**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)**

| Dose | Date (dd-Mmm-yyyy) | Time (24 hr) | Anatomical 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. 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)*

*Details:*

**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)*

*Details:*

**3. Did the patient require medical intervention?**

☐ Unknown ☐ No ☐ Yes → *If Yes, please provide details (including dates and times of intervention)*

☐ *Adrenaline* ☐ *Corticosteroids* ☐ *Antihistamine* ☐ *IV fluids*

☐ *Oxygen* ☐ *Bronchodilators* ☐ *Other (please specify)*

*Details:*

**4. Was/Is the patient seen in the Emergency Department?**

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

*Details:*

**5. Was/Is the patient hospitalized?**

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

*Details:*

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

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

*(e.g., date of admission to ICU and duration of stay)*

*Details:*

**7. Please provide information on organ involvement**

**Multiorgan involvement** ☐ Unknown ☐ No ☐ Yes → *If Yes, please indicate which organ systems were affected and provide information on the applicable systems below*

☐ Respiratory ☐ Cardiovascular ☐ Dermatological/Mucosal ☐ Gastrointestinal ☐ Other

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

- **Bilateral wheeze/bronchospasm** ☐ Unknown ☐ No ☐ Yes → *If Yes, please provide details*
- **Stridor** ☐ Unknown ☐ No ☐ Yes → *If Yes, please provide details*
- **Upper airway swelling** ☐ Unknown ☐ No ☐ Yes → *If Yes, please provide details*
- **Respiratory distress** ☐ Unknown ☐ No ☐ Yes → *If Yes, please provide details – specifically on the following:*
  - **Tachypnoea** ☐ Unknown ☐ No ☐ Yes → *If Yes, please provide details*
  - **Increased use of accessory respiratory muscles** ☐ Unknown ☐ No ☐ Yes → *If Yes, please provide details*
  - **Recession** ☐ Unknown ☐ No ☐ Yes → *If Yes, please provide details*
  - **Cyanosis** ☐ Unknown ☐ No ☐ Yes → *If Yes, please provide details*
  - **Grunting** ☐ Unknown ☐ No ☐ Yes → *If Yes, please provide details*
- **Dry cough** ☐ Unknown ☐ No ☐ Yes → *If Yes, please provide details*

**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** ☐ Unknown ☐ No ☐ Yes → *If Yes, please provide details*
**Capillary refill time > 3 sec** ☐ Unknown ☐ No ☐ Yes → *If Yes, please provide details*
**Reduced central pulse volume** ☐ Unknown ☐ No ☐ Yes → *If Yes, please provide details*
**Decreased level of consciousness** ☐ Unknown ☐ No ☐ Yes → *If Yes, please provide details*
**Loss of consciousness** ☐ Unknown ☐ No ☐ Yes → *If Yes, please provide details*
**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 prickle 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:*

| Laboratory Test | Date Performed (dd-Mmm-yyyy) | Results with units, if applicable | Reference Ranges, if applicable (or please state if abnormal or elevated/reduced) |
|---|---|---|---|
| ☐ Mast cell tryptase | | | |
| ☐ Immune markers (e.g. total IgE levels) | | | |
| ☐ Complement activation test | | | |
| ☐ Hematology | | | |
| ☐ Clinical chemistry | | | |
| ☐ Other relevant tests (please specify):_____ | | | |

## *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)*
☐ Asthma
☐ Arrythmia
☐ Urticaria
☐ Pruritus
☐ Mastocytosis
☐ 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

| Revision | Effective Date | Summary of Revisions |
|---|---|---|
| 1.0 | 23-Dec-2020 | New DCA |

# Document Approval Record

| | |
|---|---|
| **Document Name:** | DCA Pfizer-BioNTech COVID-19 Vaccine Anaphylactic Reaction |
| **Document Title:** | DCA Pfizer-BioNTech COVID-19 Vaccine Anaphylactic Reaction |

| Signed By: | Date(GMT) | Signing Capacity |
|---|---|---|
| Mucci, Massimiliano | 22-Dec-2020 17:22:31 | Manager Approval |
| Mridha, Kurshid | 22-Dec-2020 19:14:41 | Safety Risk Lead Approval |