



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">• [REDACTED] s22 [REDACTED] MOS VERA PB• [REDACTED] s22 [REDACTED] MO4 VERA PB• [REDACTED] s22 [REDACTED] MO2 VERA PB• [REDACTED] s22 [REDACTED] EL1 VERA PB• [REDACTED] s22 [REDACTED] EL1 VERA PB• [REDACTED] s22 [REDACTED] APS6 VERA PB• [REDACTED] s22 [REDACTED] APS6 VERA PB
Topic	Fatal AEFI report & COVID-19 Vaccine AstraZeneca
Key point(s)	<ul style="list-style-type: none">• 52 Female [REDACTED] s22 [REDACTED]• [REDACTED] s22 [REDACTED]• [REDACTED] s22 [REDACTED]• [REDACTED] s22 [REDACTED] ; Cerebral venous sinus thrombosis ; [REDACTED] s22 [REDACTED] <p>[REDACTED] 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
Decision(s)	Any other follow-up actions required? NFA Causality assessment outcome: WHO=A1

Adequate information available	A. Consistent with causal association to immunization <input checked="" type="checkbox"/> A1. Vaccine product-related reaction (As per published literature)	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)	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"/> A2. Vaccine quality defect-related reaction	<input type="checkbox"/> B2. Qualifying factors result in conflicting trends of consistency and inconsistency with causal association to immunization	
Adequate information not available	<input type="checkbox"/> Unclassifiable	Specify the additional information required for classification : <input type="text"/>	

*BI : Potential signal and maybe considered for investigation

** immunization stress related response