Supplemental Digital Content 3

Safety and reactogenicity assessment

Solicited local and general symptoms were recorded by parent(s)/legally acceptable representative(s) on diary cards for a 4-day period (Days 0-3) following vaccination, while unsolicited adverse events (AEs) were recorded during a 31-day period (Days 0-30) following vaccination. AEs were graded by intensity from 1 (mild) to 3 (severe). All solicited local symptoms were considered related to vaccination; the causality of all other events was assessed by the investigator.

All serious AEs (SAEs) were recorded for 31 days following vaccination. SAEs that were considered to be related to the study vaccine, study participation, a concurrent GSK medication/vaccine or any fatal SAE(s) and any AEs/SAEs leading to withdrawal from the study were recorded through the entire study period (Day 0 to study end).

AEs of specific interest, such as new onset chronic illnesses (including autoimmune disorders, asthma, type 1 diabetes and allergies) and Guillain-Barré Syndrome were recorded for 31 days following vaccination (Days 0–30). Any meningococcal disease was considered as SAE and was recorded until the study end, irrespective of seriousness.

Safety analysis was performed on the total vaccinated cohort at month 73, which included all participants who had received one dose of MenACWY-TT.