Supplemental Digital Content 4: Summary of Key Immunogenicity Analyses

Analysis/Endpoint	Type of Analysis	Method
Primary immunogenicity analyses		
Acceptability regarding response rates for PRP, diphtheria, tetanus, IPV Types 1, 2, and 3 at Postdose 3, and for all DTaP5-HB-IPV-Hib antigens at Toddler Dose	95% CI for single group proportion	Exact binomial
Non-inferiority regarding response rates for PRP, diphtheria, tetanus, IPV Types 1, 2, and 3 at Postdose 3, and for HBsAg and pertussis PT, FHA, PRN at Toddler Dose	p-value and 95% CI for response rate difference	Miettinen and Nurminen[15]
Secondary immunogenicity analyses		
Concomitant use with MMRV: Acceptability regarding response rates at Toddler Dose	95% CI for single group proportion	Exact binomial
Concomitant use with MMRV: Non-inferiority regarding response rates at Toddler Dose	p-value and 95% CI for response rate difference	Miettinen and Nurminen[15]
CI = Confidence interval, FAS = Full analysis set, FHA = Filamentous hemagglutinin, HBsAg = Hepatitis B surface antigen, IPV = Inactivated polio vaccine, PP-OW = Per-protocol-Original Windows (defined as a blood draw sample window of Days 28 to 44 following Dose 3 or the toddler dose), PP-RW = Per-protocol-Revised Windows (defined as a blood draw sample window of Days 28 to 51 following Dose 3 or the toddler dose), PRN = Pertactin, PRP = Polyribosylribitol phosphate, PT = Pertussis toxoid.		