



## 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"><li>• s22 MO5 VERA PB</li><li>• s22 MO4 VERA PB</li><li>• s22 MO2 VERA PB</li><li>• s22 EL1 VERA PB</li><li>• s22 EL1 VERA PB</li><li>• s22 APS6 VERA PB</li><li>• s22 APS6 VERA PB</li></ul>
Topic	Fatal AEFI report & COVID-19 Vaccine AstraZeneca
Key point(s)	<ul style="list-style-type: none"><li>• 44 males s 22</li><li>• s 22</li><li>• s22</li><li>• s22</li></ul> <p>Thrombosis with thrombocytopenia syndrome</p> <ul style="list-style-type: none"><li>• COD TTS</li></ul>
Follow-up action(s) (include action required, action officer, agreed date/s)	<b>Regulatory or programmatic action for consideration by TGA or OHP?</b> Confirmed Causality <b>Communication with JIC and ACV?</b> s22 report <b>Any other follow-up actions required?</b> s22 / Confirmed TTS case <b>Causality assessment outcome:</b> WHO=A1
Decision(s)	

Adequate information available	<input checked="" type="checkbox"/> <b>A. Consistent with causal association to immunization</b> <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>B. Indeterminate</b> <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"/> <b>C. Inconsistent with causal association to immunization</b> <input type="checkbox"/> C. Coincidental Underlying or emerging condition(s), or condition(s) caused by exposure to something other than vaccine
	<input type="checkbox"/> <b>Unclassifiable</b> Specify the additional information required for classification :		

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

**Figure 1**