



Note for file

TGA ICSR reference	AU-TGA-0000 [REDACTED]
Date and time	07 April 2022
Type of event	Fatal AEFI assessment team meeting Close out summary
Participant(s)	<ul style="list-style-type: none">• s22 [REDACTED] MO5 VERA PB• s22 [REDACTED] MO4 VERA PB• s22 [REDACTED] MO2 VERA PB• s22 [REDACTED] EL1 VERA PB• s22 [REDACTED] EL1 VERA PB• s22 [REDACTED] APS6 VERA PB• s22 [REDACTED] APS6 VERA PB
Topic	Fatal AEFI report & COVID-19 Vaccine AstraZeneca
Key point(s)	<ul style="list-style-type: none">• 52 Female s22 [REDACTED]• s22 [REDACTED]• s22 [REDACTED]• s22 [REDACTED]; Cerebral venous sinus thrombosis; s22 [REDACTED] <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? updated who causality based on confirmed TTS case Communication with JIC and ACV? [REDACTED] documents D21-2865537 D21-2716729 Any other follow-up actions required? NFA
Decision(s)	Causality assessment outcome: WHO=A1

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 may be considered for investigation
 ** Immunization stress related response