



Note for file

TGA ICSR reference	AU-TGA-0000s 47F
Date and time	07April 2022
Type of event	Fatal AEFI assessment team meeting Close out summary
Participant(s)	<ul style="list-style-type: none">• s22 MO5 VERA PB• s22 MO4 VERA PB• s22 MO2 VERA PB• s22 EL1 VERA PB• s22 EL1 VERA PB• s22 APS6 VERA PB• s22 APS6 VERA PB
Topic	Fatal AEFI report & COVID-19 Vaccine AstraZeneca
Key point(s)	<ul style="list-style-type: none">• 34 Female s 22• s 22• s22• s22 <p>Thrombosis with thrombocytopenia syndrome</p> <ul style="list-style-type: none">• COD TTS
Follow-up action(s) (include action required, action officer, agreed date/s)	Regulatory or programmatic action for consideration by TGA or OHP? Confirmed Causality Communication with JIC and ACV? s22 case report D21-3424248 D21-3194670 D21-2910531 Any other follow-up actions required? Confirmed TTS case
Decision(s)	Causality assessment outcome: WHO=A1 Confirmed Causality

Adequate information available	<input checked="" type="checkbox"/> A. Consistent with causal association to immunization <input type="checkbox"/> A1. Vaccine product-related reaction (As per published literature) <input type="checkbox"/> A2. Vaccine quality defect-related reaction <input type="checkbox"/> A3. Immunization error-related reaction <input type="checkbox"/> A4. Immunization anxiety-related reaction (ISRR**)	<input type="checkbox"/> B. Indeterminate <input type="checkbox"/> B1. *Temporal relationship is consistent but there is insufficient definitive evidence for vaccine causing event (may be new vaccine-linked event) <input type="checkbox"/> B2. Qualifying factors result in conflicting trends of consistency and inconsistency with causal association to immunization	<input type="checkbox"/> C. Inconsistent with causal association to immunization <input type="checkbox"/> C. Coincidental Underlying or emerging condition(s), or condition(s) caused by exposure to something other than vaccine
	<input type="checkbox"/> Unclassifiable Specify the additional information required for classification :		

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

Figure 1