

# Annex 1: Worksheet for AEFI causality assessment

## Step 1 (Eligibility)

**Patient ID/Name :** Jessica      **DoB/Age:** 37 years      **Sex: Male/Female** Female

Name one of the vaccines administered before this event	What is the Valid Diagnosis?	Does the diagnosis meet a case definition?
Comirnaty	Autoimmune encephalitis	Yes

**Create your question on causality here**  
 Has the Comirnaty Covid 19 vaccine / vaccination caused Autoimmune encephalitis (The event for review in step 2 - valid diagnosis)

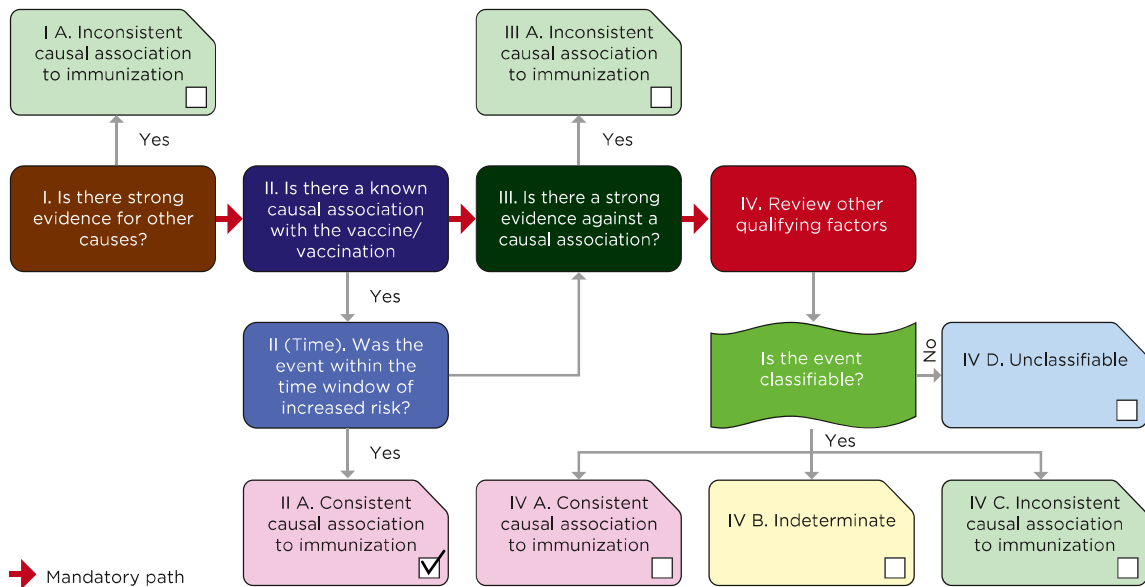
Is this case eligible for causality assessment? **Yes** Yes/No; If, "Yes", proceed to step 2

## Step 2 (Event Checklist) ✓ (check) all boxes that apply

	Y	N	UK	NA	Remarks
<b>I. Is there strong evidence for other causes?</b>					
1. In this patient, does the medical history, clinical examination and/or investigations, confirm another cause for the event?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<b>extensive testing excluded other causes</b>
<b>II. Is there a known causal association with the vaccine or vaccination?</b>					
<b>Vaccine product</b>					
1. Is there evidence in published peer reviewed literature that this vaccine may cause such an event if administered correctly?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<b>published case studies</b>
2. Is there a biological plausibility that this vaccine could cause such an event?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3. In this patient, did a specific test demonstrate the causal role of the vaccine ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<b>no specific tests available</b>
<b>Vaccine quality</b>					
4. Could the vaccine given to this patient have a quality defect or is substandard or falsified?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<b>concerns about various contaminants</b>
<b>Immunization error</b>					
5. In this patient, was there an error in prescribing or non-adherence to recommendations for use of the vaccine (e.g. use beyond the expiry date, wrong recipient etc.)?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<b>we presume the NZ health professionals followed correct procedures</b>
6. In this patient, was the vaccine (or diluent) administered in an unsterile manner?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	"
7. In this patient, was the vaccine's physical condition (e.g. colour, turbidity, presence of foreign substances etc.) abnormal when administered?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	"
8. When this patient was vaccinated, was there an error in vaccine constitution/ preparation by the vaccinator (e.g. wrong product, wrong diluent, improper mixing, improper syringe filling etc.)?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	"
9. In this patient, was there an error in vaccine handling (e.g. a break in the cold chain during transport, storage and/or immunization session etc.)?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	"
10. In this patient, was the vaccine administered incorrectly (e.g. wrong dose, site or route of administration; wrong needle size etc.)?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	"
<b>Immunization anxiety (Immunization stress related responses - ISRR)</b>					
11. In this patient, could this event be a stress response triggered by immunization (e.g. acute stress response, vasovagal reaction, hyperventilation, dissociative neurological symptom reaction etc.)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>II (time): Was the event in section II within the time window of increased risk (i.e. 'Yes' response to questions from II 1 to II 11 above)</b>					
12. In this patient, did the event occur within a plausible time window after vaccine administration?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>III. Is there strong evidence against a causal association?</b>					
1. Is there a body of published evidence (systematic reviews, GACVS reviews, Cochrane reviews etc.) <b>against</b> a causal association between the vaccine and the event?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<b>limited evidence as this is a new product</b>
<b>IV. Other qualifying factors for classification</b>					
1. In this patient, did such an event occur in the past after administration of a similar vaccine?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
2. In this patient, did such an event occur in the past independent of vaccination?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3. Could the current event have occurred in this patient without vaccination (background rate)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4. Did this patient have an illness, pre-existing condition or risk factor that could have contributed to the event?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5. Was this patient taking any medication prior to the vaccination?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6. Was this patient exposed to a potential factor (other than vaccine) prior to the event (e.g. allergen, drug, herbal product etc.)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Note: Y: Yes; N: No; UK: Unknown; NA: Not applicable.

Step 3 (Algorithm) review all steps and ✓ all the appropriate boxes



➔ Mandatory path

**Notes for Step 3:** Jessica was healthy with no underlying conditions and developed symptoms within 8 days. Extensive testing excluded other causes. Encephalitis was an expected adverse event. Condition 5 of the Medsafe provisional consent specifically mentioned autoimmune diseases. Encephalitis has been seen in post-marketing surveillance and is being monitored as an AESI.

Step 4 (Classification) ✓ all boxes that apply

	<p><b>A. Consistent with causal association to immunization</b></p> <p><input checked="" type="checkbox"/> A1. Vaccine product-related reaction (As per published literature)</p> <p><input type="checkbox"/> A2. Vaccine quality defect-related reaction</p> <p><input type="checkbox"/> A3. Immunization error-related reaction</p> <p><input type="checkbox"/> A4. Immunization anxiety-related reaction (ISRR**)</p>	<p><b>B. Indeterminate</b></p> <p><input type="checkbox"/> B1. *Temporal relationship is consistent but there is insufficient definitive evidence for vaccine causing event (may be new vaccine-linked event)</p> <p><input type="checkbox"/> B2. Qualifying factors result in conflicting trends of consistency and inconsistency with causal association to immunization</p>	<p><b>C. Inconsistent with causal association to immunization</b></p> <p><input type="checkbox"/> C. Coincidental Underlying or emerging condition(s), or condition(s) caused by exposure to something other than vaccine</p>
Adequate information available			
Adequate information not available	<p><input type="checkbox"/> Unclassifiable</p> <p>Specify the additional information required for classification : _____</p>		

\*B1 : Potential signal and maybe considered for investigation  
 \*\* Immunization stress related response

**Summarize the classification logic in the order of priority:**

With available evidence, we could conclude that the classification is \_\_\_\_\_ because: \_\_\_\_\_

With available evidence, we could **NOT** classify the case because: \_\_\_\_\_