ALL VACCINES including COVID-19: CASE INVESTIGATION FORM (CIF)
Adverse Events Following Immunisation (AEFI) AND Adverse Events of Special Interest (AESI)

ONLY for Serious and Severe Adverse Events Following Immunisation, Clusters and Adverse Events of Special Interest

SECTION A: BASIC DETAILS

Province: _____ **EPID No:** S O A - | | | | - | | | | - | | | | - | | | |
District: _____ **Country - Province - District - Year - Case no.**

NB: The EPID number must be IDENTICAL to the number on the CASE REPORTING FORM

PATIENT IDENTIFICATION

NOTE: In maternal vaccination, if mother and baby / more than one baby are affected, complete separate form for each affected individual

Vaccine recipient name & surname: _____ **Note: Use a separate form for each case in a cluster**

Sex: ☐ M ☐ F ☐ Other

Date of birth: D D / M M / Y Y Y Y **OR** Age at onset: ☐☐ Years ☐☐ Months ☐☐☐ Days

OR Age group: ☐ 0 - <1 year ☐ 1 - 5 years ☐ >5 – 18 years ☐ >18 – 60 years ☐ >60 years

Patient's full residential address with landmarks (Street name, house number, locality, etc.):

_____

_____

Telephone no: _____ Mobile no: _____ E-mail: _____

INVESTIGATOR'S DETAILS

Name & surname of reporting officer: _____

Designation / Position: _____ E-mail: _____

Telephone: _____ Mobile: _____

Date of filling this form: D D / M M / Y Y Y Y

Date of investigation: D D / M M / Y Y Y Y _ **This report is:** ☐ First ☐ Interim ☐ Final

DETAILS OF THE EVENT

Date of onset of event: D D / M M / Y Y Y Y Time of first symptom: ☐☐ Hr ☐☐ Min

Date first reported to the health authority: D D / M M / Y Y Y Y

Date of hospitalization (if applicable): D D / M M / Y Y Y Y Status on the date of investigation: ☐ Died ☐ Disabled ☐ Recovering ☐ Recovered completely ☐ Recovered with complications ☐ Unknown

If died, date of death: D D / M M / Y Y Y Y Time of death: ☐☐ Hr ☐☐ Min

Autopsy done: ☐ Yes ☐ No If **YES**, date of autopsy: D D / M M / Y Y Y Y Attach report (if available)

If **NO**, autopsy planned: Date: D D / M M / Y Y Y Y Time ☐☐ Hr ☐☐ Min

Autopsy NOT done nor planned. Provide reasons: _____

_____

IMMUNISATION HISTORY

Name of vaccinator: _____ Designation: _____

Name of vaccination site: _____

Address of vaccination site: _____

Place of vaccination: ☐ Govt. health facility ☐ Private health facility ☐ Other (specify) _____

Type of site: ☐ Fixed ☐ Mobile ☐ Outreach

Vaccination in: ☐ Campaign ☐ Routine ☐ Other (specify): _____

TRIGGER EVENTS

Minor local reactions

☐ Swelling <5cm ☐ Induration / hardness
☐ Redness ☐ Rash
☐ Other (specify): _____

_____

_____

Minor systemic reactions

☐ Excessive crying (infant) ☐ Mild fever <38°C
☐ Mild headache ☐ Mild body aches
☐ Mild pain (to touch / on movement, but not interfering with daily activities) ☐ Fainting
☐ Other (specify): _____

_____

Patient name & surname: _____ EPID Number: _____

Severe local reactions

- ☐ Pain, redness and/or swelling >3 days
- ☐ Swelling >5cm
- ☐ Swelling beyond nearest joint
- ☐ Lymphadenitis
- ☐ Abscess
- ☐ Necrosis at vaccination site
- ☐ Other (specify):

_____
_____
_____

Severe systemic reactions

- ☐ Hospitalisation
- ☐ Death
- ☐ Collapse/ shock-like state
- ☐ Fever ≥38°C
- ☐ Thrombocytopenia
- ☐ Anaphylaxis
- ☐ Seizures ☐ Febrile ☐ Afebrile
- ☐ Encephalopathy
- ☐ Sepsis
- ☐ Toxic shock syndrome
- ☐ Vomiting
- ☐ Diarrhoea
- ☐ Other (specify): _____

Foetal adverse reactions in the case of maternal immunisation:

- ☐ Decreased FHR variability
- ☐ Decreased foetal movement
- ☐ Foetal death
- ☐ Onset of preterm labour, assessed to be possibly/probably related
- ☐ Foetal anomaly assessed to be possibly/probably related (e.g. congenital anomaly feasible with pre-pregnancy or 1st trimester immunisation)
- ☐ Foetus affected by maternal immunization (e.g. live vaccine administered to mother)

VACCINE INFORMATION (Attach copy of Road to Heath Booklet or Vaccination Card)

NOTE: In the case of a foetal adverse event, ALSO record the mother's maternal vaccination details

Vaccine/s administered *(Complete ONLY for alleged vaccine/s administered before the event)*								Diluent *(Where applicable)*		
Vaccine/s given (Use trade names)	Date vaccinated	Time vaccinated	Dose number (1st, 2nd)	Batch/ Lot number	Expiry date / Manufacture date (COVID)	VVM Stage (If applies)	Manufacturer	Batch/ Lot number	Expiry date	Date & time of reconstitution

Consumables used (unless pre-filled)	**Needles**	Size: _____ Batch: _____ Expiry date: _____
	Syringes	Size: _____ Batch: _____ Expiry date: _____

SECTION B: RELEVANT PATIENT INFORMATION PRIOR TO IMMUNISATION (Use additional sheet if needed)

NOTE: In the case of a foetus/newborn potentially affected by maternal immunisation, complete questions below for mother. Where questions would apply to the foetus/newborn, please provide additional details in the space provided

Questions applicable to the VACCINEE	Findings and Remarks *Compulsory to provide explanations			
Any history of similar event?	Yes*	No	Unknown	
Any previous reactions or adverse event after immunisation?	Yes*	No	Unknown	
Any history of allergies? (vaccine, food, drugs)	Yes*	No	Unknown	
Any family history of any allergies?	Yes*	No	Unknown	
Any family history of any disease/s (relevant to AEFI)?	Yes*	No	Unknown	
Pre-existing medical condition/ congenital disorder?	Yes*	No	Unknown	
Pre-existing acute illness (30 days) prior to vaccination?	Yes*	No	Unknown	
Suffering from any medical condition currently?	Yes*	No	Unknown	
History of hospitalisation in last 30 days, with cause?	Yes*	No	Unknown	
Tested COVID-19 positive prior to vaccination? Date?	Yes*	No	Unknown	
Receiving any concomitant medication? ***If yes, name the drug, indication, doses and treatment dates.***	Yes*	No	Unknown	
Receiving any herbal and/or traditional medicines? ***If yes, name the drug, indication, doses and treatment dates.***	Yes*	No	Unknown	

For adult women: Currently pregnant: ☐ Yes (weeks) _____ ☐ No ☐ Unknown
Currently breastfeeding: ☐ Yes ☐ No

For infants: Gestation: ☐ Full-term ☐ Premature ☐ Post-term Birth weight: _____
Delivery procedure: ☐ Normal ☐ Caesarean ☐ Assisted (forceps, vacuum, etc.)
☐ With complications (Specify): _____

Patient name & surname: _____ EPID Number: _____

SECTION C: DETAILS OF FIRST EXAMINATION** OF SERIOUS/SEVERE AEFI CASE

Source of information *(Tick (✓) all that apply)*: ☐ Examination by the investigator ☐ Documents
☐ Verbal autopsy (P*lease mention source):* _____
☐ Other (Specify): _____
Name & surname of the person who first examined/treated the patient: _____
Name & surname of other persons treating the patient: _____
_____
Other sources who provided information (specify): _____
_____
_____

Signs and symptoms of the AEFI in chronological order from the time of vaccination:
_____
_____
_____
_____
_____
_____
_____
_____

Person completing the clinical details	Name & Surname: _____ Designation: _____ Contact: _____	Date: D D / M M / Y Y Y Y Time: ☐☐ Hr ☐☐ Min

***Instructions:* Attach copies of ALL available documents (including case reporting form, discharge summary, case notes, laboratory reports and autopsy reports, prescriptions for concomitant medication) and then complete additional information NOT AVAILABLE in existing documents, i.e.**

- ***If patient has received medical care***: Attach copies of all available documents (including case sheet, discharge summary, laboratory reports and autopsy reports, if available). Provide only information not available in the attached documents below.
- ***If patient has not received medical care:*** Obtain history, examine the patient and record your findings below (add additional sheets if necessary)

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_____
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Provisional / Final diagnosis at the facility ("valid diagnosis"): _____

SECTION D: DETAILS OF VACCINES PROVIDED AT THE SITE LINKED TO AEFI ON THE CORRESPONDING DAY

Vaccinees immunised for each antigen at session site. Attach record if available.	Vaccine name						
	Number of vaccinees vaccinated per session						

a) When was the patient immunised?
☐ Within the first vaccinations of the session ☐ Within the last vaccinations of the session ☐ Unknown

b) In case of multidose vials, when was the vaccine given? ☐ Within the first few doses of the vial administered ☐ Within the last doses of the vial administered ☐ Unknown

c) Time vial was opened: ☐☐ Hr ☐☐ Min

Patient name & surname: _____ EPID Number: _____

	Findings and Remarks *Compulsory to provide explanations			
d) Was there an error in prescribing or non-adherence to recommendations for use of this vaccine?	Yes*	No		
e) Based on your investigation, do you feel that the vaccine (ingredients) administered could have been unsterile?	Yes*	No	Unable to assess	
f) Based on your investigation, do you feel that the vaccine's physical condition (e.g. color, turbidity, foreign substances etc.) was abnormal at the time of administration?	Yes*	No	Unable to assess	
g) Based on your investigation, do you feel that there was an error in vaccine reconstitution/preparation by the vaccinator (e.g. wrong product, wrong diluent, improper mixing, improper syringe filling etc.)?	Yes*	No	Unable to assess	
h) Based on your investigation, do you feel that there was an error in vaccine handling (e.g. break in cold chain during transport, storage and/or immunisation session etc.)?	Yes*	No	Unable to assess	
i) Based on your investigation, do you feel that 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	
j) Number immunised from the concerned vaccine vial/ampoule				
k) Number immunised with the concerned vaccine in the same session				
l) Number immunised with the concerned vaccine having the same batch number in other locations.		Specify locations:		
m) Could this event be a stress response related to immunisation (e.g. acute stress response, vasovagal reaction, hyperventilation, dissociative neurological symptom reaction etc.)?	Yes*	No	Unable to assess	
n) Is this case a part of a cluster?	Yes*	No	Unknown	
If **YES**, how many other cases have been detected in the cluster?				
Did all the cases in the cluster receive vaccine from the same vial?	Yes*	No	Unknown	
If **NO**, number of vials used in the cluster (enter details separately)				

SECTION E: IMMUNISATION PRACTICES AT THE PLACE(S) WHERE CONCERNED VACCINE WAS USED

(Complete this section by asking and/or observing practice)

Syringes and needles used

Are AD syringes used for immunisation? ☐ Yes ☐ No ☐ Unknown

If NO, specify the type of syringes used:

☐ Glass ☐ Disposable ☐ Recycled disposable ☐ Other: _____

Needle used: _____

Specific key findings/additional observations and comments: _____

_____

_____

_____

Reconstitution procedure (complete only if applicable, ✓ NA if not applicable)	**Status**		
a) Same reconstitution syringe used for multiple vials of same vaccine?	Yes	No	NA
b) Same reconstitution syringe used for reconstituting different vaccines?	Yes	No	NA
c) Separate reconstitution syringe for each vaccine vial?	Yes	No	NA
d) Separate reconstitution syringe for each vaccination?	Yes	No	NA
e) Are vaccines and diluents used the same as those recommended by the manufacturer?	Yes	No	NA

Specific key findings/additional observations and comments:

_____

_____

_____

Patient name & surname: _____ EPID Number: _____

Injection technique of vaccinator(s) (Observe another session in the same locality)	Status		
a) Correct dose and route?	Yes	No	NA
b) Time of reconstitution mentioned on the vial? (in case of freeze dried vaccines)	Yes	No	NA
c) Non-touch technique followed?	Yes	No	NA
d) Contraindications screened prior to vaccination?	Yes	No	NA
e) How many AEFI were reported from the centre that distributed the vaccine in the last 30 days?	Yes	No	NA
f) Training received by the vaccinator? If Yes, specify date of last training D D / M M / Y Y Y Y	Yes	No	NA

Specific key findings/ additional observations and comments:

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SECTION F: COLD CHAIN AND TRANSPORT (Complete this section by asking and/or observing practice)

Last vaccine storage point	Findings and Remarks *Compulsory to provide explanations			
a) Is the temperature of the vaccine storage refrigerator monitored?	Yes	No*		
i) If **YES**, was there any deviation outside of 2–8°C after the vaccine was placed inside?	Yes*	No		
ii) If **YES**, provide details and evidence of monitoring separately.				
b) Was the incorrect procedure followed for storing vaccines, diluents and syringes followed?	Yes*	No	Unknown	
c) Was any other item (other than vaccines and diluents) in the refrigerator or freezer?	Yes*	No	Unknown	
d) Were any partially used reconstituted vaccines in the refrigerator?	Yes*	No	Unknown	
e) Were any unusable vaccines (expired, no label, VVM at stages 3 or 4, frozen) in the refrigerator?	Yes*	No	Unknown	
f) Were any unusable diluents (expired, manufacturer not matched, cracked, dirty ampoule) in the store?	Yes*	No	Unknown	

Specific key findings/additional observations and comments:

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Vaccine transportation	Findings and Remarks *Compulsory to provide explanations			
a) Specify the type of vaccine carrier used				
b) Was the vaccine carrier sent to the site on the same day as vaccination?	Yes	No*	Unknown	
c) Was the vaccine carrier returned from the site on the same day as vaccination?	Yes	No*	Unknown	
d) Was a conditioned ice-pack used?	Yes	No*	Unknown	

Specific key findings/additional observations and comments:

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SECTION G: COMMUNITY INVESTIGATION (Please visit locality and interview parents/others)

Were any similar events reported within a time period similar to when the adverse event occurred and in the same locality?

☐ Yes ☐ No ☐ Unknown If YES, how many events/episodes? _____ If YES, please describe:

_____

_____

_____

Patient name & surname: _____ EPID Number: _____

Number of caregivers interviewed: _____
Of those affected, how many are:
Vaccinated: _____ Not vaccinated: _____ Unknown: _____
Other comments:
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SECTION H: OTHER FINDINGS/OBSERVATIONS/COMMENTS (Use additional sheet if required)

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SECTION I: DETAILS OF CASE INVESTIGATION TEAM

Signed off by District EPI Coordinator: Date: D D / M M / Y Y Y Y

Name & surname: _____ Signature: _____

Signed off by Appointed District Medical Officer/Specialist: Date: D D / M M / Y Y Y Y

Name & surname: _____ Signature: _____

SECTION J: NATIONAL LEVEL TO COMPLETE

Date report received at National Level: D D / M M / Y Y Y Y **AEFI worldwide unique ID:** _____

Comments: _____
_____
_____
_____

IMPORTANT: Email this form, including all supporting documentation, within 48 hours to AEFI@health.gov.za AND copy the District EPI Surveillance Officer