Instructions for use:

This Data Capture Aid (DCA) is intended to enable the retrieval of clinical details about potential anaphylactic reactions experienced by an individual following administration of Pfizer-BioNTech COVID-19 Vaccine.

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>Time (24 hr)</th>
<th>Anatomical Site of injection</th>
<th>Route</th>
<th>Batch/Lot number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st dose</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>2nd dose</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. Please describe all the signs and symptoms of the anaphylactic reaction [please also see Section 7]: (Please include information on vital signs, e.g. blood pressure, oximetry)</td>
<td>Details:</td>
</tr>
<tr>
<td>2. Please describe the time course of the anaphylactic reaction: (Please specify time of onset following vaccination, speed of progression and duration of signs and symptoms)</td>
<td>Details:</td>
</tr>
<tr>
<td>3. Did the patient require medical intervention?</td>
<td>Details:</td>
</tr>
<tr>
<td>□ Unknown □ No □ Yes → If Yes, please provide details (including dates and times of intervention)</td>
<td>Details:</td>
</tr>
<tr>
<td>□ Adrenaline □ Corticosteroids □ Antihistamine □ IV fluids □ Oxygen □ Bronchodilators □ Other (please specify)</td>
<td>Details:</td>
</tr>
<tr>
<td>4. Was/Is the patient seen in the Emergency Department?</td>
<td>Details:</td>
</tr>
<tr>
<td>□ Unknown □ No □ Yes → If Yes, please provide details</td>
<td>Details:</td>
</tr>
<tr>
<td>5. Was/Is the patient hospitalized?</td>
<td>Details:</td>
</tr>
<tr>
<td>□ Unknown □ No □ Yes → If Yes, please provide details (e.g., date of hospitalization and duration of stay)</td>
<td>Details:</td>
</tr>
<tr>
<td>6. Was/Is the patient admitted to an Intensive Care Unit?</td>
<td>Details:</td>
</tr>
<tr>
<td>□ Unknown □ No □ Yes → If Yes, please provide details (e.g., date of admission to ICU and duration of stay)</td>
<td>Details:</td>
</tr>
<tr>
<td>7. Please provide information on organ involvement</td>
<td>Details:</td>
</tr>
<tr>
<td>Multiorgan involvement □ Unknown □ No □ Yes → If Yes, please indicate which organ systems were affected and provide information on the applicable systems below</td>
<td>Details:</td>
</tr>
<tr>
<td>□ Respiratory □ Cardiovascular □ Dermatological/Mucosal □ Gastrointestinal □ Other</td>
<td>Details:</td>
</tr>
<tr>
<td>Respiratory □ Unknown □ No □ Yes → If Yes, please provide details</td>
<td>Details:</td>
</tr>
<tr>
<td>□ Bilateral wheeze/bronchospasm □ Unknown □ No □ Yes → If Yes, please provide details</td>
<td>Details:</td>
</tr>
<tr>
<td>Stridor □ Unknown □ No □ Yes → If Yes, please provide details</td>
<td>Details:</td>
</tr>
<tr>
<td>Upper airway swelling □ Unknown □ No □ Yes → If Yes, please provide details</td>
<td>Details:</td>
</tr>
<tr>
<td>Respiratory distress □ Unknown □ No □ Yes → If Yes, please provide details specifically on the following:</td>
<td>Details:</td>
</tr>
<tr>
<td>Tachypnoea □ Unknown □ No □ Yes → If Yes, please provide details</td>
<td>Details:</td>
</tr>
<tr>
<td>Increased use of accessory respiratory muscles □ Unknown □ No □ Yes → If Yes, please provide details</td>
<td>Details:</td>
</tr>
<tr>
<td>Recession □ Unknown □ No □ Yes → If Yes, please provide details</td>
<td>Details:</td>
</tr>
<tr>
<td>Cyanosis □ Unknown □ No □ Yes → If Yes, please provide details</td>
<td>Details:</td>
</tr>
<tr>
<td>Grunting □ Unknown □ No □ Yes → If Yes, please provide details</td>
<td>Details:</td>
</tr>
<tr>
<td>Dry cough □ Unknown □ No □ Yes → If Yes, please provide details</td>
<td>Details:</td>
</tr>
</tbody>
</table>
### Hoarse voice
- Unknown
- No
- Yes → If Yes, please provide details

### Difficulty breathing (without wheeze or stridor)
- Unknown
- No
- Yes → If Yes, please provide details

### Sensation of throat closure
- Unknown
- No
- Yes → If Yes, please provide details

### Sneezing
- Unknown
- No
- Yes → If Yes, please provide details

### Rhinorrhea
- 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

#### Measured hypotension
- Unknown
- No
- Yes → If Yes, please provide details

#### Shock
- Unknown
- No
- Yes → If Yes, please provide details – specifically on the following:
  - Tachycardia
  - Capillary refill time > 3 sec
  - Reduced central pulse volume
  - Decreased level of consciousness

#### Other
- Unknown
- No
- Yes → If Yes, please provide details

**Details:**

#### Dermatological/Mucosal
- Unknown
- No
- Yes → If Yes, please provide details

#### Generalized urticaria (hives)
- Unknown
- No
- Yes → If Yes, please provide details

#### Generalized erythema
- Unknown
- No
- Yes → If Yes, please provide details

#### Angioedema (not hereditary)
- Unknown
- No
- Yes → If Yes, please provide details (e.g. local or generalized)

#### Generalized pruritus with skin rash
- Unknown
- No
- Yes → If Yes, please provide details

#### Generalized pruritus without skin rash
- Unknown
- No
- Yes → If Yes, please provide details

#### Generalized prickly sensation
- Unknown
- No
- Yes → If Yes, please provide details

#### Localized injection site urticaria
- Unknown
- No
- Yes → If Yes, please provide details

#### Red and itchy eyes
- Unknown
- No
- Yes → If Yes, please provide details

#### Other
- Unknown
- No
- Yes → If Yes, please provide details

**Details:**

#### Gastrointestinal
- 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

#### Nausea
- Unknown
- No
- Yes → If Yes, please provide details

#### Vomiting
- Unknown
- No
- Yes → If Yes, please provide details

#### Other
- Unknown
- No
- Yes → If Yes, please provide details

**Details:**

#### ANY OTHER SYMPTOMS/SIGNS
- Unknown
- No
- Yes → If Yes, please provide details

**Details**
8. Did the event require the initiation of new medication or other treatment or procedure?
   - Unknown
   - No
   - Yes  If Yes, please provide details
   Details:

9. Patient’s outcome following the potential anaphylactic reaction:
   - 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:

10. 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</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>Mast cell tryptase</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immune markers (e.g. total IgE levels)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Complement activation test</td>
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<td></td>
<td></td>
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<tr>
<td>Hematology</td>
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<tr>
<td>Clinical chemistry</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other relevant tests</td>
<td>(please specify):________</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.

11. Does the patient have a history of any previous allergies to specific products or any conditions indicative of an allergy?
   - Medication (please specify)
   - Vaccine (please specify)
   - Foods (please specify)
   - Environmental (please specify)
   - Insect bite/sting (please specify)
   - Latex (please specify)
   - Chemical (please specify)
   - Other (please specify)
   Details:

12. If there is a previous history of any allergies, does the patient take (or have readily available) any specific medication related to this
   - Adrenaline (Epipen)
   - Corticosteroid
   - Antihistamine
   - Other
   Details:
13. Was the patient taking any medications prior to the event being reported?
- Unknown
- No
- Yes → If Yes, please provide details
Details:

14. Did the patient receive any recent vaccines for any other conditions prior to the event being reported?
- Unknown
- No
- Yes → If Yes, please provide details
Details:

15. Did the patient receive any recent vaccines for SARS-CoV2 other than Pfizer-BioNTech COVID-19 Vaccine prior to the event being reported?
- Unknown
- No
- Yes → If Yes, please provide details
Details:

16. Has the patient received any other vaccines around the time of Pfizer-BioNTech COVID-19 Vaccine vaccination?
- Unknown
- No
- Yes → If Yes, please provide details
Details:

**Revision History**

<table>
<thead>
<tr>
<th>Revision</th>
<th>Effective Date</th>
<th>Summary of Revisions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>23-Dec-2020</td>
<td>New DCA</td>
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## Document Approval Record

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

<table>
<thead>
<tr>
<th>Signed By:</th>
<th>Date(GMT)</th>
<th>Signing Capacity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mucci, Massimiliano</td>
<td>22-Dec-2020 17:22:31</td>
<td>Manager Approval</td>
</tr>
<tr>
<td>Mridha, Kurshid</td>
<td>22-Dec-2020 19:14:41</td>
<td>Safety Risk Lead Approval</td>
</tr>
</tbody>
</table>