

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.mohfw.gov.in>; Co-WIN - SAFE-VAC: <https://www.cowin.gov.in>

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)		