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)

Dose	Date (dd-Mmm-yyyy)	Site of injection	Route	Batch/Lot number
1st dose				
2nd dose				

Follow-up Questions

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

1. Does the patient have a positive test for SARS-CoV2?

☐ 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)

2. Does the patient have SARS-CoV2 antibodies at diagnosis?

☐ Unknown ☐ No ☐ Yes → *If Yes, please provide details*

Details: (Please specify date of test, whether IgM /IgG or both and the titer if available)

3. Was/Is the patient hospitalized?

☐ Unknown ☐ No ☐ Yes → *If Yes, please provide details (e.g., duration of hospitalization)*

Details:

4. Was/Is the patient admitted to an Intensive Care Unit?

☐ Unknown ☐ No ☐ Yes → *If Yes, please provide details (e.g., duration of hospitalization)*

Details:

5. Is the patient still hospitalized?

☐ Unknown ☐ No ☐ Yes → *If Yes, please provide details (e.g., duration of hospitalization)*

Details:

6. If discharged, did the patient have SARS-CoV2 antibodies at hospital discharge?

☐ Unknown ☐ No ☐ Yes → *If Yes, please provide details*

Details: (Please specify date of test, whether IgM /IgG or both and the titer if available)

7. Did the patient display clinical signs at rest indicative of severe systemic illness?

☐ 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 <300 mm Hg)?)*

Details:

8. Did the patient require supplemental oxygen (including high flow or ECMO) or receive mechanical ventilation?

☐ Unknown ☐ No ☐ Yes → *If Yes, please provide details (e.g., oxygen requirements, pulse oximetry results)*

Details:

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?

Therapy	Date Started (dd-Mmm-yyyy)	Date Stopped (dd-Mmm-yyyy)	Dose/Any additional information
☐ Remdesivir			
☐ Hydroxychloroquine/chloroquine			
☐ Azithromycin			
☐ Corticosteroids			
☐ Other (Please Specify)			

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:*

Laboratory Test or Diagnostic Studies	Date Performed (dd-Mmm-yyyy)	Results with units, if applicable	Reference Ranges, if applicable (or please state if abnormal or elevated/reduced)
☐ Test for SARS-CoV-2 by PCR, or other commercial or public health assay			
☐ Imaging for COVID-Pneumonia (e.g.CXR, CT)			
☐ Other radiological investigations (e.g. MRI, angiogram, V/Q scan)			
☐ Imaging for thrombo-embolic events (e.g. doppler or CT)			
☐ 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)			
☐ Clinical chemistry (e.g. serum creatinine, glomerular filtration rate [GFR], liver enzymes, bilirubin, albumin, B-type natriuretic peptide [BNP], troponin)			
☐ Inflammatory markers (e.g. CRP, ESR, procalcitonin, ferritin, LDH, cytokines [including IL-6])			
☐ Urinalysis			
☐ Evidence of hypoxemia (e.g. PaO_2/FiO_2 [P/F ratio], SpO_2/FiO_2 [S/F ratio]), hypercapnia ($PaCO_2$) or acidosis (pH)			
☐ Other relevant tests (please specify):_____			

Past Medical History Questions

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

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)*

Details:

16. Is the patient a smoker/former smoker?

☐ Current Smoker ☐ Former smoker ☐ No

Details:

17. Was the patient taking any medications routinely prior to the event being reported?

☐ Unknown ☐ No ☐ Yes → *If Yes, please provide details*

Details:

18. Have any pre-existing diseases worsened during the SARS-CoV2 infection (please specify)

☐ Unknown ☐ No ☐ Yes → *If Yes, please provide details*

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*

Details:

Revision History

Revision	Effective Date	Summary of Revisions
2.0	05-Jan-2021	Title updated to Pfizer-BioNTech COVID-19 Vaccine VAED
1.0	07-Dec-2020	New DCA

Document Approval Record

Document Name:	DCA Pfizer-BioNTech COVID-19 Vaccine VAED
Document Title:	DCA Pfizer-BioNTech COVID-19 Vaccine VAED

Signed By:	Date(GMT)	Signing Capacity
Mridha, Kurshid	28-Dec-2020 14:30:45	Safety Risk Lead Approval
Mucci, Massimiliano	28-Dec-2020 15:16:28	Manager Approval