

Table S3. Assessment of relationship of AE to vaccination.

0	No Relationship	<p>No temporal relationship to study product and</p> <p>Alternate aetiology (clinical state, environmental or other interventions); and</p> <p>Does not follow known pattern of response to study product</p>
1	Possible	<p>Reasonable temporal relationship to study product; or</p> <p>Event not readily produced by clinical state, environmental or other interventions; or</p> <p>Similar pattern of response to that seen with other vaccines</p>
2	Probable	<p>Reasonable temporal relationship to study product; and</p> <p>Event not readily produced by clinical state, environment, or other interventions or</p> <p>Known pattern of response seen with other vaccines</p>
3	Definite	<p>Reasonable temporal relationship to study product; and</p> <p>Event not readily produced by clinical state, environment, or other interventions; and</p> <p>Known pattern of response seen with other vaccines</p>