Additional File 4

Overview of PVS QA/QC Activities

Component	Description	Major functions
Clinical		
	Development of standard operating procedure documents	Ensure standardization of activities across all facilities and RCH clinics Used for training new staff and re-training of existing staff
	Staff training and Certification	Ensure compliance with ICH-GCP guidelines Ensure that staff are proficient in study-related procedures
	Development of supervisory checklist	Enable a standard approach to internal monitoring of study staff adherence to the protocol and SSPs Ensure the supervision of clinical and laboratory activities in a structured manner
	Supportive supervisory visits to health facilities	Enable the detection of recruitment and protocol adherence issues and prompt resolution Provide support for clinical staff during busy periods Enable the real-time monitoring of study procedures at all sites
	Weekly progress meetings	To review progress in recruitment, clinical endpoint surveillance, and data quality Avenue to discuss practical challenges and solutions
	Monthly QA meetings	Reporting of aggregated monthly data reporting performance against key indicators
	Radiology	Established methods to perform and interpret X-rays according to WHO recommendations
Laboratory		
	Development of standard operating procedure documents	Provides guidelines for all laboratory processes and procedures Used for training new staff and re-training of existing staff
	External QC of conventional microbiology	Provide objective checks of the laboratory's analytical performance using an external agency and ensure long-term accuracy for peer comparison.

	Inter-operator internal QC of sweep serotyping of NP samples	Ensure consistency in results of primary endpoint measurement
	External QC using spiked nasopharyngeal specimens from MCRI	To check the performance of the project NP culture and serotyping process and procedures
	External QC using pneumococcal microarray serotyping by SGUL	To validate the latex sweep serotyping method
	100% verification of laboratory logbook serotyping results compared to LEMR results	Ensures that discrepancies arising from data entry errors and transcription errors are identified and resolved prospectively
Field		
	Weekly progress meetings	Focus on the review of query resolution and new issues arising
	Enrolment using an optimal sampling frame	Ensures eligible participants are enrolled
	Linkage of identity of individual participants	Allows the linkage of the identity of individual participants across all study database
	Vaccination delivery and recording of vaccination data using the RVS	Enables real-time vaccination data documentation and verification
Data		
	Development of Data Management Plan	Provides a detailed approach to managing data, both at the data collection centres and data management units
	Development of data-related standard operating procedures	Provides guidelines for all data collection applications usage and procedures to follow during query-solving
	Weekly generation of data quality reports	Clinical, field and laboratory data queries are generated weekly by the data manager for resolution by trial staff
	Monthly QA data reports	Prepare monthly QA data reports for primary and secondary endpoints
	Periodic data support visits to the various trial sites	Enable the data team to engage the trial staff on the types of queries generated and assist them in resolving the queries

- RCH, Reproductive and Child Health; ICH-GCP, International Conference on Harmonisation – Good Clinical Practice NP, Nasopharyngeal; WHO, World Health Organization; QA, Quality Assurance; QC, Quality Control; MRCI, Murdoch Children's Research Institute; SGUL, St Georges University of London; RVS, Real-time electronic Vaccination recording System; LEMR, Laboratory Electronic Medical Records; SOP, Standard Operating Procedures