



## Vaccine Safety Investigation Group Causality Assessment Expert Panel Worksheet for AEFI Causality Assessment

This template has been developed in line with the World Health Organization Causality Assessment of an Adverse Event Following Immunization (AEFI): User manual for the revised WHO classification, 2nd ed., p 59-60, 2019 update. World Health Organization. <https://apps.who.int/iris/handle/10665/340802>.

### Patient details

TGA ICSR	AU-TGA-0000s 47F
Patient initials	s22
Age at time of event	63 years
Gender	Male
Sources of information	s22
Quality of information	

### Vaccine and AEFI diagnosis details

Vaccine involved	ChAdOx1-S COVID-19 Vaccine AstraZeneca
Vaccine brand name	VAXZEVRIA
Date(s) administered	
Event/Diagnosis	Acute disseminating encephalomyelitis (ADEM)
Does the diagnosis meet a case definition?	Brighton Collaboration Classification: Level 1 ADEM Reference: <a href="#">SPEAC D2.5.2.1 ADEM-Case-Definition-Companion-Guide V1.0 format12063-1.pdf (brightoncollaboration.us)</a>



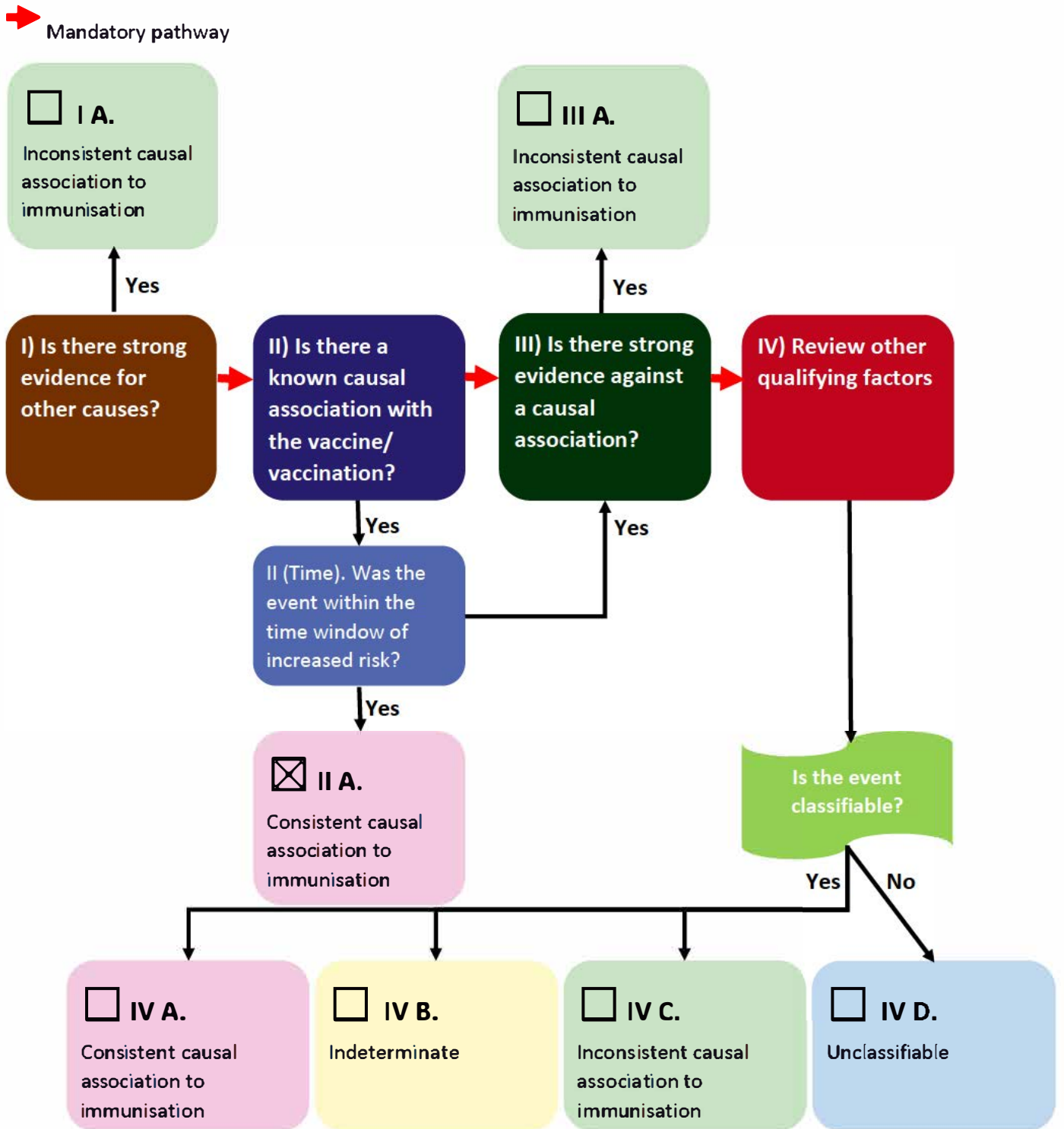






## Step 2: The algorithm

Review all steps and check the appropriate boxes:



### Notes for Step 3:

Click or tap here to enter text.

### Step 3: Classification and Outcome

#### Classification

Check all boxes that apply:

Adequate information			Adequate information not available
<b>A. Consistent with causal association to immunisation</b>	<b>B. Indeterminate</b>	<b>C. Inconsistent with causal association to immunisation</b>	<b>U. Unclassifiable</b>
<input checked="" type="checkbox"/> <b>A1.</b> Vaccine product-related reaction (As per published literature)	<input type="checkbox"/> <b>B1.</b> *Temporal relationship is consistent but there is insufficient definitive evidence for vaccine causing event (may be new vaccine-linked event)	<input type="checkbox"/> <b>C. Coincidental</b> Underlying or emerging condition(s), or condition(s) caused by exposure to something other than vaccine	<input type="checkbox"/> <b>U. Specify the additional information required for classification:</b>  <div style="border: 1px solid #ccc; padding: 5px; margin-top: 10px;">           Click or tap here to enter text.         </div>
<input type="checkbox"/> <b>A2.</b> Vaccine quality defect-related reaction	<input type="checkbox"/> <b>B2.</b> Qualifying factors result in conflicting trends of consistency and inconsistency with causal association to immunisation		
<input type="checkbox"/> <b>A3.</b> Immunisation error-related reaction			
<input type="checkbox"/> <b>A4.</b> Immunisation anxiety-related reaction (ISRR**)			
<p>* B1: Potential signal and maybe considered for investigation            ** Immunisation stress related response</p>			

#### Outcome

Summarise the classification logic in the order of priority:

With available evidence, we could conclude that the classification is	Vaccine product-related reaction	because:
<div style="background-color: black; color: red; padding: 2px;">s22</div> <div style="background-color: black; height: 15px; margin-top: 5px;"></div>		

With available evidence, we could NOT classify the case because:
<div style="border: 1px solid #ccc; padding: 5px; margin-top: 10px;">           Click or tap here to enter text.         </div>

## Signature

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- To setup your signature: Right click the X → 'Signature Setup'
- To sign: Right click the X → 'Sign'

X

s22

VSIG Chair

Return completed form via email to [Committees@health.gov.au](mailto:Committees@health.gov.au) and Cc [TGAVaccineSurveillance@health.gov.au](mailto:TGAVaccineSurveillance@health.gov.au).