Instructions for use:

This Data Capture Aid (DCA) is intended to capture the available clinical details about the nature and severity of COVID-19 illness experienced, particularly in relation to potential cases of vaccine lack of effect or vaccine associated enhanced disease (VAED).

Select questions as needed to obtain any DCA-defined information described below that was not included in the initial report.

AER/Manufacturer Report #: ____________________

Suspect product: ____________________

Reported event term prompting special follow-up activities: ____________________

AE onset date (dd-Mmm-yyyy): ____________________

Patient Age (e.g., 65 years): ____________________

Patient Gender:  
- Male
- Female
- Not Stated

Race:  
- White
- Black or African American
- Native American
- Alaska Native
- Native Hawaiian
- Asian
- Other
- Refused or Don’t Know

Ethnic Group:  
- Hispanic/LatinX
- Non-Hispanic/Non-LatinX

Reporter Information

Name of reporter completing this form (If other than addressee, provide contact information below):

| Phone Number: | Fax Number: | Email Address: |

1. Product information (Pfizer-BioNTech COVID-19 Vaccine)

<table>
<thead>
<tr>
<th>Dose</th>
<th>Date (dd-Mmm-yyyy)</th>
<th>Site of injection</th>
<th>Route</th>
<th>Batch/Lot number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st dose</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2nd dose</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
### Follow-up Questions

Please provide additional details on a separate page if needed and reference the question number.

<table>
<thead>
<tr>
<th>Question</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Does the patient have a positive test for SARS-CoV2?</td>
<td>□ Unknown □ No □ Yes → If Yes, please provide details (and indicate if this is a new infection or a recurrence) Details: (Please specify date of test and type of test – e.g., nasal swab reverse transcription–polymerase chain reaction (RT-PCR) test or nucleic acid amplification–based test (NAAT) or antigen test)</td>
</tr>
<tr>
<td>2. Does the patient have SARS-CoV2 antibodies at diagnosis?</td>
<td>□ Unknown □ No □ Yes → If Yes, please provide details Details: (Please specify date of test, whether IgM /IgG or both and the titer if available)</td>
</tr>
<tr>
<td>3. Was/Is the patient hospitalized?</td>
<td>□ Unknown □ No □ Yes → If Yes, please provide details (e.g., duration of hospitalization) Details:</td>
</tr>
<tr>
<td>4. Was/Is the patient admitted to an Intensive Care Unit?</td>
<td>□ Unknown □ No □ Yes → If Yes, please provide details (e.g., duration of hospitalization) Details:</td>
</tr>
<tr>
<td>5. Is the patient still hospitalized?</td>
<td>□ Unknown □ No □ Yes → If Yes, please provide details (e.g., duration of hospitalization) Details:</td>
</tr>
<tr>
<td>6. If discharged, did the patient have SARS-CoV2 antibodies at hospital discharge?</td>
<td>□ Unknown □ No □ Yes → If Yes, please provide details Details: (Please specify date of test, whether IgM /IgG or both and the titer if available)</td>
</tr>
<tr>
<td>7. Did the patient display clinical signs at rest indicative of severe systemic illness?</td>
<td>□ Unknown □ No □ Yes → If Yes, please provide details (e.g., Fever, RR ≥30 breaths per minute, HR ≥125 beats per minute, use of vasopressors to maintain BP, SpO2 ≤93% on room air, PaO2/FiO2 &lt;300 mm Hg) Details:</td>
</tr>
<tr>
<td>8. Did the patient require supplemental oxygen (including high flow or ECMO) or receive mechanical ventilation?</td>
<td>□ Unknown □ No □ Yes → If Yes, please provide details (e.g., oxygen requirements, pulse oximetry results) Details:</td>
</tr>
</tbody>
</table>
| 9. Please provide information on any new or worsened symptoms/signs during the COVID-19 illness experienced (including date of onset/worsening) | Multiorgan failure □ Unknown □ No □ Yes → If Yes, please indicate which organ systems were affected and provide information on the applicable systems below
   □ Respiratory □ Cardiovascular □ Gastrointestinal/Hepatic □ Vascular □ Renal □ Neurological □ Hematological □ Dermatological □ Other |
### Respiratory
- [ ] Unknown
- [ ] No
- [ ] Yes → If Yes, please provide details

- **Dyspnea**
  - [ ] Unknown
  - [ ] No
  - [ ] Yes → If Yes, please provide details

- **Tachypnea**
  - [ ] Unknown
  - [ ] No
  - [ ] Yes → If Yes, please provide details

- **Hypoxemia**
  - [ ] Unknown
  - [ ] No
  - [ ] Yes → If Yes, please provide details

- **COVID-pneumonia**
  - [ ] Unknown
  - [ ] No
  - [ ] Yes → If Yes, please provide details

- **Respiratory failure**
  - [ ] Unknown
  - [ ] No
  - [ ] Yes → If Yes, please provide details

- **Acute Respiratory Distress Syndrome (ARDS)**
  - [ ] Unknown
  - [ ] No
  - [ ] Yes → If Yes, please provide details

- **Other**
  - [ ] Unknown
  - [ ] No
  - [ ] Yes → If Yes, please provide details

**Details:**

### Cardiovascular
- [ ] Unknown
- [ ] No
- [ ] Yes → If Yes, please provide details

- **Heart failure**
  - [ ] Unknown
  - [ ] No
  - [ ] Yes → If Yes, please provide details

- **Cardiogenic shock**
  - [ ] Unknown
  - [ ] No
  - [ ] Yes → If Yes, please provide details

- **Acute myocardial infarction**
  - [ ] Unknown
  - [ ] No
  - [ ] Yes → If Yes, please provide details

- **Arrhythmia**
  - [ ] Unknown
  - [ ] No
  - [ ] Yes → If Yes, please provide details

- **Myocarditis**
  - [ ] Unknown
  - [ ] No
  - [ ] Yes → If Yes, please provide details

- **Other**
  - [ ] Unknown
  - [ ] No
  - [ ] Yes → If Yes, please provide details

**Details:**

### Gastrointestinal/Hepatic
- [ ] Unknown
- [ ] No
- [ ] Yes → If Yes, please provide details

- **Vomiting**
  - [ ] Unknown
  - [ ] No
  - [ ] Yes → If Yes, please provide details

- **Diarrhea**
  - [ ] Unknown
  - [ ] No
  - [ ] Yes → If Yes, please provide details

- **Abdominal pain**
  - [ ] Unknown
  - [ ] No
  - [ ] Yes → If Yes, please provide details

- **Jaundice**
  - [ ] Unknown
  - [ ] No
  - [ ] Yes → If Yes, please provide details

- **Acute liver failure**
  - [ ] Unknown
  - [ ] No
  - [ ] Yes → If Yes, please provide details

- **Other**
  - [ ] Unknown
  - [ ] No
  - [ ] Yes → If Yes, please provide details

**Details:**

### Vascular
- [ ] Unknown
- [ ] No
- [ ] Yes → If Yes, please provide details

- **Deep vein thrombosis**
  - [ ] Unknown
  - [ ] No
  - [ ] Yes → If Yes, please provide details

- **Pulmonary embolism**
  - [ ] Unknown
  - [ ] No
  - [ ] Yes → If Yes, please provide details

- **Limb ischemia**
  - [ ] Unknown
  - [ ] No
  - [ ] Yes → If Yes, please provide details

- **Vasculitis**
  - [ ] Unknown
  - [ ] No
  - [ ] Yes → If Yes, please provide details

- **Other (in particular any other thromboembolic events)**
  - [ ] Unknown
  - [ ] No
  - [ ] Yes → If Yes, please provide details

**Details:**

### Renal
- [ ] Unknown
- [ ] No
- [ ] Yes → If Yes, please provide details

- **Acute kidney injury**
  - [ ] Unknown
  - [ ] No
  - [ ] Yes → If Yes, please provide details

- **Renal failure**
  - [ ] Unknown
  - [ ] No
  - [ ] Yes → If Yes, please provide details

- **Other**
  - [ ] Unknown
  - [ ] No
  - [ ] Yes → If Yes, please provide details

**Details:**
Neurological  □ Unknown  □ No  □ Yes  → If Yes, please provide details
   Altered consciousness  □ Unknown  □ No  □ Yes  → If Yes, please provide details
   Convulsions/seizures  □ Unknown  □ No  □ Yes  → If Yes, please provide details
   Encephalopathy  □ Unknown  □ No  □ Yes  → If Yes, please provide details
   Meningitis  □ Unknown  □ No  □ Yes  → If Yes, please provide details
   Cerebrovascular accident  □ Unknown  □ No  □ Yes  → If Yes, please provide details and indicate if ischemic or hemorrhagic
   Other  □ Unknown  □ No  □ Yes  → If Yes, please provide details

Details:

Hematological  □ Unknown  □ No  □ Yes  → If Yes, please provide details
   Thrombocytopenia  □ Unknown  □ No  □ Yes  → If Yes, please provide details (see also Q14)
   Disseminated intravascular coagulation  □ Unknown  □ No  □ Yes  → If Yes, please provide details (see also Q14)
   Other  □ Unknown  □ No  □ Yes  → If Yes, please provide details

Details:

Dermatological  □ Unknown  □ No  □ Yes  → If Yes, please provide details
   Chillblains  □ Unknown  □ No  □ Yes  → If Yes, please provide details
   Erythema multiforme  □ Unknown  □ No  □ Yes  → If Yes, please provide details
   Other  □ Unknown  □ No  □ Yes  → If Yes, please provide details

Details:

OTHER (e.g. multisystem inflammatory syndrome [MIS])  □ Unknown  □ No  □ Yes  → If Yes, please provide details

Details:

10. Did the patient receive any additional therapies for COVID-19?

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Date Started (dd-Mmm-yyyy)</th>
<th>Date Stopped (dd-Mmm-yyyy)</th>
<th>Dose/Any additional information</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Remdesivir</td>
<td></td>
<td></td>
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<tr>
<td>☐ Hydroxychloroquine/chloroquine</td>
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<tr>
<td>☐ Azithromycin</td>
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<tr>
<td>☐ Corticosteroids</td>
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<tr>
<td>☐ Other (Please Specify)</td>
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</tr>
</tbody>
</table>

11. Did the event require the initiation of new medication or other treatment or procedure?
□ Unknown  □ No  □ Yes  → If Yes, please provide details
Details:
12. **Patient's outcome with COVID-19:**
- [ ] Recovering
- [ ] Recovered
- [ ] Not recovered
- [ ] Unknown
- [ ] Fatal, Date (dd-Mmm-yyyy): …………………….

If outcome is fatal, was an autopsy performed?
- [ ] Unknown
- [ ] No
- [ ] Yes → If Yes, please provide autopsy findings

**Details:**

13. **How many days from the SARS-CoV2 diagnosis did it take before the SARS-CoV2 antigen test became negative?**

14. **Were any of the following laboratory tests or diagnostic studies performed?** Please specify laboratory data with units, date of test, and reference ranges; and please provide printouts and photographs if available:

<table>
<thead>
<tr>
<th>Laboratory Test or Diagnostic Studies</th>
<th>Date Performed (dd-Mmm-yyyy)</th>
<th>Results with units, if applicable</th>
<th>Reference Ranges, if applicable (or please state if abnormal or elevated/reduced)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test for SARS-CoV-2 by PCR, or other commercial or public health assay</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Imaging for COVID-Pneumonia (e.g. CXR, CT)</td>
<td></td>
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<tr>
<td>Other radiological investigations (e.g. MRI, angiogram, V/Q scan)</td>
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</tr>
<tr>
<td>Imaging for thrombo-embolic events (e.g. doppler or CT)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Hematology (e.g. leucocyte count [including neutrophil and lymphocyte counts], hemoglobin, platelet count, coagulation parameters [PT, PTT, D-Dimer, INR], fibrinogen, B and T cell function assays)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical chemistry (e.g. serum creatinine, glomerular filtration rate [GFR], liver enzymes, bilirubin, albumin, B-type natriuretic peptide [BNP], troponin)</td>
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<td></td>
</tr>
<tr>
<td>Inflammatory markers (e.g. CRP, ESR, procalcitonin, ferritin, LDH, cytokines [including IL-6])</td>
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<td></td>
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</tr>
<tr>
<td>Urinalysis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Evidence of hypoxemia (e.g. PaO2/FiO2 [P/F ratio], SpO2/FiO2 [S/F ratio]), hypercapnia (PaCO2) or acidosis (pH)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other relevant tests (please specify):</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Past Medical History Questions

Please provide additional details on a separate page if needed and reference the question number.

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer Options</th>
</tr>
</thead>
</table>
| 15. Does the patient have a history of any of the following?            | Hypertension  
Diabetes  
Heart Disease (please specify)  
Lung Disease (please specify)  
Liver disease (please specify)  
Kidney disease (please specify)  
Cancer (please specify)  
Immunosuppressive disorder (please specify)  
Obesity  
Other (please specify) |
| 16. Is the patient a smoker/former smoker?                              | Current Smoker  
Former smoker  
No |
| 17. Was the patient taking any medications routinely prior to the event being reported? | Unknown  
No  
Yes → If Yes, please provide details |
| 18. Have any pre-existing diseases worsened during the SARS-CoV2 infection (please specify) | Unknown  
No  
Yes → If Yes, please provide details |
| 19. Has the patient been treated with immunomodulating or immunosuppressing medications or received any other vaccines around the time of COVID-19 vaccination? | Unknown  
No  
Yes → If Yes, please provide details |

### Revision History

<table>
<thead>
<tr>
<th>Revision</th>
<th>Effective Date</th>
<th>Summary of Revisions</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.0</td>
<td>05-Jan-2021</td>
<td>Title updated to Pfizer-BioNTech COVID-19 Vaccine VAED</td>
</tr>
<tr>
<td>1.0</td>
<td>07-Dec-2020</td>
<td>New DCA</td>
</tr>
</tbody>
</table>
# Document Approval Record

<table>
<thead>
<tr>
<th>Document Name:</th>
<th>DCA Pfizer-BioNTech COVID-19 Vaccine VAED</th>
</tr>
</thead>
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<td>Document Title:</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Signed By:</th>
<th>Date(GMT)</th>
<th>Signing Capacity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mridha, Kurshid</td>
<td>28-Dec-2020 14:30:45</td>
<td>Safety Risk Lead Approval</td>
</tr>
<tr>
<td>Mucci, Massimiliano</td>
<td>28-Dec-2020 15:16:28</td>
<td>Manager Approval</td>
</tr>
</tbody>
</table>