BIO-MED
PRIVATE LIMITED

Format No. : BM/PV/ANX/001B
SOP Ref. : BM/PV/001
Revision No. : 08
Effective Date : 01/02/2024
To be reviewed : 31/01/2026
Replaces Revision : 07

AEFI CASE REPORTING FORM

AEFI REPORTING ID : _____ (TO BE ALOTTED BY BIOMED)

(To be submitted within 24 hours of case notification)

- **REPORTER DETAILS :**

Notified by (Name):	Designation (please circle): health worker/ government doctor/ private practitioner/ community/ media/ others (specify)
Date: __ __/ __ __/ __ __ __ __	_____ _____
Contact phone number (with STD code):	Email ID : _____

ADDRESS AT THE SITE OF EVENT:		
State	**District**	
Complete Address:		

- **PATIENT INITIAL:-**

Patient Name:																

Age/ Date of Birth:	Sex	Male	Female
Weight (in Kg) _____			

- **EVENT DETAILS :-**

Date of reaction started : _____ **Date of reaction stopped :** _____

Suspected adverse event(s) (tick at least one):

☐ Severe local reaction ☐ Seizures

○ *>3 days* ○ *febrile*

○ *Beyond nearest joint* ○ *afebrile*

☐ Abscess ☐ Sepsis ☐ Encephalopathy ☐ Toxic Shock Syndrome

☐ Thrombocytopenia ☐ Anaphylaxis ☐ Intussusceptions

☐ Fever ≥ 39 °C (102 °F) ☐ Hypotonic hypo-responsive episode (HHE)

Acute flaccid paralysis ☐ Sudden Unexplained death syndrome ☐

Other ☐ (Specify below)

Describe AEFI (signs and symptoms):

_____

_____

- **VACCINATION DETAILS :-**

BIO-MED
PRIVATE LIMITED

Details of vaccine, diluents & Vitamin A given to the patient on day of event

Name of vaccines received (write vaccine & diluent details in separate rows)	Dose no. (zero/ first/ second etc. as applicable)	Name of manufacturer	Batch/ lot no.	Mfg. date	Expiry date	Date of opening of vial	Time of opening the vial (for reconstituted vaccine)	No. of other beneficiaries who received vaccine from the SAME vial in this session

Date & time of Start of vaccination:-

Date & time of Stop of vaccination:-

Seriousness (Yes/NO):-If Yes then proceed further & If No then write the outcome of Event.

Death

If Died, Date of Death	D	D	M	M	Y	Y	Y	Y	Time of Death	H	H	M	M	(AM	PM)

Post mortem done? (*encircle*)	Yes/ No/ Planned on (Date) _____	If Yes, Date _____ Time _____

Hospitalization

Hospitalization: No/Yes (date)	D	D	M	M	Y	Y	Y	Y	Time of Hospitalization	H	H	M	M	a. m.	p. m.

Name and address of hospital (if hospitalized): _____

_____

_____

Congenital Anomaly ☐ **Required intervention to prolonged hospitalization** ☐

Life threatening ☐ **Disability** ☐

Other (specify)_____

_____

BIO-MED
PRIVATE LIMITED

- **Outcome :-**

Fatal ☐ **Unknown** ☐ **Recovered** ☐

Recovering ☐ **Not Recovered** ☐

FOR OFFICE USE ONLY:-

- **Causality Assessment :-**

Review By : **Proposed date of investigation (If required): - ____/____/____**

(Sign/Date)

Comments: