CASE INVESTIGATION FORM (CIF)

(To be submitted in SAFE-VAC / Co-WIN – SAFE-VAC within 10 days of notification) *Mandatory Field

AEFI Case ID : IND (AEFI) / S T / D S T / Y R / N U M (from SAFE-VAC, for all vaccines except COVID-19 vaccines)

AEFI Case ID : IND (CO-AEFI) / S T / D S T / Y R / N U M (from Co-WIN - SAFE-VAC, for COVID-19 vaccines)

Section A: Basic details (Please refer to CRF of this case for personal details of patient)

Name of the Lead Investigator*:	Designation*:
Contact phone number* : E mail*:	Date of case visit and investigation: __ __ / __ __ / __ __ __ __ (date when the case was contacted/investigated)

Address of session site*: Village or Urban area: Block Name: District: State:	**Place of Vaccination*:** Govt Health Facility / Outreach / Private Health Facility / Others (specify): _____ Source of vaccine: Government supply / Privately purchased / Others (specify): _____
Date of Vaccination*: __ __ / __ __ / __ __ __ __ Time of Vaccination: __ __ : __ __ AM/PM	**Vaccination in*:** Routine Immunization / Campaign (MI, Pulse Polio, MR, JE, COVID 19 / Others (specify):_____ **Type of Session Site:** Fixed / outreach / mobile / others (specify):_____

Section B : Patient details

Patient Name*:				
Date of Birth of patient * DD/MM/YYYY	Age: _____ years ___ Months ___ days	Sex*:	Male	Female
Mother's Name:				
Spouse/Father's Name:				
Complete Address* with landmarks *(Street name, house number, village, block, Tehsil, PIN No., Telephone No. etc.):*				
PIN:	Phone:			

For women in reproductive age group:

1. Status of pregnancy at the time of vaccination: Yes / No / Don't know
2. If Yes, duration of pregnancy at the time of vaccination: 1-3 months / 4-6 months / 7-9 months
3. Lactating at the time of vaccination: Yes / No / Don't know

Section C : Details of vaccine(s) and diluent(s) administered to the AEFI case during this session (to be filled by MO incharge or DIO of area where vaccination took place)

Name of vaccines received (write vaccine & diluent details in separate rows)*	Dose no. (birth / zero / 1st / 2nd / 3rd / booster 1 / booster 2 / campaign)*	Name of Manufacturer/Brand name*	Batch / Lot No.	Expiry date*	Mfg. date	Date & Time of opening vaccine vial / vaccine reconstitution	No. of **OTHER** beneficiaries who received vaccine from **SAME** vial in this session

Date & Time of first symptom*: DD / MM / YYYY at ___:___AM/ PM	Hospitalization*: Yes / No
Name and address of hospital:	
Date & Time of hospitalization*: DD / MM / YYYY at ___:___AM / PM	Hospital Reg. No. (OPD/Admission/Bed Head Ticket):

Date & time of death*: DD / MM / YYYY (if died) at ___:___AM/ PM Place of death: Home / Hospital / On the way to hospital / Others	Post mortem done: YES / NO / Unknown If done, date of post mortem: DD / MM / YYYY
If hospitalized, outcome *: Discharged / Still Hospitalized / Left Against Medical Advice (LAMA) / Absconded / Referred / Death / Brought dead	
Current status of patient*: Recovered completely / recovered with sequalae / still under treatment / death / unknown	
Describe AEFI (sequence of events, signs and symptoms after vaccination)*:	

Section D Relevant patient information prior to immunization:

Criteria	Finding	Provide details here if "yes" marked to any question@
Any past history of similar reaction event (without vaccination)?	Yes / No / Unknown	
Any adverse event after previous vaccination(s)	Yes / No / Unknown	
Any history of allergies for drugs, vaccine, food or other products?	Yes / No / Unknown	
Any concomitant medication at the time of vaccination, if any (If yes, name the drug, indication, doses, treatment dates/duration)?	Yes / No / Unknown	
Any pre-existing illness / comorbidity / congenital disorder?	Yes / No / Unknown	
Any pre-existing acute illness 30 days prior to vaccination?	Yes / No / Unknown	
Any history of hospitalization 30 days prior to vaccination (mention reason)?	Yes / No / Unknown	
Family history of any disease (relevant to AEFI) or allergy	Yes / No / Unknown	
Has the patient tested COVID-19 positive prior to this vaccination? If yes- Type of test (RTPCR/Rapid test/CBNAAT/TRUNAAT): Date of the test:	Yes / No / Unknown	
Has the patient been in contact with a COVID-19 positive individual within 30 days prior to vaccination?	Yes / No / Unknown	
Has the patient developed symptoms compatible with COVID-19 in the past?	Yes / No / Unknown	

If patient is an infant or baby born to pregnant woman vaccinated during pregnancy, give birth details:	Remarks
1. Birth Weight:	
2. Duration of pregnancy ☐ Full term ☐ Pre-mature ☐ Postdated ☐ Unknown	
3. Place of birth ☐ Home delivery ☐ Institutional ☐ Unknown	
4. Delivery procedure ☐ Normal ☐ Caesarian ☐ Assisted with forceps/vacuum ☐ Unknown	
5. Any antenatal / postnatal complications: Yes / No / Unknown; if yes please specify _____	

Section E Detailed clinical assessment, investigation, diagnosis and treatment of reported AEFI case@

@Instructions:

• *In case of Unexplained Death in infant* - please fill Verbal Autopsy form as per the guidelines

• *If patient has taken medical care* - attach copies of all available documents (including OPD prescriptions, prescription for concomitant medication, case sheet, discharge summary, laboratory/investigation reports and post mortem reports, if available) and then complete additional information NOT AVAILABLE in the attached documents

• *If patient has not taken any medical care* - obtain history, examine the patient and write down your findings below (add additional sheets as required)

Source of information (✓ *all that* apply): ☐ AEFI Case Reporting Form ☐ Examination by the investigator ☐ Medical case records ☐ AEFI Verbal autopsy form ☐ Interview with patient / caregiver ☐ Telephonic enquiry with patient / caregiver ☐ Interview with treating physician ☐ Other_____

Date of examination: **Signs and Symptoms:**

Consciousness: Alert / Drowsy / Unconscious / Other (specify and describe) ……

Vitals: Pulse …….. Temperature …….. Respiratory rate …….. BP …….. Weight ……..

Skin: Rash/Cyanosis/Petechiae/Pallor/Jaundice/Others (specify and describe) ……..

COVID-19 test status after vaccination (if conducted, with date and type of test)

Test conducted: Y / N If Y, date of test: Test result: Positive / Negative / Not known Type of test:

Has anyone in the family of the patient tested COVID 19 positive after vaccination? Y/N. If Y, then date of test:

Has the patient developed symptoms compatible with COVID 19 infection after vaccination? Y/N. If Y, then date of test:

Systemic examination findings (mention the important positive and negative findings):

Treatment provided:

Provisional / Final diagnosis (as per the treating doctor and/or the Investigation team [encircle one] , if no medical care received):

Section F Investigation at vaccination site

Details of vaccines provided on vaccination day at the site linked to AEFI

Number immunized for each vaccine at session site. Attach record if available.	Vaccine name												
	No of doses administered												
	Number of vaccine vials used												

1. Sequence of patient -
   a. At session site on day of vaccination:
      ☐ Within the first half beneficiaries at the session site ☐ Within the last half beneficiaries the session site ☐ Unknown
   b. For a multi dose vaccine vial (since the vial has been opened):
      ☐ Within the first half beneficiaries of the vaccine vial ☐ Within the last half beneficiaries of the vaccine vial ☐ Unknown

   If required, sequence of vaccination of all subjects (affected and not affected) should be established and mentioned on a separate sheet

2. Multidose vials administered to the case		No. of beneficiaries vaccinated from each vial on session day	No. of beneficiaries vaccinated from same vial since opening or reconstitution	No. of times each vial was issued to sessions before being issued to this session
a.				
b.				
c.				
d.				
e.				

3. **Is this case a part of a cluster?**	Yes / No / Unknown
A If yes, how many other cases have been detected in the cluster?	
B Did all the cases in the cluster receive vaccine from the same vial?	Yes / No / Unknown
C If no, Number of vials used in the cluster	

4. If similar events have been reported from other session sites, comments:

Immunization practices <u>at the place (s) where concerned vaccine was used</u> (based on observations and assessment)			
5. **Syringes and Needles Used:**			
• Were/Are AD syringes used for immunization? • If no specify the type of syringes:	Yes / No / Unknown		
Specific key findings/additional observations and comments:			
6. **Reconstitution: (complete only if applicable, ✓ NA if not applicable)**			
• Reconstitution procedure (✓)	Status		
Same reconstitution syringe used for multiple vials of same vaccine?	Yes	No	NA
Same reconstitution syringe used for reconstituting different vaccines?	Yes	No	NA
Separate reconstitution syringe for each vaccine vial?	Yes	No	NA
• Were/Are the diluents used same as recommended by the manufacturer?	Yes	No	NA
7. **Vaccine handling and vaccination** (examine the available used vaccine vials and observe an immunization session, if needed)			
• Noncompliance to recommendations for use of this vaccine (e.g. any contraindication ignored?)	Yes / No / Unknown		
• Wrong selection of the beneficiary(ies) (e.g. NOT age appropriate for the vaccine)	Yes / No / Unknown		
• Unsterile condition of the vaccine (ingredients) or diluent administered (sterile/unsterile)	Yes / No / Unknown		
• Abnormal vaccine's physical condition (e.g. colour, turbidity, presence of foreign substances, etc.)	Yes / No / Unknown		
• Error in vaccine reconstitution/preparation by the vaccinator (e.g., wrong product, wrong diluent, improper mixing, improper syringe filling etc.)	Yes / No / Unknown		
• Date and time of opening the vial clearly NOT mentioned on the vials being used in the session under observation	Yes / No / Unknown		
• Error in vaccine handling (break in cold chain during transport, storage and/or immunization session etc.)	Yes / No / Unknown		
• Error in vaccine administration (e.g. wrong dose, site or route of administration, wrong needle size, not following good injection practice etc.)?	Yes / No / Unknown		
Specific key findings/additional observations and comments:			

Section G **Cold Chain and Transport (Answer the following based on observations and assessment)**	
Last vaccine storage point:	
• The temperature of the ILR/vaccine storage refrigerator monitored (thermometer and documentation)	Yes / No
○ If, 'yes', any deviation outside of 2- 8°C after the concerned vaccine vial was received at cold chain point	Yes / No
○ If, 'yes' attach relevant monitoring documents separately	
• Correct procedure of storing vaccines, diluents and syringes followed	Yes / No / Unknown
• Any other item (other than vaccines and diluents) available in the refrigerator or freezer	Yes / No / Unknown
• Partially used reconstituted vaccines available in the refrigerator	Yes / No / Unknown
• Unusable vaccines (expired, no label, VVM stage 3 & 4, frozen) available in the refrigerator	Yes / No / Unknown
• Unusable diluents (expired, manufacturer not matched, cracked, dirty ampoule) available in the store/refrigerator	Yes / No / Unknown
Specific key findings / additional observations and comments:	
Vaccine Transportation:	
• Type of vaccine carrier used	4-icepacks / 2-icepacks / other
• Conditioned ice-pack used in the vaccine carrier	Yes / No / Unknown
• Vaccine carrier sent to the session site on the same day of vaccination	Yes / No / Unknown
• Vaccination carrier returned from the session site on the same day of vaccination	Yes / No / Unknown
• All empty/partially used/unused vaccine vials (and diluents) return to cold chain point on the same day of vaccination	Yes / No / Unknown
• Comment on vaccine handling (any error, e.g. Break in cold chain during transport, storage and/or immunization session etc.)?	
Specific key findings/additional observations and comments:	

Section H Community Investigation (Please visit locality and interview parents/ others)

Any similar events reported recently in the locality? Yes / No/ Unknown
If Yes, Describe:

If Yes, How many events / episodes and the category of people affected (children, adults, any specific locality/area)?

Of those affected, how many are
- Vaccinated:_____
- Not Vaccinated:_____
- Unknown:_____

Other findings beyond vaccine or vaccination:

Section I District AEFI Committee Review

a)	*What was the provisional diagnosis of the case concluded by the District AEFI committee?*		
b)	*Please describe the events, clinical and epidemiological findings in support of provisional diagnosis.*		
c)	*Any biological product sent (CSF, Blood, urine, tissue extracts) for testing? Note: for AEFI resulting within 28 days following JE vaccine, send sample of CSF, Serum to nearest NIV lab in Pune or Gorakhpur or Mumbai*		
d)	Did the district AEFI committee recommend sending vaccine samples for quality testing?	Yes	No
e)	Was local drug inspector involved in collecting additional samples?		
f)	Specify any other relevant investigation done and attach reports.		

Details of Vaccine/ Diluent samples sent to CDL Kasauli

Vaccine/Diluent Name	Site of collection	Used Vial/Amp. Quantity	Batch no, Lot no, date of expiry	Date Sent	Unused Vial / Amp. Quantity	Batch no, Lot no, date of expiry	Date Sent

Details of Syringe/ Needle samples sent to CDL Kolkata

Type of Syringes	Quantity	Site of collection	Batch no, Lot no, date of expiry	Date Sent	Type of Needles	Quantity	Batch no, Lot no, date of expiry	Date Sent

Based on the investigation, answer the following: *(Please provide explanation in the remark column for any 'yes')*

A	Could the vaccine given to this patient have quality defect or is substandard or falsified?	Yes / No / Unable to assess	Remark
B	In this case, was there an error in prescribing or non-adherence to recommendations for use of this vaccine? (e.g. use beyond the expiry date, wrong recipient etc.)	Yes / No / Unable to assess	Remark
C	In this case, was the vaccine (ingredients) or diluent administered in an unsterile manner?	Yes / No / Unable to assess	Remark
D	In this case, was the vaccine's physical condition (e.g. colour, turbidity, presence of foreign substances etc.) abnormal when administered?	Yes / No / Unable to assess	Remark
E	When this case was vaccinated, was there an error in vaccine reconstitution / preparation by the vaccinator (e.g., wrong product,	Yes / No / Unable to assess	Remark

	wrong diluent, improper mixing, improper syringe filling etc.?		
F	In this case, was there an error in vaccine handling? (e.g. Break in cold chain during transport, storage and/or immunization session etc.)?	Yes / No / Unable to assess	Remark
G	In this case, was the vaccine was administered incorrectly (e.g. wrong dose, site or route of administration, wrong needle size, not following good injection practice etc.)?	Yes / No / Unable to assess	Remark
H	In this case, could this event be a stress response triggered by immunization (e.g. acute stress response, vasovagal reaction, hyperventilation or anxiety etc.)?	Yes / No / Unable to assess	Remark

Section J: Attached copies of reports / documents etc. with this Case Investigation Form:

Sl. No.	List of document copies received (check appropriate box)	Available and submitted with CIF	Will be available, pending for submission	Not applicable	Applicable, but not available	Remarks (if any)
1.	Case Reporting Form (CRF)					
2.	Hospital patient treatment records / hospital discharge summary *(in case of hospitalized cases)* / doctor's OPD prescription / day care treatment record / OPD treatment record)					
3.	Doctor's prescription / treatment record for past / preexisting illness					
4.	Any clinical laboratory test report (Pathology / Microbiology / Hematology / Blood / CSF / Urine / AFP / any radiology imaging report / EEG report, etc.)					
5.	Post Mortem Report – preliminary *(in case of death)*					
6.	Post Mortem Report – final *(in case of death)*					
7.	Verbal Autopsy Form (in case of unexplained death/ not hospitalized)					
8.	Laboratory result of vaccine (if sent for testing)					
9.	Laboratory result of syringes/other drugs (if sent for testing)					
10.	Any other document relevant to case					

District AEFI Committee members

Name	Designation	Phone Number	Signature
1.			
2.			
3.			
4.			
5.			
6.			
7.			

Section K: DIO/ RCHO/ District Nodal Person *(Officer forwarding this report)*

DIO/ DRCHO/ District Nodal Person *(Officer forwarding this report)*

Name …… Designation…… Mobile No*: ……

Email id*: …… Signature…… Date/ Seal: ……

Complete Office address (with Pin code) ……

……

District Immunization Officer to complete and submit in **SAFE-VAC / Co-WIN SAFE-VAC (for COVID-19 vaccines)** within 10 days of receiving the above information. SAFE-VAC: **https://safevac.nhp.gov.in; Co-WIN - SAFE-VAC:**

For any support or help, write to: aefiindia@gmail.com; safevac.chi@gmail.com