

AEFI Causality Assessment AU-TGA-0000S 47F

Patient Details

RG	s22
Date of birth/age	77
Sex	F
Sources of information	s22
Quality of information	

Vaccine and AEFI diagnosis details

Vaccine involved	ChAdOx1-S	
Vaccine brand name	Vaxzevria; formerly COVID-19 vaccine AstraZeneca	
Vaccine batch number	Unknown	
Date administered	s22	
Event/Diagnosis	– Guillain Barre Syndrome	
Case definition	TGA has assessed this illness as meeting Level 1 Brighton	
	Collaboration criteria for the diagnosis of Guillain Barre Syndrome	

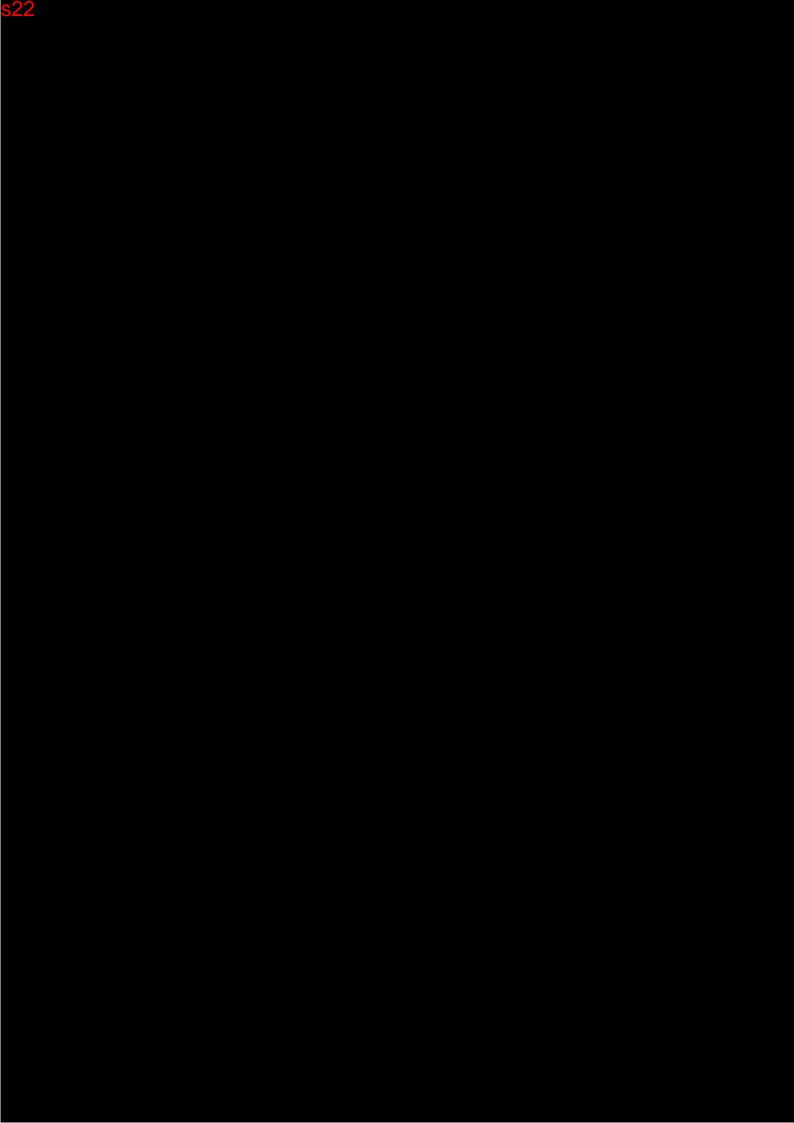
Assessment details

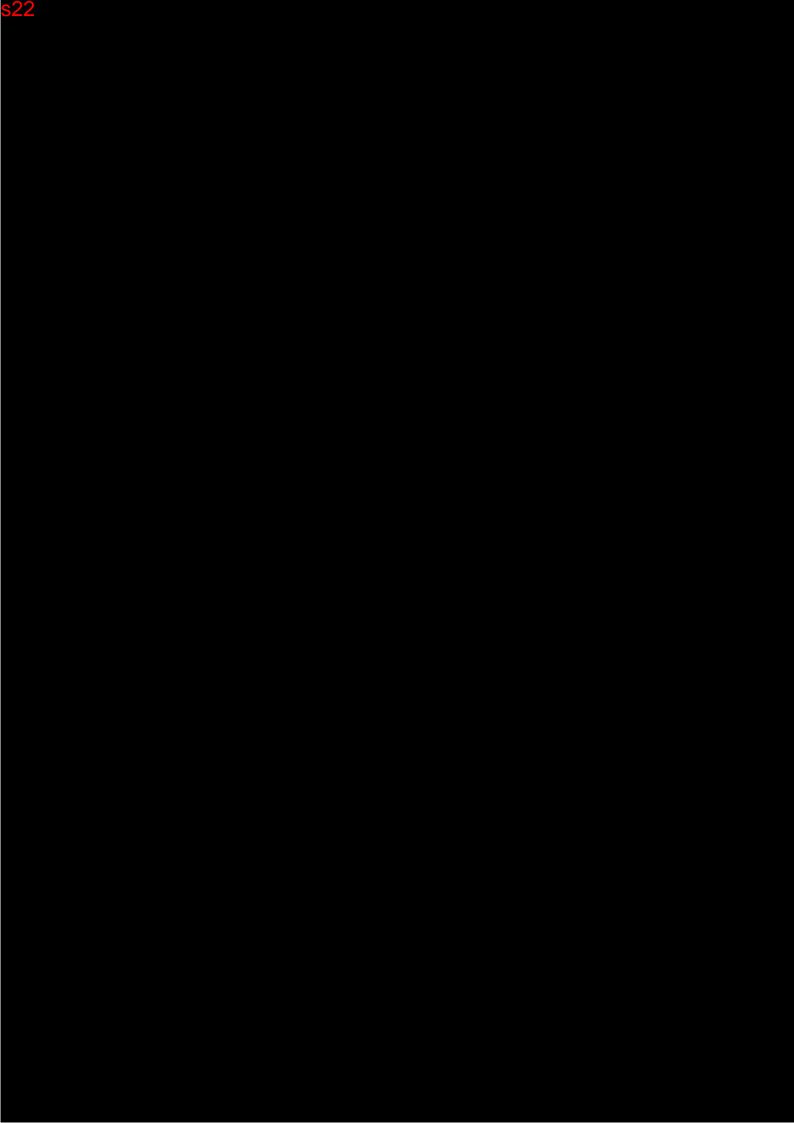
Assessors	s22	
Others present		
Date of assessment	07/12/2021	

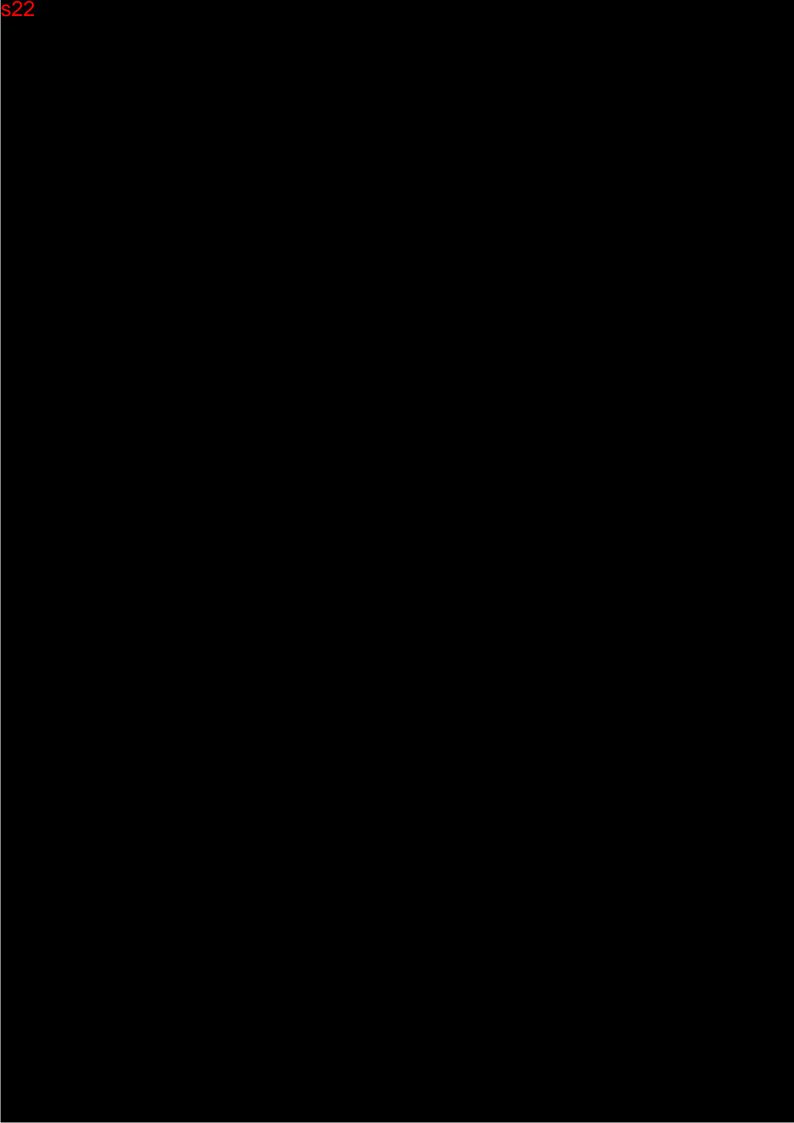
This template has been developed in line with the World Health Organization Causality
Assessment of an Adverse Event Following Immunization (AEFI): user manual for the revised WHO classification (Second Edition), 2018. The template should be used in conjunction with the WHO document.

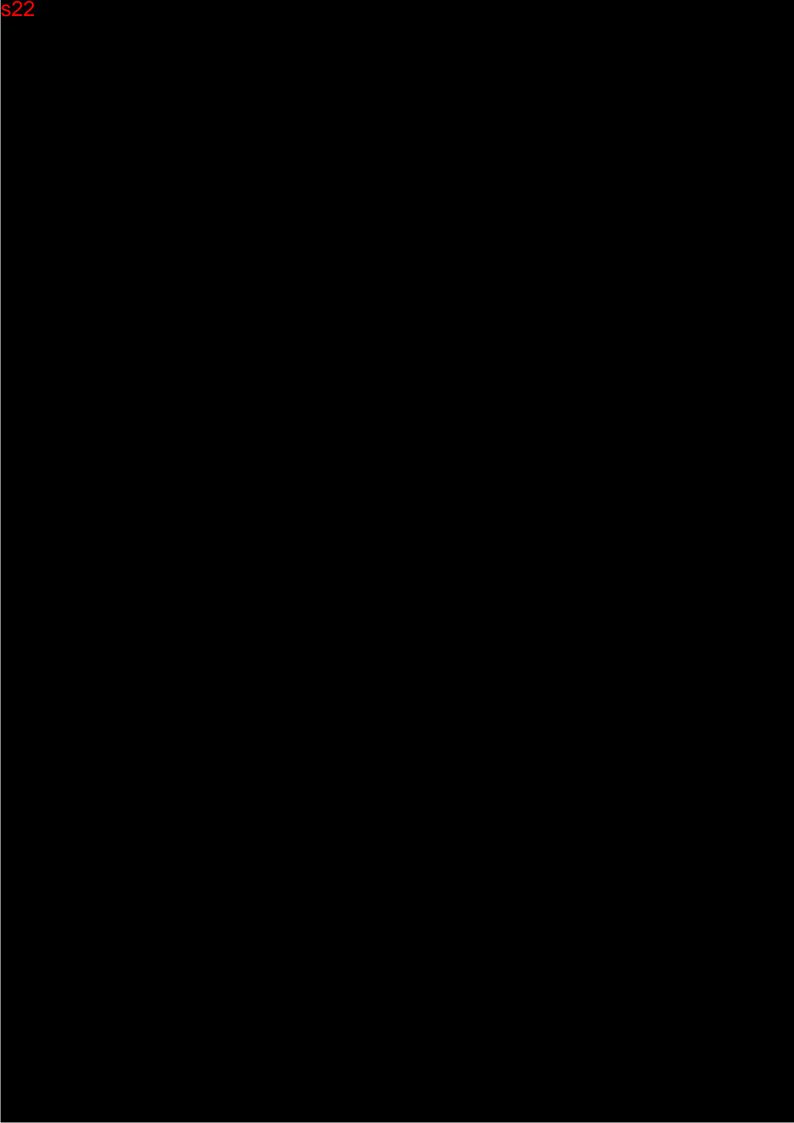
The AEFI causality assessment process is guided by the following three steps:

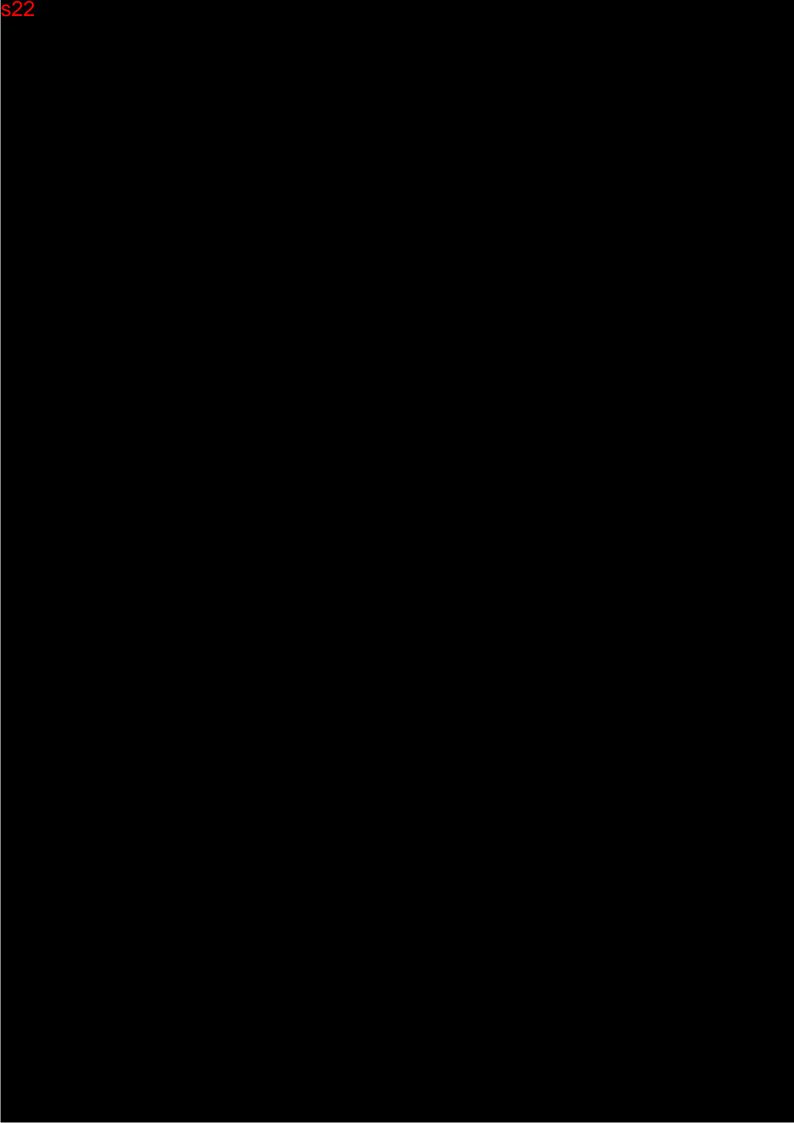
- 1. **Checklist:** the checklist is designed to assemble key information on the AEFI.
- **2. Algorithm:** information from the checklist is applied to the algorithm to assist in the decision-making of the reviewers. The algorithm helps to determine if the AEFI could be consistent or inconsistent with an association to immunisation, an indeterminate outcome or unclassifiable.
- **3. Classification:** the final classification of the AEFI is determined based on the findings from step 1 and 2.











Review each of the four steps in the algorithm and select the relevant conclusion for each step in Table 1. Summarise the responses in the checklist next to the corresponding conclusion in the Table 1 or as a summary note (see headings after table).

Table 1: Steps and conclusions from the algorithm

Step	Conclusion	
I. Is there strong evidence for other	⊠ No	
causes?		
II. Is there a known causal		
association with the		
vaccine/vaccination?		
III. Is there strong evidence against a	⊠ No	
causal association?		
IV. Review other qualifying factors.	☐ Consistent causal association to immunization	
	☐ Indeterminate	
	☐ Inconsistent causal association to immunisation	
	☐ Unclassifiable	

- A. Summary of factors suggesting consistent causal association to immunisation
- B. Summary of factors suggesting indeterminate causal association to immunisation
- C. Summary of factors suggesting inconsistent causal association to immunisation

Other Considerations

Step 3 – Classification

Select the relevant classification(s) in the Table 2 based on the conclusions from step 2.

Table 2: Adapted from page 25 of the World Health Organization Causality assessment of an adverse event following immunization (AEFI): user manual for the revised WHO classification (Second edition)

A. Consistent with causal association to immunisation	B. Indeterminate	C. Inconsistent with causal association to immunisation
 ✓ A1. Vaccine product-related reaction (As per published literature) ☐ A2. Vaccine quality defect-related reaction ☐ A3. Immunization error-related reaction ☐ A4. Immunisation anxiety-related reaction 	 □ B1. Temporal relationship is consistent but there is insufficient definitive evidence for vaccine causing event (may be a new vaccine-linked event) □ B2. Reviewing factors result in conflicting trends of consistency and inconsistency with causal association to immunisation 	☐ C. Coincidental Underlying or emerging condition(s), or conditions caused by exposure to something other than vaccine.
☐ Unclassifiable Specify the additional information	on required for classification:	
Summarise the classification logical With the available evidence, we relevant final classification A. Consistent causal association to the summarise the classification logical summarise the summarise the classification logical summarise the summarise the classification logical summarise the summarise that summarise the summ	could conclude that the most likely	classification is: [select the
⋈ A1. Vaccine product-related related rel	eaction; or	
☐ A2. Vaccine quality defect-rela	ated reaction; or	
☐ A3. Immunisation error-relate	d reaction; or	
☐ A4. Immunisation anxiety-rela	ted reaction	
B. Indeterminate		
☐ B1. Consistent temporal relati	onship but insufficient evidence for	causality
☐ B2. Conflicting trends of consi	stency and inconsistency with caus	ality
C. Inconsistent causal association	to immunisation	
☐ C. Coincidental		
Reasons:		

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- <u>Likely causal association between AZ vaccination and GBS, based on post-licensure, surveillance observational studies.</u>
- Onset of symptoms occurred within a plausible time window
- No alternate explanation/trigger evident

