**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1019

**Subject No:** 10191010

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

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Status:** Data Complete, Frozen

**Site Name:** (1019) Diagnostics Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 04:44

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**Generated Time (GMT):** 29-Mar-2021 04:44

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

**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Deleted

**Site No:** 1019

**Site Name:** (1019) Diagnostics Research Group

**Subject No:** 10191010

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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**Item** | **Date** | **User** | **Comment**
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***Confidential***

FDA-CBER-2021-5683-0895354
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**User:** (b) (4), (b) (6)  
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| | | | Not Applicable |
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Header Text: c4591001
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Form: OXYGENATION PARAMETERS - Comments
Form Version: 06-Jul-2020 21:52
Form Status: Data Complete, Frozen
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Generated Time (GMT): 29-Mar-2021 04:44

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**Subject No:** 10191010  
**Generated By:** (b) (4)  
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**Generated Time (GMT):** 29-Mar-2021 04:44

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**Form:** IMAGING - Comments

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

**Site No:** 1019

**Site Name:** (1019) Diagnostics Research Group

**Subject No:** 10191010

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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

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**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

**Form:** IMAGING - Comments

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

**Site No:** 1019

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**Subject No:** 10191010

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**Form:** IMAGING - Comments

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**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

**Form:** IMAGING - Comments

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**Form:** IMAGING - Comments

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

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

**Site No: 1019**

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Subject No: 10191010  
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- CRF_Sign
- CRF_Sign_1

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**Affidavit:**

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

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

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

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**Affidavit:**

N/A

<table>
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<th>Name</th>
<th>Signature Meaning</th>
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<td>Dec-03-2020 13:53:34 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>BOOK</td>
<td>Signed</td>
</tr>
</tbody>
</table>

**Affidavit:**

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

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

To this I do attest by supplying my user name and password and clicking the button marked Submit below.
<table>
<thead>
<tr>
<th>Visit</th>
<th>Investigator Signature - Unscheduled</th>
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<tbody>
<tr>
<td>Form</td>
<td>CASEBOOK SIGNATURE FORM - Signature History</td>
</tr>
<tr>
<td>Site No</td>
<td>1019</td>
</tr>
<tr>
<td>Subject No</td>
<td>10191010</td>
</tr>
<tr>
<td>Generated By</td>
<td>(b) (4)</td>
</tr>
<tr>
<td>Form Version</td>
<td>22-Apr-2020 21:04</td>
</tr>
<tr>
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<td>(1019) Diagnostics Research Group</td>
</tr>
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<td>Subject Initials</td>
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<td>29-Mar-2021 04:44</td>
</tr>
</tbody>
</table>

**Affidavit:**

N/A

| _{(b)} (6)_ | Approved | Nov-16-2020 13:51:22 (UTC-06:00) Central Time (US & Canada) | BOOK | Signed |

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

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

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

| _{(b)} (6)_ | Approved | Nov-13-2020 22:44:10 (UTC-06:00) Central Time (US & Canada) | BOOK | Signed |

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

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

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

| _{(b)} (6)_ | Approved | Nov-11-2020 08:13:58 (UTC-06:00) Central Time (US & Canada) | BOOK | Signed |

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

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

To this I do attest by supplying my user name and password and clicking the button marked Submit below.
Affidavit:
By my dated signature below, I, [redacted], 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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<th>Signed</th>
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</thead>
</table>

Affidavit:
By my dated signature below, I, [redacted], 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:
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<tr>
<td>By my dated signature below, I, ( \text{(b) (6)} ), verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.</td>
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<td>To this I do attest by supplying my user name and password and clicking the button marked Submit below.</td>
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**Form:** CASEBOOK SIGNATURE FORM - Signature History  
**Form Version:** 22-Apr-2020 21:04  
**Site No:** 1019  
**Subject No:** 10191010  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 04:44

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<tr>
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### 1. Select appropriate response - Protocol version

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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
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<tbody>
<tr>
<td>Aug-11-2020 14:23:27</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: 24 JUL 2020</td>
<td>Initial Entry</td>
</tr>
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<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
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### 2. Select appropriate response - What cohort does the subject belong to?

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

<table>
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<th>Reason</th>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> OBTAINED Date Written Consent Obtained</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
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<td>Aug/11/2020</td>
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### 1. Subject ID

<table>
<thead>
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<th>Reason</th>
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<td>Sep-03-2020 06:02:06</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>(b) (4)</td>
<td>Query 1: Closed</td>
<td>event added in Inform</td>
</tr>
<tr>
<td>Sep-02-2020 07:33:47</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>(b) (4)</td>
<td>Query 1: Answered</td>
<td>Entered</td>
</tr>
<tr>
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<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>auto calc</td>
<td>Data Entry: 10191010</td>
<td>Item copied from previous form</td>
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<tr>
<td></td>
<td></td>
<td>(autocalc)</td>
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### 2. Birth Date:

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<td>Query 1: Closed</td>
<td>DOB added in SDB. Issue resolved</td>
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<tr>
<td>Sep-11-2020 04:43:02</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>(b) (4)</td>
<td>Query 1: Reissued:Candidate</td>
<td>SAE RECON: TO check next SAE listing if DOB will be added</td>
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<tr>
<td>Sep-10-2020 08:38:39</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>(b) (4)</td>
<td>Query 1: Answered</td>
<td>Follow Up form submitted on 10SEP20</td>
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<td>(b) (4)</td>
<td>Query 1: Opened</td>
<td>SAE RECON:AER#2020339743 ,the date of birth was missing in SAE form but</td>
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**Final On: 01-Apr-2021 04:47 (GMT)**
### 3. Sex:

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*Aug-11-2020 14:30:03 (UTC-06:00) Central Time (US & Canada)*

Data Entry:

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<td>Initial Entry</td>
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<td>Time (US &amp; Canada)</td>
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<td>(6)</td>
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Data Entry:

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<td>FEMALE</td>
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5. Race: (Check X all that apply):

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<td><strong>Data Entry:</strong> Aug/11/2020</td>
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### 1.a

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<td>(UTC-06:00) Central Time</td>
<td>ACV0F6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Criterion Description: Transcription Error</td>
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<td>Time (US &amp; Canada)</td>
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<td>Data Entry: Criterion Description: Male or female participants between the ages of 18 and 65 years, inclusive, or 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent on study phase)</td>
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#### 1.a Description of Inclusion Criterion Not Met

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<td>Time (US &amp; Canada)</td>
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<td>Query 1: Reissued:Opened</td>
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<tr>
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<tr>
<td>Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study phase)</td>
<td>Amendment 5 (24Jul2020). INC EXC form is not applicable. Please add Form level comment as “Not Applicable”</td>
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### 1. Date of Completion/Discontinuation/Death

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### 2. Phase of Disposition:

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<tbody>
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<td>Date</td>
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<td>Initial Entry</td>
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<td>Term: Cataracts - bilateral</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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- **Line/MH Number:** 2
- **Medical History Term:** Myopia - bilateral
- **Start Date:** UNK/UNK/1984
- **Ongoing:** YES

**Reason:**

- **Initial Entry**

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1019

**Site Name:** (1019) Diagnostics Research Group

**Subject No:** 10191010

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44
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- **Medical History Term:** Chronic Obstructive Pulmonary Disease
- **Start Date:** UNK/UNK/1984
- **Ongoing:** YES
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- **Line/MH Number:** 10
- **Medical History Term:** CPAP
- **Start Date:** UNK/UNK/1989
- **Ongoing:** YES
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|                   |                |                       | **Line/MH Number:** 11 | **Medical History Term:** bronchitis | **Start Date:** Nov/12/2010 | **Ongoing:** NO | **End Date:** Nov/24/2010 | Initial Entry |
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### 1.k Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

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Medical History Term: Hypertension
Start Date: UNK/UNK/2004
Ongoing: YES
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### 1.1 Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

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Medical History Term: Heart murmur  
Start Date: UNK/UNK/2004  
Ongoing: YES | Initial Entry |
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### 1.o Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

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<td>Please specify whether the peripheral vascular disease is arterial or venous and update the reported term accordingly.</td>
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### 1.p Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

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End Date: UNK/UNK/1981
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### 1.r Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

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***Confidential***
### 1.s Line/MH Number:

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

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Medical History Term: Chronic kidney disease stage III
Start Date: Apr/25/2018
Ongoing: YES
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### 1.t Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

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End Date: UNK/UNK/1980 | Initial Entry |
| (US & Canada)         |                           |            |             |              |              |

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### Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies

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**Medical History Term:** Insomnia

**Start Date:** UNK/UNK/2014

**Ongoing:** YES

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**Line/MH Number:** 24

**Medical History Term:** Tension headaches

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***Confidential***
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## 1.y Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

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

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**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1019  
**Subject No:** 10191010  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 04:44
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**1.ac Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

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

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<td>does not receive systemic corticosteroids</td>
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<td>GPDCCLN: please confirm patient do not receive systemic corticosteroids (i.e. Exclusion # 13 not met). thank you</td>
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### 1.ae Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

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

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Line/MH Number: 33 
Medical History Term: Fibromyalgia 
Start Date: Apr/UNK/2014 
Ongoing: YES | Initial Entry |
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| Initial Entry | 34 |

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**Site Name:** (1019) Diagnostics Research Group
**Subject No:** 10191010
**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History
**Form Status:** Data Complete, Locked, Frozen, Verified
**Generated By:** (b) (4)
**Generated Time (GMT):** 29-Mar-2021 04:44

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***Confidential***

FDA-CBER-2021-5683-0895426
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### 1.aj Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

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<td>Time (US &amp; Canada)</td>
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<td>Medical History: Recurrent back pain term: in lumbar</td>
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1.1a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

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

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- Line/MH Number: 40
- Medical History Term: Shoulder implant, right - insertion
- Start Date: UNK/UNK/2013
**Form**: GENERAL MEDICAL HISTORY - eCRF Audit Trail History  
**Form Version**: 22-Apr-2020 21:03  
**Form Status**: Data Complete, Locked, Frozen, Verified  
**Site No**: 1019  
**Site Name**: (1019) Diagnostics Research Group  
**Subject No**: 10191010  
**Subject Initials**: ---  
**Generated By**: (b) (4)  
**Generated Time (GMT)**: 29-Mar-2021 04:44

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**Aug-11-2020 15:34:38 (UTC-06:00) Central Time (US & Canada)**

**ACV0PFEINFP6000 auto calc (autocalc)**

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

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<td>Query 1: Closed</td>
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<td>Query 1: Opened</td>
<td>Clarify SHOULDER IMPLANT, RIGHT as follows... Device only term. Are you reporting INSERTION? REMOVAL? INFECTION OF? Other? If so, update the verbatim term as such. Otherwise clarify and edit the term. Thank you.</td>
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***Confidential***
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**Start Date:** UNK/UNK/2009
**Ongoing:** NO
**End Date:** Jul/UNK/2010

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**Form Status:** Data Complete, Locked, Frozen, Verified  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1019  
**subject No:** 10191010  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 04:44

**Data Entry:**
- **Line/MH Number:** 46 (autocalc)
- **Medical History Term:** Stress fracture, right ankle
- **Start Date:** Aug/UNK/2010
- **Ongoing:** NO
- **End Date:** Oct/5/2010

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**Initial Entry**
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Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1019
Subject No: 10191010
Generated By: (b) (4)

Aug-11-2020 15:39:41
(UTC-06:00) Central Time
(US & Canada)
ACV0PFEINF6000
auto calc
(autocalc)

Data Entry:
Line/MH Number: 47
Medical History Term: Depression
Start Date: UNK/UNK/2001
Ongoing: YES

Initial Entry

FDA-CBER-2021-5683-0895443
### 1.au Line/MH Number:

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

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

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Medical History: Diabetes mellitus type 2
Start Date: UNK/UNK/2002
Ongoing: YES
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<td>Medical History Term: Hypothyroidism</td>
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<td>GPDCLIN: Please confirm disease is stable (inclusion criterion #3 is met) and that exclusion criterion #13 (systemic therapy) is not MET. thank you</td>
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<td>GPDCLIN: Please can you confirm that subject does not meet exclusion criterion #13 as a result of psoriasis. Thanks</td>
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| Medical History | Anal fistulaectomy |
| Start Date: UNK/UNK/1981 |
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| End Date: UNK/UNK/1981 |

Initial Entry

(b) (4)
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### 1.bh Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

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

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

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Ongoing: NO
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<td>Left wrist tendonitis</td>
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### 1.bn Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

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

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Page 418 of 707
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**1.bq Line/MH Number:**

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

**1.bq Start Date:**

**1.bq Ongoing:**

**1.br**

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***Confidential***
### 1.br Line/MH Number:

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

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**Medical History Term:** atrial fibrillation
### 1.bs Line/MH Number:

| Date: Aug-11-2020 16:00:59 (UTC-06:00) Central Time (US & Canada) | Location: ACV0PFEINFP6000 | User: auto calc (autocalc) | Value: 71 | Reason: Initial Entry |

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

| Date: Aug-11-2020 16:00:59 (UTC-06:00) Central Time (US & Canada) | Location: ACV0PFEINFP6000 | User: (b) (4), (b) (6) | Value: atrial fibrillation | Reason: Initial Entry |

### 1.bs Start Date:

| Date: Aug-11-2020 16:00:59 (UTC-06:00) Central Time (US & Canada) | Location: ACV0PFEINFP6000 | User: (b) (4), (b) (6) | Value: Nov/1/2017 | Reason: Initial Entry |

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### 1.bt

| Date: Aug-11-2020 16:01:59 (UTC-06:00) Central Time (US & Canada) | Location: ACV0PFEINFP6000 | User: auto calc (autocalc) | Value: | Reason: Initial Entry |

| Data Entry: | Line/MH Number: 72 | Medical History Term: implantable loop recorder | Start Date: Nov/1/2017 | Ongoing: YES |
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### 1.bt Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

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

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**Medical History Term:** edema- bilateral lower extremities

**Start Date:** Apr/25/2018

**Ongoing:** YES
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### 1.bv Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

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

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

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|                       |                           |           |            | Term:         |             |
|                       |                           |           |            | Start Date:   | UNK/UNK/1990  |
|                       |                           |           |            |               |            |
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### 1.bz Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

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### Medical History

**Term:** chronic constipation  
**Start Date:** Apr/UNK/2010  
**Ongoing:** YES

#### 1.ca Line/MH Number:

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

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### 3. Unit:

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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>
<td>Aug-11-2020 16:01:00 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>LB</td>
<td>Initial Entry</td>
</tr>
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</table>

### 4. Height:

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<th>Value</th>
<th>Reason</th>
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<tbody>
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<td>Aug-11-2020 16:01:00 (UTC-06:00) Central Time (US &amp; Canada)</td>
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<td>ACV0PFEINFP6000</td>
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### 6. Body Mass Index:

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<tr>
<td>Aug-11-2020 16:01:00 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
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<td>Initial Entry</td>
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### 7.a

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<tr>
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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Aug-11-2020 16:08:43 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Record Identifier:: 1</td>
<td>Transcription Error</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Temperature: 97.8</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td>Temperature Unit: F</td>
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<tr>
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<td></td>
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<td>Temperature Location:: EAR</td>
</tr>
<tr>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Record Identifier:: 1</td>
<td>Initial Entry</td>
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<tr>
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<td></td>
<td>Temperature: 96.3</td>
</tr>
<tr>
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<td></td>
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<td></td>
<td>Temperature Unit: F</td>
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<td>Temperature Location:: EAR</td>
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### 7.a Temperature:

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<tr>
<td>Aug-11-2020 16:08:43 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Closed</td>
<td>Close Auto Query</td>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: 97.8</td>
<td>Transcription Error</td>
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<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Opened</td>
<td>Temperature 96.3 F is outside of Normal Range 97 - 99.5 F.</td>
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**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1019

**Subject No:** 10191010

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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**Header Text:** c4591001

**Visit:** V1_DAY1_VAX1_L

**Site Name:** (1019) Diagnostics Research Group

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**Data Entry:** F

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**Reason:** Initial Entry
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<tbody>
<tr>
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<td>Initial Entry</td>
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<td></td>
<td></td>
<td>(autocalc)</td>
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<td>auto calc</td>
<td>Initial Entry</td>
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### 4. Laboratory Name and Address (Derived)

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<th>Reason</th>
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<tbody>
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<td>auto calc</td>
<td>Initial Entry</td>
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<td></td>
<td></td>
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<td>(autocalc)</td>
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### 5. Specimen Type:

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### 6.a

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***Confidential***

Page 433 of 707

FDA-CBER-2021-5683-0895485
### 6.a Sponsor ID:

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### 6.a Not Done:

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<td>(b) (4), (b) (6)</td>
<td>Data Entry: NOT DONE</td>
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## Back to Form

### 1. Randomization Date:

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<tbody>
<tr>
<td>Aug-11-2020 16:03:02</td>
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<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
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### 2. Randomization Number:

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<tr>
<td>Aug-11-2020 15:56:54 (UTC-06:00) Central Time (US &amp; Canada)</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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<tr>
<td>Aug-11-2020 15:57:17 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Deleted</td>
<td>Close Auto Query</td>
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<td>auto query (autoquery)</td>
<td>Query 1: Candidate</td>
<td>'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.</td>
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<tr>
<td>Aug-11-2020 15:56:54 (UTC-06:00) Central Time (US &amp; Canada)</td>
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<td><strong>Data Entry:</strong> YES Date of Collection: Aug/11/2020</td>
<td>Initial Entry</td>
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### 5.a

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<td><strong>Data Entry:</strong> Sample ID: BM86C1</td>
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### 5.a Sample ID

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### 5.b Sample ID

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### 1. Data Origin

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<td>Aug-11-2020 15:56:20</td>
<td>ACV0PFEINF06000</td>
<td>auto calc</td>
<td><strong>Data Entry:</strong> SITE</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td></td>
<td>(autocalc)</td>
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</table>

### 2. Sample Type

<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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### 3. Sample Collected?

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<tbody>
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<td>Query 1: Deleted</td>
<td>Close Auto Query</td>
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<td>Aug-11-2020 15:56:20</td>
<td>ACV0PFEINF06000</td>
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<td>Query 1: Candidate</td>
<td>'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.</td>
</tr>
<tr>
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<td></td>
<td>(autoquery)</td>
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</tr>
<tr>
<td>Aug-11-2020 15:56:20</td>
<td>ACV0PFEINF06000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> YES Date of Collection: Aug/11/2020</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td></td>
<td>(BM85ZL)</td>
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### 5.a

<table>
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<td>Value</td>
<td>Reason</td>
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<td>Aug-11-2020 15:56:41</td>
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<td>(b) (4)</td>
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</table>

**5.a Sample ID**

**Form Version:** 22-Apr-2020 21:03  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1019  
**Site Name:** (1019) Diagnostics Research Group  
**Subject No:** 10191010  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 04:44
**Back to Form**

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

<table>
<thead>
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<th>User</th>
<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Aug-11-2020 16:04:19</td>
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<td>Data Entry: NO</td>
<td>Initial Entry</td>
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### 2. Treatment Name

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<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Aug-11-2020 16:04:19</td>
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<td>auto calc (autocalc)</td>
<td>Data Entry: BLINDED THERAPY</td>
<td>Initial Entry</td>
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</table>

### 3. Formulation:

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<th>User</th>
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<th>Reason</th>
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<tbody>
<tr>
<td>Aug-11-2020 16:04:19</td>
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<td>auto calc (autocalc)</td>
<td>Data Entry: INJECTION</td>
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### 4. Dose Date Time:

<table>
<thead>
<tr>
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<th>Location</th>
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<th>Value</th>
<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Aug-11-2020 16:04:19</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Aug/11/2020 10:15</td>
<td>Initial Entry</td>
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</table>

### 5. Anatomical Location:

<table>
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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
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<td>auto calc (autocalc)</td>
<td>Data Entry: DELTOID MUSCLE</td>
<td>Initial Entry</td>
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### 6. Body Side:

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<tbody>
<tr>
<td>Aug-11-2020 16:04:19</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: LEFT</td>
<td>Initial Entry</td>
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### 7. Route:

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<tbody>
<tr>
<td>Aug-11-2020 16:04:19</td>
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<td>auto calc (autocalc)</td>
<td>Data Entry: INTRAMUSCULAR</td>
<td>Initial Entry</td>
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### 10. Timeframe Subject Was Observed

<table>
<thead>
<tr>
<th>Date</th>
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<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Aug-11-2020 16:04:19</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

<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>Aug-11-2020 16:04:19</td>
<td>ACV0PFEINFP6000</td>
<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>
<th>Location</th>
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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Sep-10-2020 01:16:26</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Closed</td>
</tr>
<tr>
<td>Sep-08-2020 08:37:13</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Answered</td>
</tr>
<tr>
<td>Sep-04-2020 06:46:31</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Opened</td>
</tr>
<tr>
<td>Aug-11-2020 16:06:44</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT</td>
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</table>

**Data Entry:**

Initial Entry
### 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>Sep-16-2020 04:21:37 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Closed</td>
<td>DOV changed on COVID illness visit</td>
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<tr>
<td>Sep-15-2020 12:17:35 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Answered</td>
<td>Pt notified site at visit 2 visit</td>
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<tr>
<td>Sep-15-2020 04:10:06 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000.InFormAdapter.Discrepancy</td>
<td>DMW QUERY</td>
<td>(b) (4)</td>
<td>Query 1: Opened</td>
</tr>
<tr>
<td>Sep-01-2020 12:44:29 (UTC-06:00) Central Time (US &amp; Canada)</td>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: Sep/1/2020</td>
<td>Initial Entry</td>
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</tbody>
</table>
1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

<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>Sep-01-2020 12:46:00</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>NO</td>
<td>Data Entry: NO</td>
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2.a

<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>Sep-01-2020 12:46:00</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>NO</td>
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</table>

2.a Symptom:

<table>
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<th>Reason</th>
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<tbody>
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<td>ACV0PFEINFP6000</td>
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2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

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2.b

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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Sep-15-2020 08:18:34</td>
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<td>ACV0PFEINFP6000</td>
<td>NO</td>
<td>Data Entry: NO</td>
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Symptom:: FATIGUE

New Information
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<th>Symptom</th>
<th>Were fever or systemic symptoms present on the last day the Subject Diary was completed?</th>
<th>Stop Date</th>
<th>Data Entry Type</th>
<th>Data Entry Notes</th>
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<tbody>
<tr>
<td>Sep-14-2020 14:08:14</td>
<td>14:08:14 (UTC-06:00) Central Time (US &amp; Canada)</td>
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<td>FA TI GU E</td>
<td>YES</td>
<td>NO</td>
<td>Transcription Error</td>
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<tr>
<td>Sep-03-2020 08:43:06</td>
<td>08:43:06 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>FATIGUE</td>
<td>YES</td>
<td>NO</td>
<td>Transcription Error</td>
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<td>ACV0PFEINFP6000</td>
<td>FA TI GU E</td>
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<td></td>
<td>Initial Entry</td>
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</table>
| Were fever or systemic symptoms present on the last
day the Subject Diary was completed?: | NO |

(b) (4)
### 2.b Symptom:

<table>
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<th>Date</th>
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<th>Reason</th>
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<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong></td>
<td>Initial Entry</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td></td>
<td></td>
<td>FATIGUE</td>
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### 2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

<table>
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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Sep-15-2020 12:00:30</td>
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<td>Query 3: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
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</tr>
<tr>
<td>Sep-15-2020 08:18:34</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 3: Answered</td>
<td>New Information</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
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<tr>
<td>Sep-15-2020 08:18:34</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong></td>
<td>New Information</td>
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<tr>
<td></td>
<td></td>
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<td>Ongoing?</td>
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</tr>
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<td></td>
<td></td>
<td><strong>NO</strong></td>
<td></td>
</tr>
<tr>
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<td><strong>Stop Date:</strong></td>
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<tr>
<td></td>
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<td></td>
<td>Aug/12/2020</td>
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</tr>
<tr>
<td>Sep-15-2020 04:44:41</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 3: Opened</td>
<td>e-Diary: Per diary records, FATIGUE present on Last day however inform entered with 'No' for the same. Please verify and update. If diary entered in error, please enter stop date as last date of diary or consider raising DCF to correct diary data.</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
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<tr>
<td>Sep-15-2020 03:05:50</td>
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<td>Query 2: Closed</td>
<td>Closed by DM:</td>
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<tr>
<td>Date/Time</td>
<td>User</td>
<td>Action</td>
<td>Notes</td>
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<td>Sep-14-2020 14:08:14 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 2: Answered, Transcription Error</td>
<td></td>
</tr>
<tr>
<td>Sep-14-2020 14:08:14 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO, Transcription Error</td>
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</tr>
<tr>
<td>Sep-12-2020 01:03:06 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Balaji Prabu R (b) (4)</td>
<td>Query 2: Opened, As per e-diary, Fatigue started on 12Aug2020, but stop date is reported as 11AUG2020. Please clarify.</td>
<td></td>
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<tr>
<td>Sep-09-2020 03:29:54 (UTC-06:00) Central Time (US &amp; Canada)</td>
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<td>(b) (4), (b) (6)</td>
<td>Query 1: Closed, Closed by DM: (b) (6)</td>
<td></td>
</tr>
<tr>
<td>Sep-03-2020 08:43:06 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Answered, Transcription Error</td>
<td></td>
</tr>
<tr>
<td>Sep-03-2020 08:43:06 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: YES, Ongoing? NO, Stop Date: Aug/11/2020, Transcription Error</td>
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</tr>
<tr>
<td>Sep-02-2020 13:42:16 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Opened, e-Diary: Per eDiary records, FATIGUE is reported on Last day however the last day in inform is entered as 'No' for the same. Please verify and update. Else, clarify. Thanks</td>
<td></td>
</tr>
<tr>
<td>Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO, Initial Entry</td>
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</tr>
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</table>

2.c

***Confidential***
### 2.3 Symptom:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
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<td>ACV0PFEINFP6000</td>
<td>(b) (6)</td>
<td>Data Entry: HEADACHE</td>
<td>Initial Entry</td>
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</table>

### 2.4 Were fever or systemic symptoms present on the last day the Subject Diary was completed?

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (6)</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

### 2.5

<table>
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<th>Reason</th>
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<tbody>
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<td>ACV0PFEINFP6000</td>
<td>(b) (6)</td>
<td>Data Entry: HEADACHE</td>
<td>Initial Entry</td>
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</table>

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FDA-CBER-2021-5683-0895502
**2.d Symptom:**

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<th>Reason</th>
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<tbody>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: CHILLS</td>
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</table>

**2.2 Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

<table>
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<th>Reason</th>
</tr>
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<tbody>
<tr>
<td>Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
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**2.e Symptom:**

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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
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**2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

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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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**2.f**

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### 2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

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<td>(b) (4), (b) (6)</td>
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</table>

Data Entry:
Symptom:: DIARRHEA

---

### 2.g

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<th>User</th>
<th>Value</th>
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<td>(b) (4), (b) (6)</td>
<td>NO</td>
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Data Entry:
Symptom:: NEW OR WORSENED MUSCLE PAIN

Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO
### 2.g Symptom:

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### 2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

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### 2.h Symptom:

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<td>Data Entry: NEW OR WORSENED JOINT PAIN</td>
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### 2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

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<td>Data Entry: NO</td>
<td>Initial Entry</td>
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### 3. Injection Site Location:

<table>
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<th>Reason</th>
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</thead>
<tbody>
<tr>
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<td>auto calc (autocalc)</td>
<td>Data Entry: DELTOID MUSCLE</td>
<td>Initial Entry</td>
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### 4. Injection Site Body Side:

<table>
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<th>Reason</th>
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</thead>
<tbody>
<tr>
<td>Sep-01-2020 12:46:00 (UTC-06:00) Central Time (US &amp; Canada)</td>
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<td>Initial Entry</td>
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### 5.a

<table>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: Injection Site Reaction: REDNESS</td>
<td>Initial Entry</td>
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<td>Were injection site reactions present on the last day the Subject Diary was completed?: NO</td>
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### 5.a Injection Site Reaction:

<table>
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<th>Reason</th>
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### 5.a Were injection site reactions present on the last day the Subject Diary was completed?

<table>
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<tbody>
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### 5.b

<table>
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<tr>
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<tbody>
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</table>
### 5.5 Injection Site Reaction:

<table>
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<td>Time (US &amp; Canada)</td>
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### 5.b Were injection site reactions present on the last day the Subject Diary was completed?

<table>
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<th>Location</th>
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<tbody>
<tr>
<td>Sep-01-2020 12:46:00</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4),</td>
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### 5.c

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<tbody>
<tr>
<td>Sep-15-2020 08:18:16</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4),</td>
<td>PAIN AT INJECTION SITE</td>
<td>New Information</td>
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<tr>
<td>Time (US &amp; Canada)</td>
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**Data Entry:**

Were injection site reactions present on the last day the Subject Diary was completed?

Stop Date: Aug/12/2020

Transcription Error
Injection Site Reaction: PAIN AT INJECTION SITE

Were injection site reactions present on the last day the Subject Diary was completed?:

NO

---

Injection Site Reaction: PAIN AT INJECTION SITE

Were injection site reactions present on the last day the Subject Diary was completed?:

YES

Ongoing?:

NO

Stop Date:

Aug/11/2020

---

Injection Site Reaction: PAIN AT INJECTION SITE

Were injection site reactions present on the last day the Subject Diary was completed?:

NO
### 5.c Injection Site Reaction:

<table>
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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
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<td><strong>Data Entry:</strong> PAIN AT INJECTION SITE</td>
<td>Initial Entry</td>
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### 5.c Were injection site reactions present on the last day the Subject Diary was completed?

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<tr>
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<td><strong>Query 3: Closed</strong></td>
<td>Response satisfies query</td>
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<td>auto query (autoquery)</td>
<td><strong>Query 3: Answered</strong></td>
<td>New Information</td>
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<td>Sep-15-2020 08:18:16</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> YES</td>
<td>New Information</td>
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<tr>
<td>Sep-15-2020 04:45:59</td>
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<td>(b) (4), (b) (6)</td>
<td><strong>Query 3: Opened</strong></td>
<td>e-Diary: Per diary records, PAIN AT INJECTION SITE present on Last day however inform entered with 'No' for the same. Please verify and update. If diary entered in error, please enter stop date as last date of diary or consider raising DCF to correct diary</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
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<td>Sep-15-2020 03:04:50</td>
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<td><strong>Query 2: Closed</strong></td>
<td>Closed by DM: (b) (b)</td>
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<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
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***Confidential***
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<td>Balaji Prabu R</td>
<td>Query 2: Opened</td>
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<td>(b) (4)</td>
<td>As per e-diary, Pain at injection site started on 12Aug2020, but stop date is reported as 11AUG2020. Please clarify.</td>
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<tr>
<td>Sep-09-2020 03:31:52</td>
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<td>e-Diary: Per eDiary records, PAIN AT INJECTION SITE is reported on Last day however the last day in inform is entered as 'No' for the same. Please verify and update. Else, clarify. Thanks</td>
</tr>
<tr>
<td>Sep-01-2020 12:46:00</td>
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2.a

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<td>Data Entry:</td>
<td>Initial Entry</td>
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<td>Initial Entry</td>
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<td>12:46:26</td>
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<td>(b) (6)</td>
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2.a Temperature:

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(b) (4), (b) (6)
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### 4. Laboratory Name and Address (Derived)

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### 6.a

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**6.a Not Done:**

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### 2. Sample Type

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### 3. Sample Collected?

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<td>Query 1: Deleted</td>
<td>Close Auto Query</td>
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### 5.a

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### 5.a Sample ID

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**Data Entry:** BM8649

**Reason:** Initial Entry
### 1. Was there a temporary delay of vaccination?

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### 2. Treatment Name

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### 3. Formulation:

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### 4. Dose Date Time:

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### 5. Anatomical Location:

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10. Timeframe Subject Was Observed

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

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1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

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2.a

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<td>Were fever or</td>
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2.a Symptom:

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2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

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2.b

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2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

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<th>Reason</th>
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<td>Data Entry:</td>
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<td>Symptom::</td>
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<td>Reason</td>
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Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO

---

2.5

<table>
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Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO
### 2.c Symptom:

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### 2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

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### 2.d

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### 2.d Symptom:

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### 2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

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**2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

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**2.f**

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### 2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

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### 2.g

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### 2.g Symptom:

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### 2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

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<td>Date/Datum</td>
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<td>Value</td>
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<tr>
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<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: DELTOID MUSCLE</td>
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<td>Initial Entry</td>
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<tr>
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<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Injection Site Reaction:: REDNESS</td>
<td>Initial Entry</td>
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5.a Injection Site Reaction:

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5.a Were injection site reactions present on the last day the Subject Diary was completed?

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5.b

<table>
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<td><strong>Data Entry:</strong> Injection Site Reaction:: SWELLING</td>
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### 5.b Injection Site Reaction:

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<th>Reason</th>
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<tbody>
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### 5.b Were injection site reactions present on the last day the Subject Diary was completed?

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### 5.c Injection Site Reaction:

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### 5.c Were injection site reactions present on the last day the Subject Diary was completed?

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***Confidential***
### 1. Data Origin

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### 2. Sample Type

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### 3. Sample Collected?

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<td>Close Auto Query</td>
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<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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### 5.c Sample ID

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### 5.d

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### 5.d Sample ID

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### 1. Date of Visit

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<td>Query 9: Answered</td>
<td>page updated</td>
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non-collection of sample by providing reason. Contact CRA for any further assistance.

Sep-20-2020 04:06:27 (UTC-06:00) Central Time (US & Canada)

Sep-18-2020 09:15:48 (UTC-06:00) Central Time (US & Canada)

Sep-18-2020 09:15:29 (UTC-06:00) Central Time (US & Canada)

Sep-18-2020 09:15:29 (UTC-06:00) Central Time (US & Canada)

Sep-18-2020 09:15:29 (UTC-06:00) Central Time (US & Canada)

Sep-18-2020 09:15:29 (UTC-06:00) Central Time (US & Canada)

Sep-18-2020 06:17:03 (UTC-06:00)

Sep-18-2020 06:17:03 (UTC-06:00) Central Time (US & Canada)
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Page 484 of 707
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<td>Close Auto Query</td>
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**Form Status**: Data Complete, Frozen, Verified  
**Site No**: 1019  
**Site Name**: (1019) Diagnostics Research Group  
**Subject No**: 10191010  
**Generated By**: (b) (4)  
**Generated Time (GMT)**: 29-Mar-2021 04:44

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### 4.a Symptoms:

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### 4.a Was symptom present?

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***Confidential***
### 4.b Symptoms:

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Subject No: 10191010
Generated By: (b) (4)

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Initial Entry
Transcription Error
Initial Entry
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**4.g Was symptom present?**

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**Symptoms:** DIARRHEA
**Symptom Present:** Not Applicable
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**4.h Symptoms:**

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### 4.i Symptoms:

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

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<th><strong>User</strong></th>
<th><strong>Value</strong></th>
<th><strong>Reason</strong></th>
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<td>Query 2: Answered</td>
<td>hospital data added</td>
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| Nov-11-2020 05:10:07 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Reissued: Opened | [DM - please unfreeze CRF pages under this visit so site can add updated information on this hospitalization]CLINQUERY:Please enter on the relevant CRF form any available information(vital signs, pulse oxymet, respiratory treatment, lab results, imaging…)

---

***Confidential***
**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020  
**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History  
**Form Version:** 15-Sep-2020 21:53  
**Form Status:** Data Complete, Frozen, Verified  
**Site No:** 1019  
**Site Name:** (1019) Diagnostics Research Group  
**Subject No:** 10191010  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 04:44  

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<td>[DM - please unfreeze CRF pages under this visit so site can add updated information on this hospitalization]CLINQUERY: Please enter on the relevant CRF form any available information (vital signs, pulse oxymet, respiratory treatment, lab results, imaging...)</td>
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<td>CLINQUERY: Subject had COVID-19 Illness and was hospitalized. Please enter on the relevant CRF form any available information (vital signs, pulse oxymet, respiratory treatment, lab results, imaging...). Please make every effort to obtain this</td>
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<tr>
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<td>Response satisfies query</td>
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***Confidential***

FDA-CBER-2021-5683-0895562
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<td>subject was hospitalized, however hospitalization CRF has not been</td>
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<td>Rupal N Shah</td>
<td></td>
<td></td>
<td>update this form as appropriate or else clarify,</td>
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<td>Has the subject been in intensive care due to potential COVID-19</td>
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<td></td>
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<td>illness?</td>
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**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

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

**Form Status:**

**Site No:** 1019

**Site Name:** (1019) Diagnostics Research Group

**Subject No:** 10191010

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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<tr>
<td>Time (US &amp; Canada)</td>
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<tr>
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### 2. Hospitalization Term:

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<td>that the subject was</td>
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<td>hospitalized, therefore, this</td>
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<td>form is not expected to be</td>
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<tr>
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### 3. Admission Date:

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### 4. Ongoing?

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

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### 3. Treatment:

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<th>Reason</th>
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### 4. Treatment:

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### 6. Ongoing?

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<td><strong>Subject No:</strong> 10191010</td>
<td><strong>Generated Time (GMT):</strong> 29-Mar-2021 04:44</td>
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### 2. Was a diagnosis obtained for Potential COVID-19 Illness?

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**Note:**
- If Diagnosis is not obtained, answer the question as "NO" and enter toxicity grade between 1-5 as per CCG section.
- Please review and update as appropriate.
- Dm Query: Unfrozen. Per CCG, this form is a required CRF, please complete as appropriate.
- Please unfreeze.
CLIQUERY: per CCG, this form is a required CRF, please complete as appropriate. If Diagnosis is not obtained, answer the question as "NO" and enter toxicity grade between 1-5 as per CCG section 8.13.5 as it relates to Symptoms.
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*(b) (4), (b) (6)*
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### 2. Laboratory Name and Address

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### 5.a

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### 5.a LNMT

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### Date and Details

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High: 18  
Unit: mg/dL | Initial Entry |
| Nov-11-2020 08:13:58 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry:  
Not Applicable | Initial Entry |
| Sep-21-2020 15:41:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry:  
Not Applicable | Initial Entry |

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Sponsor-Defined Id entifier: 48  
Test:: Not Applicable  
Result:: 1.01  
Not Done::  
Lab Normal Range: Low 0.6  
High: 1.3  
Unit: mg/dL | Initial Entry |
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Form Version: 30-Jul-2020 21:28
Form Status: Data Complete, Frozen
Site No: 1019
Site Name: (1019) Diagnostics Research Group
Subject No: 10191010
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 04:44

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**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen

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**Form Status:** Data Complete, Frozen
**Site Name:** (1019) Diagnostics Research Group
**Subject Initials:** ---
**Generated Time (GMT):** 29-Mar-2021 04:44

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**Page 554 of 707**

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***Confidential***

FDA-CBER-2021-5683-0895606
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- **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History
- **Form Version:** 30-Jul-2020 21:28
- **Form Status:** Data Complete, Frozen
- **Site No:** 1019
- **Site Name:** (1019) Diagnostics Research Group
- **Subject No:** 10191010
- **Subject Initials:** ---
- **Generated By:** (b) (4)
- **Generated Time (GMT):** 29-Mar-2021 04:44

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**Form Version:** 30-Jul-2020 21:28  
**Site No:** 1019  
**Subject No:** 10191010  
**Generated By:** [b] (4)  
**Generated Time (GMT):** 29-Mar-2021 04:44  
**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History  
**Form Status:** Data Complete, Frozen  
**Site Name:** (1019) Diagnostics Research Group  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 04:44
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**Form Status:** Data Complete, Frozen

**Site No:** 1019

**Site Name:** (1019) Diagnostics Research Group

**Subject No:** 10191010

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Sponsor-Defined Identifier:** Not Applicable

**Test:** Not Applicable

**Result:** Not Done:

**Lab Normal Range:** Not Applicable
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**5.j**

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Page 575 of 707
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<td>Balaji Prabu R (b) (4)</td>
<td>Query 1: Opened</td>
<td>Check all assessments performed on 27 and 28th Aug2020. If multiple values were recorded on a single day, at a minimum the most abnormal should be recorded, i.e. the lowest Diastolic Blood Pressure &amp; Systolic Blood Pressure and the highest HR and RR.</td>
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<table>
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### 2.a

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2.a Systolic:

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### 2.a Heart Rate in beats/minute:

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**Form:** VITAL SIGNS - COVID - Audit Trail  
**Form Version:** 10-Oct-2020 15:59  
**Site No:** 1019  
**Subject No:** 10191010  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 04:44

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

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**Subject No:** 10191010  
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**Generated Time (GMT):** 29-Mar-2021 04:44

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**Clinically significant or not clinically significant. Thank you**

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### Vital Signs

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#### 2.a Respiratory Rate in respirations/minute:
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**Visit:** POT_COVID_ILL 1 - Unscheduled Visit  
on Aug/17/2020  
**Form:** VITAL SIGNS - COVID - eCRF Audit Trail History  
**Form Version:** 10-Oct-2020 15:59  
**Form Status:** Incomplete, Data Complete, Deleted  
**Site No:** 1019  
**Site Name:** (1019) Diagnostics Research Group  
**Subject No:** 10191010  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 04:44

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

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### 2.a Heart Rate in beats/minute:

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***Confidential***

Page 605 of 707
### Vital Signs - COVID - eCRF Audit Trail History

**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020  
**Form:** VITAL SIGNS - COVID - eCRF Audit Trail History

**Form Status:** Data Complete, Deleted  
**Form Version:** 10-Oct-2020 15:59

**Site No:** 1019  
**Site Name:** (1019) Diagnostics Research Group

**Subject No:** 10191010  
**Subject Initials:** ---

**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 04:44

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**Systolic::** 17  
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**Respiratory Rate in respirations/minute::** 18  
**Heart Rate in beats/minute::** 75

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### Vital Signs - COVID - eCRF Audit Trail History

**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020  
**Form:** VITAL SIGNS - COVID - eCRF Audit Trail History  
**Site Name:** (1019) Diagnostics Research Group  
**Subject No:** 10191010  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 04:44

### VITAL SIGNS - COVID - eCRF Audit Trail History

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#### Heart Rate in beats/minute:

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### Data Entry:

- Systolic BP 175 is outside of Normal Range 90 - 140.
- Clinically significant or not clinically significant. Thank you per medical records.
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### VITAL SIGNS - COVID - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:59  
**Form Status:** Data Complete, Deleted  
**Site No:** 1019  
**Subject No:** 10191010  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 04:44

#### 2.a Diastolic:

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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Nov-11-2020 22:07:48 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Closed</td>
<td>Response satisfies query</td>
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<tr>
<td>Nov-11-2020 13:31:13 (UTC-06:00) Central Time (US &amp; Canada)</td>
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<td>Query 1: Answered</td>
<td>per hospital doctors NCS</td>
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<tr>
<td>Nov-11-2020 12:50:56 (UTC-06:00) Central Time (US &amp; Canada)</td>
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<td>(b) (4), (b) (6)</td>
<td>Query 1: Reissued:Opened</td>
<td>DM Q: Please confirm if Clinically significant or not clinically significant. Thank you</td>
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<tr>
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<td>Query 1: Answered</td>
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<td>auto query (autoquery)</td>
<td>Query 1: Opened</td>
<td>Diastolic BP 109 is outside of Normal Range 60 - 90.</td>
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### VITAL SIGNS - COVID - eCRF Audit Trail History

**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020  
**Form:** VITAL SIGNS - COVID - eCRF Audit Trail History  
**Form Version:** 10-Oct-2020 15:59  
**Form Status:** Data Complete, Deleted  
**Site No:** 1019  
**Site Name:** (1019) Diagnostics Research Group  
**Subject No:** 10191010  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 04:44  

#### 2.a Respiratory Rate in respirations/minute:

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<th>Date</th>
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<th>Value</th>
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#### 2.a Heart Rate in beats/minute:

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<td>Changed data per query</td>
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<td>Feb-04-2021 01:51:44</td>
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<td>Balaji Prabu R (b) (4)</td>
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<td>Check all assessments performed on 27Aug2020. If multiple values were recorded on a single day, at a minimum the most abnormal should be recorded, i.e. the lowest Diastolic &amp; Systolic Blood Pressure and the highest Heart Rate &amp; Respiratory rate</td>
</tr>
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### 2.a

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<td>Systolic::</td>
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<td>Respiratory Rate in respirat ions/minute:</td>
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<td>Heart Rate in beats/minute:</td>
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### 2.a Systolic:

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### 2.a Diastolic:

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<tr>
<td>Nov-11-2020 13:31:33</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Answered per hospital doctors NCS</td>
</tr>
<tr>
<td>Nov-11-2020 12:50:56</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Reissued:Opened DM Q: Please confirm if Clinically significant or not clinically significant. Thank you</td>
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<tr>
<td>Nov-11-2020 08:27:51</td>
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<tr>
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<td>auto query (autoquery)</td>
<td>Query 1: Opened Diastolic BP 48 is outside of Normal Range 60 - 90.</td>
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### 2.a Respiratory Rate in respirations/minute:

<table>
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<th>Location</th>
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<th>Value</th>
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<table>
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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>Nov-11-2020 08:27:40</td>
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<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
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<th>Value</th>
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<tbody>
<tr>
<td>Nov-11-2020 08:27:40</td>
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</table>
**1. Date:**

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-11-2020 10:36:49 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong> Aug/27/2020</td>
<td>Initial Entry</td>
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**2.a**

<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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<tr>
<td>Nov-11-2020 10:36:49 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td><strong>Data Entry:</strong></td>
<td>Initial Entry</td>
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**2.a Record Identifier:**

<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>Nov-11-2020 10:36:49 (UTC-06:00) Central Time (US &amp; Canada)</td>
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**2.a Systolic:**

<table>
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<th>Date</th>
<th>Location</th>
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<tbody>
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<td>Query 1: Answered</td>
<td>per hospital doctors NCS</td>
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<tr>
<td>Nov-11-2020 12:50:56 (UTC-06:00) Central Time (US &amp; Canada)</td>
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<td>(b) (4), (b) (6)</td>
<td>Query 1: Reissued:Opened</td>
<td>DM Q: Please confirm if</td>
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### Time (US & Canada) | (b) (4), (b) (6) | Clinically significant or not clinically significant. Thank you per medical records
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#### 2.a Diastolic:

<table>
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<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
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#### 2.a Respiratory Rate in respirations/minute:

<table>
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<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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#### 2.a Heart Rate in beats/minute:

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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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### 2.a

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<th>Reason</th>
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<td>Nov-11-2020 10:37:59</td>
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### 2.a Record Identifier:

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<th>Reason</th>
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### 2.a Systolic:

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<td>per hospital doctors NCS</td>
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<tr>
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<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
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<td>(b) (4), (b) (6)</td>
<td>Query 1: Reissued:Opened</td>
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<td>DM Q: Please confirm if</td>
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### Time (US & Canada)

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<th>Value</th>
<th>Reason</th>
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<td>Systolic BP 192 is outside of Normal Range 90 - 140.</td>
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### 2.a Diastolic:

<table>
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<th>Value</th>
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### 2.a Respiratory Rate in respirations/minute:

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<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
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### 2.a Heart Rate in beats/minute:

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### 2.a

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<tr>
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<td>respirat ions/minute:</td>
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<tr>
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<td>Heart Rate in beats/minute:</td>
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### 2.a Systolic:

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<td>Query 1: Reissued:Opened</td>
<td>DM Q: Please confirm if</td>
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### VITAL SIGNS - COVID - eCRF Audit Trail History

**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020  
**Form:** VITAL SIGNS - COVID - eCRF Audit Trail History  
**Form Version:** 10-Oct-2020 15:59  
**Site No:** 1019  
**Subject No:** 10191010  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 04:44

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#### THIS REPEATING FORM HAS BEEN DELETED

**Clinically significant or not clinically significant. Thank you.**

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#### 2.a Respiratory Rate in respirations/minute:

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#### 2.a Heart Rate in beats/minute:

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### 2.a Respiratory Rate in respirations/minute:

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### 2.a Heart Rate in beats/minute:

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**Header Text:** c4591001

**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:59

**Site No:** 1019

**Site Name:** (1019) Diagnostics Research Group

**Subject No:** 10191010

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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**THIS REPEATING FORM HAS BEEN DELETED***

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**confirm if Clinically significant or not clinically significant. Thank you**

---

**(UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | as per medical records**

---

**Systolic BP 146 is outside of Normal Range 90 - 140.**

---

**Data Entry: 146 | Initial Entry**
**Header Text:** c4591001

**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

**Form Version:** 10-Oct-2020 15:59

**Site No:** 1019

**Subject No:** 10191010

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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**Form:** VITAL SIGNS - COVID - eCRF Audit Trail History

**Form Status:** Data Complete, Deleted

**Site Name:** (1019) Diagnostics Research Group

**Subject Initials:** ---

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

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### 2.a Record Identifier:
### **POT_COVID_ILL 1 - Unscheduled Visit** on Aug/17/2020

**Form Status**: Data Complete, Deleted

**Site Name**: (1019) Diagnostics Research Group

**Subject Initials**: ---

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#### 2.a Systolic:

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### 2.a Respiratory Rate in respirations/minute:

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### 2.a Heart Rate in beats/minute:

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<th>Reason</th>
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### Vital Signs

**1. Date:**

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<td>Respiratory Rate in respirations/minute: 16</td>
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#### Respiratory Rate

**Date**: Nov-11-2020 10:57:15 (UTC-06:00) Central Time (US & Canada)

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#### Heart Rate

**Date**: Nov-11-2020 10:57:15 (UTC-06:00) Central Time (US & Canada)

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**Back to Form**

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### Time (US & Canada) - Vital Signs

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**2.a Diastolic:**

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**2.a Respiratory Rate in respirations/minute:**

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**2.a Heart Rate in beats/minute:**

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#### 2.a

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| Nov-11-2020 11:02:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000              | (b) (4), (b) (6) | Data Entry: Record Identifier:: 1  
Systolic:: 12  
Diastolic:: 63  
Respiratory Rate in respirations/minute: 16  
Heart Rate in beats/minute: 73 | Initial Entry   |

#### 2.a Record Identifier:

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**2.a Heart Rate in beats/minute:**

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Form: VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail
Form Version: 30-Jul-2020 21:28
Site No: 1019
Site Name: (1019) Diagnostics Research Group
Subject No: 10191010
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 04:44

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Unknown | Initial Entry |

2.a SPO2 Pulse Oximetry %
## VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020  
**Form Version:** 30-Jul-2020 21:28  
**Site No:** 1019  
**Subject No:** 10191010  
**Generated By:** (b) (4)  

**Site Name:** (1019) Diagnostics Research Group  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 04:44  

**Form Status:** Data Complete, Deleted  

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Form: VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail
Form Version: 10-Oct-2020 16:04
Site No: 1019
Subject No: 10191010
Generated By: (b) (4)
Site Name: (1019) Diagnostics Research Group
Subject Initials: ---
Form Status:
Generated Time (GMT): 29-Mar-2021 04:44

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Form Version: 10-Oct-2020 16:04
Site No: 1019
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Site Name: (1019) Diagnostics Research Group
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**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020

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

**Form Version:** 10-Oct-2020 16:04

**Site No:** 1019

**Subject No:** 10191010

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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Form: VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail

Site No: 1019
Subject No: 10191010
Generated By: (b) (4)

Form Status:
Site Name: (1019) Diagnostics Research Group
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 04:44

FDA-CBER-2021-5683-0895697
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**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Aug/17/2020  
**Form Version:** 10-Oct-2020 16:04  
**Site No:** 1019  
**Subject No:** 10191010  
**Generated By:** (b) (4)  

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**Form Status:**  
**Site Name:** (1019) Diagnostics Research Group  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 04:44  

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**Site Name:** (1019) Diagnostics Research Group  
**Subject No:** 10191010  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 04:44

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

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- **User**: (b) (4), (b) (6)
- **Value**: Oxygen Saturation: 99.0
- **Reason**: Initial Entry

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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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**5. Start Date:**

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**6. Ongoing?**
### Audit Trail History

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**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF

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

**Site Name:** (1019) Diagnostics Research Group

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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**FDA-CBER-2021-5683-0895720**
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<td>Initial Entry</td>
</tr>
</tbody>
</table>

### 4. Assessment:

<table>
<thead>
<tr>
<th>Date</th>
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<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-21-2020 15:43:01 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Not Applicable</td>
<td>Initial Entry</td>
</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>Oct-06-2020 13:23:44 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Oct/6/2020</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

### 2. Phase of Disposition:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-06-2020 13:23:44 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: VACCINATION</td>
<td>Initial Entry</td>
</tr>
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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>Oct-06-2020 13:23:44 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: COMPLETED</td>
<td>Initial Entry</td>
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</table>
1. Date of Completion/Discontinuation/Death:

<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>Dec-02-2020 13:51:22 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Dec/2/2020</td>
<td>Initial Entry</td>
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</table>

2. Phase of Disposition:

<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>
<tr>
<td>Dec-02-2020 13:51:22 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: FOLLOW-UP</td>
<td>Initial Entry</td>
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3. Status:

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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>
<td>Dec-02-2020 13:52:02 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Closed</td>
<td>Close Auto Query</td>
</tr>
<tr>
<td>Dec-02-2020 13:51:22 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Opened</td>
<td>Response to &quot;Status&quot; is LOST TO FOLLOW-UP but &quot;Specify Status&quot; is missing.</td>
</tr>
<tr>
<td>Dec-02-2020 13:51:22 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: LOST TO FOLLOW-UP</td>
<td>Initial Entry</td>
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4. Specify Status:

<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>
<tr>
<td>Dec-02-2020 13:52:02 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: lost to follow up</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>
**Back to Form**

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
</table>
| Sep-02-2020 07:32:47  
(UTC-06:00) Central Time  
(US & Canada) | ACV0PFEINFP6000 | (b) (4),    | Form Created  |             |
<p>|                  |                            | (b) (6)     |               |             |</p>
<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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</thead>
<tbody>
<tr>
<td>Sep-18-2020 09:30:20</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4),</td>
<td>Form Created</td>
<td></td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td></td>
<td>(b) (6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td>Location</td>
<td>User</td>
<td>Value</td>
<td>Reason</td>
</tr>
<tr>
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<td>---------------------------------</td>
<td>---------</td>
<td>----------------</td>
<td>--------------</td>
</tr>
<tr>
<td>Oct-06-2020 13:19:18 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Form Created</td>
<td></td>
</tr>
</tbody>
</table>
### Category

<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>Sep-02-2020 07:32:47 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINF6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: ADVERSE EVENT</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

### AE ID

<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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</thead>
<tbody>
<tr>
<td>Sep-02-2020 07:32:47 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINF6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: 1</td>
<td>Initial Entry</td>
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</tbody>
</table>

### 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>Sep-15-2020 10:03:09 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINF6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Closed</td>
<td>CLINICAL - 14 Sep 2020 email from Salim Bouguermouh that SARS-COV-2 testing on 11 Aug 2020 and 01 Sep 2020 at the central lab were both Negative.</td>
</tr>
<tr>
<td>Sep-15-2020 07:49:31 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINF6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 3: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Sep-14-2020 14:44:30 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINF6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 3: Answered</td>
<td>NCS per PI</td>
</tr>
<tr>
<td>Sep-14-2020 14:21:21 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINF6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Answered</td>
<td>completed</td>
</tr>
<tr>
<td>Sep-14-2020 12:08:17 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINF6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 3: Opened</td>
<td>CLINICAL SAE report of CT scan results report bilat lower lung nodules. Consider clinical</td>
</tr>
<tr>
<td>Date/Time</td>
<td>User ID</td>
<td>Query Status</td>
<td>Notes</td>
<td></td>
</tr>
<tr>
<td>------------------------</td>
<td>--------------------</td>
<td>--------------</td>
<td>-------</td>
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</tr>
<tr>
<td>Sep-14-2020 11:13:36</td>
<td>ACV0PFEINFP6000</td>
<td>Query 2: Opened</td>
<td>Clin: Per protocol Amendment 5 - Section 8.3.7., COVID-19 related event “DIARRHEA” does not qualify as AE and please should be documented ALSO on the COVID Illness CRF form. A Nasal SWAB will not be collected since the symptoms ended on 29Aug2020.</td>
<td></td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>Salim Bouguermouh</td>
<td>(b) (4)</td>
<td></td>
<td></td>
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<tr>
<td>Sep-14-2020 11:13:14</td>
<td>ACV0PFEINFP6000</td>
<td>Query 1: Closed</td>
<td>Clin: Per protocol Amendment 5 - Section 8.3.7., COVID-19 related event “DIARRHEA” does not qualify as AE and please should be documented ALSO on the COVID Illness CRF form. A Nasal SWAB will not be collected since the symptoms ended on 29Aug2020.</td>
<td></td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>Salim Bouguermouh</td>
<td>(b) (4)</td>
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<td></td>
</tr>
<tr>
<td>Sep-03-2020 14:55:14</td>
<td>ACV0PFEINFP6000</td>
<td>Query 1: Opened</td>
<td>Clin: Per protocol Amendment 5 - Section 8.3.7., COVID-19 related event “DIARRHEA” does not qualify as AE and please should be documented only on the COVID Illness</td>
<td></td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>Salim Bouguermouh</td>
<td>(b) (4)</td>
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<td></td>
</tr>
</tbody>
</table>
CRF form. A Nasal SWAB will not be collected since the symptoms ended on 29Aug2020.

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-18-2020 15:08:47</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Closed</td>
<td>Response satisfies query</td>
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<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
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<td>Sep-18-2020 15:08:16</td>
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<td>Query 2: Closed</td>
<td>Response satisfies query</td>
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<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
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<tr>
<td>Sep-18-2020 14:09:22</td>
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<td>Data Entry:</td>
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<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
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<td>Aug/17/2020 00:00</td>
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<tr>
<td>Sep-18-2020 09:30:58</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Answered</td>
<td>2nd AE entered to clarify</td>
</tr>
<tr>
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<td>Sep-18-2020 09:30:40</td>
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<td>(b) (4), (b) (6)</td>
<td>Query 1: Answered</td>
<td>2nd AE added to clarify</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
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<tr>
<td>Sep-18-2020 07:53:38</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 2: Opened</td>
<td>ClinQuery SAE information states diarrhea began 8/17 &amp; required hospitalization on 8/27. To report onset of diarrhea, consider a 2nd AE entry of diarrhea (non-serious) for 8/17-26, with appropriate grade.</td>
</tr>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
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<td>Sep-18-2020 04:36:21</td>
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<td>(b) (4), (b) (6)</td>
<td>Query 1: Opened</td>
<td>SAE RECON: AER#2020339743</td>
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</table>
5. Is the adverse event still ongoing?

<table>
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<tr>
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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Sep-21-2020 11:06:04 (UTC-06:00) Central Time (US &amp; Canada)</td>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
<td>End Date Time: Aug/27/2020 00:00</td>
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<tr>
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<td>Transcription Error</td>
</tr>
<tr>
<td>Sep-21-2020 11:05:48 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
<td>End Date Time: Aug/29/2020 00:00</td>
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<tr>
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<td></td>
<td>Transcription Error</td>
</tr>
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<td>Sep-21-2020 11:05:31 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
<td>End Date Time: Aug/27/2020 00:00</td>
</tr>
<tr>
<td></td>
<td></td>
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<td>Transcription Error</td>
</tr>
<tr>
<td>Sep-02-2020 07:32:47 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
<td>End Date Time: Aug/29/2020 00:00</td>
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<tr>
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<td>Initial Entry</td>
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</table>

6. Toxicity Grade:

<table>
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<tr>
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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: 2</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal: Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).
<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-28-2020 23:27:52</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 4: Closed; will follow for SAE update with the requested COVID test info</td>
</tr>
<tr>
<td>Oct-28-2020 13:18:10</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 4: Answered; Follow-up form submitted.</td>
</tr>
<tr>
<td>Oct-25-2020 20:28:48</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 4: Opened; COVID testing has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form [#2020339743] to provide whether COVID testing was performed (yes/no) and if yes, the results.</td>
</tr>
<tr>
<td>Sep-20-2020 08:31:58</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 3: Deleted; Close Auto Query</td>
</tr>
<tr>
<td>Sep-18-2020 14:09:30</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 3: Candidate; For AE Diarrhea: Response to &quot;Is the adverse event serious?&quot; is 'No' but &quot;Serious Adverse Event Number&quot; is present.</td>
</tr>
<tr>
<td>Sep-18-2020 14:09:30</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO; Transcription Error</td>
</tr>
<tr>
<td>Sep-03-2020 06:02:33</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 2: Deleted; Close Auto Query</td>
</tr>
<tr>
<td>Sep-02-2020 07:33:18</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Closed; Close Auto Query</td>
</tr>
<tr>
<td>Date/Time</td>
<td>User ID</td>
<td>Event Description</td>
<td></td>
<td></td>
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<tr>
<td>-------------------------------</td>
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<td>-----------------------------------------------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sep-02-2020 07:33:18 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data Entry: YES</td>
<td>Is this serious event associated with congenital anomaly or birth defect?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NO</td>
<td>Did this serious event result in death?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NO</td>
<td>Did this serious event require or prolong hospitalization?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NO</td>
<td>Did this serious event result in persistent or significant disability/incapacity?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NO</td>
<td>Is this serious event life threatening?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NO</td>
<td>Other medically important serious event</td>
<td></td>
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<tr>
<td></td>
<td>YES</td>
<td></td>
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<tr>
<td>Sep-02-2020 07:32:47 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Query 2: Candidate</td>
<td>For AE Diarrhea: Response to &quot;Is the adverse event serious?&quot; is 'Yes' but &quot;Serious Adverse Event Number&quot; is blank.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sep-02-2020 07:32:47 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto query (autoquery)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Query 1: Opened</td>
<td>'Is the adverse event serious?' is marked as YES, but responses to all of the seriousness criteria are NO. At</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
8. Is this adverse event the result of a study Medication Error?  
If Yes, record the type of medication error on the Medication Error Log.

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
</table>

---

Data Entry:

YES  
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  
Other medically important serious event  

NO

---

least one seriousness criterion is expected to be YES for serious events. Please review and update as appropriate.
<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-18-2020 14:10:51</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4),</td>
<td>Data Entry: NOT RELATED</td>
<td>Transcription Error</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(b) (6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>If Not Related to study treatment(s), this event is due to:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>OTHER</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>If Other, specify:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Pre-Existing conditions</td>
</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>Sep-02-2020 07:32:47</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4),</td>
<td>Data Entry: NOT RELATED</td>
<td>Initial Entry</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(b) (6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>If Not Related to study treatment(s), this event is due to:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>OTHER</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>If Other, specify:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Unknown</td>
</tr>
</tbody>
</table>

10. Latest Action Taken with Study Treatment:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-02-2020 07:32:47</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4),</td>
<td>Data Entry: NOT APPLICABLE</td>
<td>Initial Entry</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(b) (6)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

11. Was a Concomitant Medication given?

| Date                  | Location         | User       | Value | Reason | |
|----------------------|------------------|------------|-------|--------| |
| Sep-02-2020 07:32:47  | ACV0PFEINFP6000  | (b) (4),   | Data Entry: NO | Initial Entry |
|                      |                  | (b) (6)    |        |        | |

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>
</table>
13. What was the outcome of this adverse event?:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-02-2020 07:32:47 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: RECOVERED/RESOLVED</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-02-2020 07:32:47 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

15. Serious Adverse Event Number: For Pfizer Use Only

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-20-2020 08:31:58 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: AE 1 was updated to non serious and AE #2 was updated as Serious event</td>
<td></td>
</tr>
<tr>
<td>Sep-03-2020 06:02:33 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: 2020339743</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>
### 1. Category:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-05-2020 14:20:35 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> ADVERSE EVENT</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>Sep-30-2020 07:20:22 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong></td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Sep-18-2020 09:30:20 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> ADVERSE EVENT</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

### 2. AE ID:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-05-2020 14:20:35 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> 2</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>Sep-30-2020 07:20:35 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> Not Done</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>Sep-30-2020 07:20:22 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong></td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Sep-18-2020 09:30:20 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> 2</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec-17-2020 10:17:06 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 7: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Date/Time</td>
<td>Event ID</td>
<td>Response Details</td>
<td>Action</td>
<td></td>
</tr>
<tr>
<td>---------------------------------</td>
<td>---------------------</td>
<td>----------------------------------------------------------------------------------</td>
<td>-----------------------</td>
<td></td>
</tr>
<tr>
<td>Dec-17-2020 10:16:41 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 6: Closed</td>
<td></td>
</tr>
<tr>
<td>Dec-17-2020 07:58:14 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Response satisfies query</td>
<td></td>
</tr>
<tr>
<td>Dec-17-2020 07:58:05 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 7: Answered</td>
<td></td>
</tr>
<tr>
<td>Dec-06-2020 09:55:19 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Updated SAE sent</td>
<td></td>
</tr>
<tr>
<td>Dec-06-2020 09:49:01 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 7: Opened</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>CLINICAL SAE report contains no relevant Med Hx conditions for event of Diarrhea; however Med Hx CRF contains potentially relevant conditions diabetes, diabetic neuropathy, chronic constipation (on Macrogel). Please review, and update SAE as appropriate</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>CLINICAL Thank you. Updated SAE reports a primary infection (although site Unk); however, no anti-infective treatment was administered. Please update with the evidence for infection, or</td>
<td></td>
</tr>
<tr>
<td>Date/Time</td>
<td>Site</td>
<td>Subject</td>
<td>Action</td>
<td>Details</td>
</tr>
<tr>
<td>-----------</td>
<td>------</td>
<td>---------</td>
<td>--------</td>
<td>---------</td>
</tr>
<tr>
<td>Dec-02-2020 13:10:22 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 6: Answered</td>
<td>SAE submitted to address query</td>
</tr>
<tr>
<td>Nov-25-2020 09:56:20 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 6: Opened</td>
<td>CLINICAL Please submit a SAE (#2020339743) followup with info on diarrhea treatment, &amp; clarify statement &quot;The primary infection site was known (as reported)&quot;); eg which infection/what site/what was the workup for diarrhea &amp; 'primary infection'</td>
</tr>
<tr>
<td>Oct-06-2020 22:14:52 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>Salim Bouguermouh (b) (4)</td>
<td>Query 5: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Oct-05-2020 14:20:35 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Diarrhea</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>Oct-05-2020 14:20:25 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry:</td>
<td>Initial Entry</td>
</tr>
<tr>
<td>Oct-05-2020 14:02:39</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 5: Answered</td>
<td>entered data</td>
</tr>
<tr>
<td>Date/Time</td>
<td>Event</td>
<td>Details</td>
<td></td>
<td></td>
</tr>
<tr>
<td>--------------------------------</td>
<td>----------------------------</td>
<td>----------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oct-05-2020 07:51:23</td>
<td>ACV0PFEINFP6000</td>
<td>Salim Bouguermouh (b) (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Query 1: Closed</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Response satisfies query</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oct-05-2020 07:25:00</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Query 4: Closed</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Clin query addresses this</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oct-01-2020 15:31:24</td>
<td>ACV0PFEINFP6000</td>
<td>Salim Bouguermouh (b) (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Query 5: Opened</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Clin: My apologies for the error. This SAE</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>with no COVID positive result should be</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>reported on both Covid visit and AE CRF</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>forms to allow data reconciliation with</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>safety database. Please enter the data a</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>second time.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oct-01-2020 09:53:59</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Query 4: Answered</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>please delete entry. Per prior query. AE</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>has been removed and moved to COVID illness</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>CRF.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sep-30-2020 12:23:55</td>
<td>ACV0PFEINFP6000.InFormAdapter.Discrepancy</td>
<td>PFETMS Oracle (b) (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Query 4: Opened</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Null Term: Verbatim term must not be null/</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>blank.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sep-30-2020 10:49:59</td>
<td>ACV0PFEINFP6000.InFormAdapter.Discrepancy</td>
<td>PFETMS Oracle (b) (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Query 3: Closed</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Discrepancy has been closed.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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***Confidential***
<table>
<thead>
<tr>
<th>Generated Time (GMT): 29-Mar-2021 04:44</th>
</tr>
</thead>
<tbody>
<tr>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
</tr>
<tr>
<td>Sep-30-2020 09:33:29 (UTC-06:00) Central Time (US &amp; Canada)</td>
</tr>
<tr>
<td>Sep-30-2020 09:33:09 (UTC-06:00) Central Time (US &amp; Canada)</td>
</tr>
<tr>
<td>Sep-30-2020 08:52:33 (UTC-06:00) Central Time (US &amp; Canada)</td>
</tr>
<tr>
<td>Sep-30-2020 07:20:22 (UTC-06:00) Central Time (US &amp; Canada)</td>
</tr>
<tr>
<td>Sep-30-2020 07:20:22 (UTC-06:00) Central Time (US &amp; Canada)</td>
</tr>
</tbody>
</table>
| Sep-30-2020 02:12:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Salim Bouguermouh | (b) (4) | Query 1: Reissued: Opened | Clin: Per protocol COVID-19 listed symptom DIARRHEA should be please documented ONLY on the COVID Illness CRF form irrespective of other...
<table>
<thead>
<tr>
<th>Date/Time</th>
<th>User ID</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sep-29-2020 12:54:19 (UTC-06:00)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
</tr>
<tr>
<td>Central Time (US &amp; Canada)</td>
<td></td>
<td>Query 1: Answered</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No nasal swab was needed per PI. Per Medical Records, no SARS-COV-2 test was done.</td>
</tr>
<tr>
<td>Sep-29-2020 10:41:44 (UTC-06:00)</td>
<td>ACV0PFEINFP6000</td>
<td>Salim Bouguermouh (b) (4)</td>
</tr>
<tr>
<td>Central Time (US &amp; Canada)</td>
<td></td>
<td>Query 1: Reissued: Opened</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Clin: potential Covid illness visit CRF completed as ERRONEOUS VISIT, please clarify. Please confirm and provide the reason why no NASAL SWAB was collected. Please confirm that no SARS-COV-2 test was done since the subject was hospitalized.</td>
</tr>
<tr>
<td>Sep-29-2020 07:17:54 (UTC-06:00)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
</tr>
<tr>
<td>Central Time (US &amp; Canada)</td>
<td></td>
<td>Query 1: Answered</td>
</tr>
<tr>
<td></td>
<td></td>
<td>potential covid illness visit crf completed</td>
</tr>
<tr>
<td>Sep-23-2020 07:35:14 (UTC-06:00)</td>
<td>ACV0PFEINFP6000</td>
<td>Salim Bouguermouh (b) (4)</td>
</tr>
<tr>
<td>Central Time (US &amp; Canada)</td>
<td></td>
<td>Query 1: Reissued: Opened</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Clin: please COVID-19 protocol listed symptom DIARRHEA should HAVE triggered a COVID Illness Visit irrespective of other potential diagnosis</td>
</tr>
<tr>
<td>Sep-21-2020 11:29:16</td>
<td>ACV0PFEINFP6000</td>
<td>Erica Weaver (b) (4)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Query 2: Closed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Site updated 1st outcome to 27/Aug.</td>
</tr>
<tr>
<td>Date/Time (UTC)</td>
<td>Event</td>
<td>Details</td>
</tr>
<tr>
<td>----------------</td>
<td>-------</td>
<td>---------</td>
</tr>
<tr>
<td>Sep-21-2020 07:54:00</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sep-21-2020 07:39:53</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sep-21-2020 01:04:54</td>
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<td>DMW QUERY (b) (4)</td>
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<tr>
<td>Sep-20-2020 21:41:38</td>
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<td>(b) (4)</td>
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### 4. Start Date Time:

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<tr>
<td>Oct-05-2020 14:01:12</td>
<td>(UTC-06:00) Central Time</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Aug/27/2020 UNK:UNK</td>
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<tr>
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<td>(US &amp; Canada)</td>
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<td>(UTC-06:00) Central Time</td>
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### 5. Is the adverse event still ongoing?

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<td>(UTC-06:00) Central Time</td>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO End Date Time: Aug/29/2020 UNK:UNK</td>
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<td>(US &amp; Canada)</td>
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<td>Data Entry: NO End Date Time: Aug/29/2020 UNK:UNK</td>
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<td>(US &amp; Canada)</td>
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<td>(UTC-06:00) Central Time</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
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### 6. Toxicity Grade:

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<tr>
<td>Date/Time</td>
<td>User ID</td>
<td>Data Entry</td>
<td>Notes</td>
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</table>
7. **Is the adverse event serious?**

*If Yes, NOTIFY PFIZER IMMEDIATELY.*

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

<table>
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<tr>
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<th>Value</th>
<th>Reason</th>
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<td>FU SAE has been submitted.</td>
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<td></td>
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<tr>
<td>Time (US &amp; Canada)</td>
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<td></td>
<td></td>
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<tr>
<td>Mar-08-2021 14:20:36</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 4: Reissued:Opened</td>
<td>GPDCLIN: Please ensure a FU SAE is submitted if this serious criteria was not included in previous report.</td>
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<tr>
<td>Time (US &amp; Canada)</td>
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<tr>
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<td>auto query (autoquery)</td>
<td>Query 4: Answered</td>
<td>New Information</td>
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<tr>
<td>Time (US &amp; Canada)</td>
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<td></td>
<td>Is this serious event associated with congenital anomaly or birth defect?</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Did this serious event result in death?</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Did this serious event require or prolong hospitalization?</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Did this serious event result in persistent or significant disability/incapacity?</td>
<td></td>
</tr>
<tr>
<td>Time</td>
<td>Event Description</td>
<td>Query Status</td>
<td>Comment</td>
<td></td>
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<tr>
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<td>Mar-07-2021 23:41:08</td>
<td>ACV0PFEINFP6000 (b) (4), (b) (6)</td>
<td>Opened</td>
<td>GPDCLIN: Grade 4 event is a life threatening event however, answer to question: Is this serious event life threatening? is NO. Please review and clarify.</td>
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</tr>
<tr>
<td>Mar-05-2021 06:54:52</td>
<td>ACV0PFEINFP6000 (b) (4), (b) (6)</td>
<td>Candidate</td>
<td>GPDCLIN: Grade 4 event is a life threatening event however, answer to question: Is this serious event life threatening? is NO. Please review and clarify.</td>
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<tr>
<td>Mar-05-2021 06:54:33</td>
<td>ACV0PFEINFP6000 (b) (4), (b) (6)</td>
<td>Closed</td>
<td>Re-issued as candidate.</td>
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<tr>
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<td>Opened</td>
<td>GPDCLIN: Grade 4 event is a life threatening event however, answer to question: Is this serious event life threatening? is NO. Please review and clarify.</td>
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</tr>
<tr>
<td>Oct-05-2020 14:01:12</td>
<td>ACV0PFEINFP6000 (b) (4), (b) (6)</td>
<td>Data Entry:</td>
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<td></td>
<td>Initial Entry</td>
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<tr>
<td>Time (US &amp; Canada)</td>
<td>Data Entry:</td>
<td>Form Status: Data Complete, Answered Queries</td>
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<td>Subject Initials: ---</td>
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<td></td>
<td>Form: ADVERSE EVENT REPORT - eCRF Audit Trail History</td>
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<td>Visit: Logs - Unscheduled</td>
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<tr>
<th>Event Description</th>
<th>Data Entry:</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is this serious event associated with congenital anomaly or birth defect?</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>Did this serious event result in death?</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>Did this serious event require or prolong hospitalization?</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>Did this serious event result in persistent or significant disability/incapacity?</td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td>Is this serious event life threatening?</td>
<td>NO</td>
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<tr>
<td>Other medically important serious event</td>
<td>YES</td>
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<table>
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<th>Event Time</th>
<th>Event Description</th>
<th>Data Entry:</th>
<th>Notes</th>
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<tr>
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<td>Data Entry: Transcription Error</td>
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<tr>
<td>Sep-20-2020 08:36:28 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>auto query (autoquery)</td>
<td>Query 2: Deleted</td>
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<td>Query 1: Closed</td>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: Transcription Error</td>
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</table>

---

FDA-CBER-2021-5683-0895747
h 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

Other medically important serious event
NO

Sep-18-2020 09:30:20 (UTC-06:00) Central Time (US & Canada)
ACV0PFEINFP6000
auto query (autoquery)
Query 2: Candidate
For AE Diarrhea: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.

Sep-18-2020 09:30:20 (UTC-06:00) Central Time (US & Canada)
ACV0PFEINFP6000
auto query (autoquery)
Query 1: Opened
'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.
**Data Entry:**

**Event Description:**
- Is this serious event associated with congenital anomaly or birth defect?
  
  **YES**
  
  **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**

- Other medically important serious event
  
  **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>Data Entry</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Oct-05-2020 14:01:12 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>NO</td>
<td>Initial Entry</td>
<td></td>
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<tr>
<td>Date</td>
<td>Location</td>
<td>User</td>
<td>Value</td>
<td>Reason</td>
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<tr>
<td>Oct-05-2020 14:01:12 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: Unknown</td>
<td>Initial Entry</td>
<td></td>
</tr>
<tr>
<td>Sep-30-2020 07:21:38 (UTC-06:00) Central Time (US &amp; Canada)</td>
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<td>Data Entry: Transcription Error</td>
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<tr>
<td>Sep-18-2020 09:30:20 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Initial Entry</td>
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<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Response satisfies query</td>
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<td>Sep-18-2020 14:20:27 (UTC-06:00) Central Time (US &amp; Canada)</td>
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<td>Data Entry: Query 1: Closed</td>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: Query 1: Answered</td>
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<tr>
<td>Sep-21-2020 07:56:43 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Query 1: Opened</td>
<td>GPD Clin: Can you please elaborate on what pre-existing</td>
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</table>

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

- **Data Entry:**
- **Reason:**
  - Initial Entry
  - Response satisfies query
  - Query 1: Answered
  - Query 1: Closed
  - Query 1: Opened
  - Transcription Error
condition the SAE is related to?

Data Entry: NOT RELATED
If Not Related to study treatment(s), this event is due to:

OTHER
If Other, specify:
pre-existing condition

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<td>Data Entry: NOT APPLICABLE</td>
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<td>ACV0PFEIFN6000</td>
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11. Was a Concomitant Medication given?

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<tbody>
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<td>Query 1: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Mar-09-2021 14:23:28 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEIFN6000</td>
<td>auto query (autoquery)</td>
<td>Query 1: Answered</td>
<td>Transcription Error</td>
</tr>
<tr>
<td>Mar-09-2021 14:23:28 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEIFN6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: YES</td>
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</tr>
<tr>
<td>Mar-09-2021 09:35:22 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEIFN6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Opened</td>
<td>GPDCLIN: concomitant medication as well</td>
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12. Was a Non-Drug Treatment given?

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<th>Value</th>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
</tr>
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<td>Time (US &amp; Canada)</td>
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<td>(b) (4), (b) (6)</td>
<td>Data Entry: Transcription Error</td>
<td>Initial Entry</td>
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<tr>
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<td>(b) (4), (b) (6)</td>
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<tr>
<td>Time (US &amp; Canada)</td>
<td>Time (US &amp; Canada)</td>
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</table>

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

<table>
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<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
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<tbody>
<tr>
<td>Oct-05-2020 14:01:12</td>
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<td>Initial Entry</td>
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<tr>
<td>Time (US &amp; Canada)</td>
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<tr>
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<tr>
<td>Time (US &amp; Canada)</td>
<td>Time (US &amp; Canada)</td>
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<td>Time (US &amp; Canada)</td>
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</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>
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</thead>
<tbody>
<tr>
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<td>Initial Entry</td>
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<td>(US &amp; Canada)</td>
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<tr>
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<tr>
<td>Sep-18-2020 09:30:20</td>
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<td>Initial Entry</td>
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### 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>
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<tbody>
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<td>Initial Entry</td>
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<td>(US &amp; Canada)</td>
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<td>2020339743</td>
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### 1. Category:

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<th>Value</th>
<th>Reason</th>
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<td>auto calc (autocalc)</td>
<td>Data Entry: ADVERSE EVENT</td>
<td>Initial Entry</td>
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### 2. AE ID:

<table>
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<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-06-2020 13:19:18 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>auto calc (autocalc)</td>
<td>Data Entry: 3</td>
<td>Initial Entry</td>
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</tbody>
</table>

### 3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-13-2020 14:45:31 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Closed</td>
<td>Response satisfies query</td>
</tr>
<tr>
<td>Nov-13-2020 13:39:42 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Answered</td>
<td>unable to clarify medical term. AE term will remain as written</td>
</tr>
<tr>
<td>Nov-13-2020 12:31:05 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Reissued:Opened</td>
<td>GPDCLIN: please clarify if there is a more precise medical term that can be provided. thank you</td>
</tr>
<tr>
<td>Nov-13-2020 07:10:34 (UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Answered</td>
<td>Pt was unable to recall what was stated a minute or two ago while talking on the phone. This is documented in a progress note</td>
</tr>
<tr>
<td>Nov-10-2020 23:35:25</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Query 1: Opened</td>
<td>GPDCLIN: Please</td>
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</table>
**4. Start Date Time:**

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
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<tbody>
<tr>
<td>Oct-06-2020 13:19:18</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: Oct/2/2020 UNK:UNK</td>
<td>Initial Entry</td>
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</table>

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-06-2020 13:19:18</td>
<td>ACV0PFEINFP6000</td>
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<td>Data Entry: NO End Date Time: Oct/2/2020 UNK:UNK</td>
<td>Initial Entry</td>
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</table>

**6. Toxicity Grade:**

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-06-2020 13:19:18</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: 2</td>
<td>Initial Entry</td>
</tr>
</tbody>
</table>
7. Is the adverse event serious?

*If Yes, NOTIFY PFIZER IMMEDIATELY.*

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-06-2020 13:19:18</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
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</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct-06-2020 13:19:18</td>
<td>(UTC-06:00) Central Time (US &amp; Canada)</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (6)</td>
<td>Data Entry: NO</td>
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</table>

9. Is this event related to study treatment:

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
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<tbody>
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10. Latest Action Taken with Study Treatment:

<table>
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<tr>
<th>Date</th>
<th>Location</th>
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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Oct-06-2020 13:19:18</td>
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<td>ACV0PFEINFP6000</td>
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11. Was a Concomitant Medication given?

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

<table>
<thead>
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<th>Value</th>
<th>Reason</th>
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<tbody>
<tr>
<td>Oct-06-2020 13:19:18</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (5)</td>
<td>Data Entry: NO</td>
<td>Initial Entry</td>
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</table>

13. What was the outcome of this adverse event?

<table>
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<tr>
<th>Date</th>
<th>Location</th>
<th>User</th>
<th>Value</th>
<th>Reason</th>
</tr>
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<tbody>
<tr>
<td>Oct-06-2020 13:19:18</td>
<td>ACV0PFEINFP6000</td>
<td>(b) (4), (b) (5)</td>
<td>Data Entry: RECOVERED/RESOLVED</td>
<td>Initial Entry</td>
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</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>
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<tbody>
<tr>
<td>Oct-06-2020 13:19:18</td>
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<td>(b) (4), (b) (5)</td>
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<td>Initial Entry</td>
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### 1. Subject Status

<table>
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<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-02-2020 13:51:22 (UTC-06:00) Central Time (US &amp; Canada)</td>
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<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> DISCONTINUED</td>
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<tr>
<td>Oct-06-2020 13:23:44 (UTC-06:00) Central Time (US &amp; Canada)</td>
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<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> FOLLOW-UP</td>
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<td>Aug-11-2020 16:03:02 (UTC-06:00) Central Time (US &amp; Canada)</td>
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<td>auto calc (autocalc)</td>
<td><strong>Data Entry:</strong> SCREENED</td>
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### 2. Subject Status Date

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### I. Casebook Signature

<table>
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<tr>
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<th>Reason</th>
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**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History  
**Form Status:** Data Complete, Verified  
**Site No:** 1019  
**Site Name:** (1019) Diagnostics Research Group  
**Subject No:** 10191010  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 04:44