




Note for file

TGA ICSR reference	AU-TGA-0000734187
Date and time	13 May 2022
Type of event	Fatal AEFI assessment team meeting
Participant(s)	Close out summary <ul style="list-style-type: none">• s22 MO5 s22• s22 MO4 s22• s22 EL1 s22• s22 EL1 s22• s22 APS6 s22• s22 APS6 s22
Topic	Fatal AEFI report & COMIRNATY COVID-19 vaccine
Key point(s)	<ul style="list-style-type: none">• 5 yo Male s22• Abdominal pain; Cardiac arrest• s22• D22-5464447 s22 zip file• s22• COD
Follow-up action(s) (include action required, action officer, agreed date/s)	<p>Regulatory or programmatic action for consideration by TGA or OHP? Specify - state "Nil" if none</p> <p>Communication with JIC and ACV? RFI to JIC 10/05/2022</p> <p>Any other follow-up actions required? Await Coroner and s22</p>
Decision(s)	Causality assessment outcome: WHO=U

<p>Adequate information available</p> <p></p>	<p>A. Consistent with causal association to immunization</p> <p><input type="checkbox"/> A1. Vaccine product-related reaction (As per published literature)</p> <p><input type="checkbox"/> A2. Vaccine quality defect-related reaction</p> <p><input type="checkbox"/> A3. Immunization error-related reaction</p> <p><input type="checkbox"/> A4. Immunization anxiety-related reaction (ISRR**)</p>	<p>B. Indeterminate</p> <p><input type="checkbox"/> B1. *Temporal relationship is consistent but there is insufficient definitive evidence for vaccine causing event (may be new vaccine-linked event)</p> <p><input type="checkbox"/> B2. Qualifying factors result in conflicting trends of consistency and inconsistency with causal association to immunization</p>	<p>C. Inconsistent with causal association to immunization</p> <p><input type="checkbox"/> C. Coincidental Underlying or emerging condition(s), or condition(s) caused by exposure to something other than vaccine</p>
	<p><input type="checkbox"/> Unclassifiable</p> <p>Specify the additional information required for classification :</p> <div style="border: 1px solid black; height: 20px; width: 500px;"></div>		

*B1 : Potential signal and maybe considered for investigation

** Immunization stress related response