



**Section D : Details of adverse event(s)**

1. Type of Adverse Event: Serious / Severe
2. If serious AEFI specify: Death / Hospitalization / Cluster / Persistent or significant disability / Congenital anomaly or birth defect / Media, community or parental concern

If this is a part of a cluster\*: Yes / No / Unknown  
 If yes number of other cases in the cluster \_\_\_\_\_ Cluster ID (as generated by SAFE-VAC): \_\_\_\_\_

**Adverse event(s) - clinical\* (TICK AS MANY AS APPLICABLE):**

- |  |  |   |   |
|--|--|---|---|
| <input type="checkbox"/> Severe local reaction   | <input type="checkbox"/> Fever                                   | <input type="checkbox"/> Seizures             | <input type="checkbox"/> Injection site abscess |
| <input type="checkbox"/> Sepsis                  | <input type="checkbox"/> Encephalopathy                          | <input type="checkbox"/> Toxic shock syndrome | <input type="checkbox"/> Thrombocytopenia       |
| <input type="checkbox"/> Allergic reaction       | <input type="checkbox"/> Anaphylaxis                             | <input type="checkbox"/> Intussusception      | <input type="checkbox"/> Lymphadenitis          |
| <input type="checkbox"/> Acute Flaccid Paralysis | <input type="checkbox"/> Hypotonic Hypo-responsive Episode (HHE) | <input type="checkbox"/> Unexplained Death    | <input type="checkbox"/> Anxiety reaction       |

**Additional for COVID vaccine**

- |  |   |  |
|--|---|--|
| <input type="checkbox"/> Joint pain / swelling of recent onset   | <input type="checkbox"/> Painful single limb swelling   | <input type="checkbox"/> Chest pain / fainting / palpitation |
| <input type="checkbox"/> Recent ECG / Echo / angiography changes   | <input type="checkbox"/> Breathlessness / difficulty in breathing / worsening of existing respiratory problem |  |
| <input type="checkbox"/> Altered sensorium / Loss of consciousness   | <input type="checkbox"/> Acute disseminated encephalomyelitis   | <input type="checkbox"/> Guillain-Barre syndrome             |
| <input type="checkbox"/> Meningoencephalitis   | <input type="checkbox"/> Mono-neuropathy / Poly-neuropathy  | <input type="checkbox"/> Rashes                              |
| <input type="checkbox"/> Loss of taste / smell   | <input type="checkbox"/> Acute liver injury / Acute Liver Failure   | <input type="checkbox"/> Chilblain-like lesions /vasculitis  |
| <input type="checkbox"/> Acute kidney injury / Acute Renal Failure / Hematuria / Oliguria / Edema of legs / Hypertension | <input type="checkbox"/> Lymphadenopathy  |  |
| <input type="checkbox"/> Coagulation / bleeding disorder (Thromboembolism, Hemorrhage)                                   |   |  |
| <input type="checkbox"/> Worsening of existing disease (Cardiac / Respiratory / Liver / Kidney / Diabetes etc.)          | <input type="checkbox"/> Others (specify).....  |  |

**Pregnancy related events**

- Maternal death  Fetal loss (abortion)  Premature delivery  Still birth  Neonatal mortality  Congenital anomaly in newborn

Date & Time of first symptom*: DD / MM / YYYY at ___:___AM/ PM	Hospitalization (In-patient admission)*: Yes / No
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Name and address of hospital:

Date & Time of hospitalization*: DD / MM / YYYY at ___:___AM / PM	Hospital Reg. No. (OPD/Admission/Bed Head Ticket):
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If hospitalized, outcome\*: Discharged / Still Hospitalized / Left Against Medical Advice (LAMA) / Absconded / Referred / Death / Brought dead

Current status of patient\*: Recovered completely / recovered with sequelae / still under treatment / death / unknown

Date & Time of Death*: DD / MM / YYYY (if died) at ___:___AM / PM	Post mortem done: Yes / No / Unknown
Place of death: Home / Hospital / On the way to hospital / Others	Date of Post mortem: DD / MM / YYYY

Describe AEFI (sequence of events, signs and symptoms after vaccination) \*:

Signature and name of Reporting Medical Officer:

**Section E: Decision making details**  
 District Immunization Officer to complete and submit in SAFE-VAC / Co-WIN SAFE-VAC (for COVID-19 vaccines) within 24 hours of receiving the above information. SAFE-VAC: <https://safevac.nhp.gov.in>; Co-WIN - SAFE-VAC:

Date report received at District level: \_\_\_ / \_\_\_ / \_\_\_  
 Date investigation planned: \_\_\_ / \_\_\_ / \_\_\_

**DIO/ District Nodal Person (Officer forwarding this report)**  
 Name ..... Designation..... Mobile No\*: .....  
 Email id\*: ..... Signature..... Date/ Seal: .....  
 Complete Office address (with Pin code) .....