

## **Case definitions**

BCG injection site abscess was defined as a localised collection of pus,  $\geq 1.5$  cm in diameter at the injection site. BCG-associated lymphadenopathy was defined as palpable regional (ipsilateral axilla or neck) lymph node enlargement. Participants reporting lymphadenopathy  $\geq 1.5$  cm in diameter or persistent ( $>2$  weeks duration) were recommended to seek medical assessment.

An SAE was defined as an adverse event that resulted in death, was immediately life-threatening, required hospitalisation or prolongation of existing hospitalisation, resulted in persistent or significant disability/incapacity, or was a congenital anomaly/birth defect, regardless of causal relation to vaccination. Elective surgery or other elective hospitalisation were not considered SAE.