

Supplemental Digital Content 5: Proportion of Subjects Reaching the Immunogenicity Endpoint and GMT for Each Antigen Postdose 3

		DTaP5-HB-IPV-Hib			Control		
Time Point	Endpoint	n	Response	(95% CI)	n	Response	(95% CI)
Anti-PRP Response							
1 Month Postdose 3	% ≥0.15 µg/mL	55		(96.92, 99.25)	52		(83.75, 89.72)
	% ≥1.0 µg/mL	0	98.36		1	86.95	
		55		(79.89, 86.30)	52		(32.51, 40.96)
		0	83.27		1	36.66	
	GMT	55			52		
		0	3.90	(3.46, 4.41)	1	0.65	(0.58, 0.73)
Anti-HBsAg Response							
1 Month Postdose 3	% ≥10 mIU/mL	51		(96.17, 98.92)	48		(93.92, 97.62)
		0	97.84		3	96.07	
		51		(210.11, 261.29)	48		(214.29, 273.80)
	GMT	0	234.31		3	242.22	
Anti-Diphtheria Response							
1 Month Postdose 3	% ≥0.01 IU/mL	54		(98.98, 100)	51		(98.93, 100)
	% ≥0.1 IU/mL	2	99.82		7	99.81	
		54		(40.96, 49.50)	51		(42.25, 51.02)
		2	45.20		7	46.62	
	GMT	54			51		
		2	0.11	(0.10, 0.12)	7	0.11	(0.11, 0.12)
Anti-Tetanus Response							
1 Month Postdose 3	% ≥0.01 IU/mL	53		(99.32, 100)	50		(99.34, 100)
	% ≥0.1 IU/mL	1	100.00		8	100.00	
		53		(98.97, 100)	50		(98.61, 99.95)
		1	99.81		8	99.61	
	GMT	53			50		
		1	0.70	(0.67, 0.73)	8	0.53	(0.51, 0.56)
Anti-Pertussis PT Response							
Pre-Vaccination 1	GMT	60			59		
		2	3.41	(3.18, 3.66)	6	3.63	(3.38, 3.90)
1 Month Postdose 3	% seroresponset	52		(98.35, 99.88)	50		(97.18, 99.44)
		9	99.43		8	98.62	
		53		(123.92, 135.50)	51		(79.54, 87.99)
	GMT	4	129.58		4	83.66	
Anti-Pertussis FHA Response							
Pre-Vaccination 1	GMT	60			59		
		2	6.58	(6.00, 7.22)	7	6.98	(6.39, 7.64)
1 Month Postdose 3	% seroresponset	52		(86.03, 91.55)	50		(94.70, 98.04)
		8	89.02		8	96.65	
		53		(46.90, 49.51)	51		(91.70, 96.80)
	GMT	4	49.51		4	96.80	

		3	52.27)	3	102.18)
Anti-Pertussis PRN Response					
Pre-Vaccination 1	GMT	60 1	4.91 (4.47, 5.40)	59 6	5.37 (4.89, 5.90)
1 Month Postdose 3	% serorespon se [†]	52 8	(83.55, 86.74 89.52)	50 8	(89.65, 92.32 94.48)
		53	(42.72,	51	(72.63,
	GMT	4	46.76 51.17)	4	77.79 83.32)
Anti-Pertussis FIM* Response					
Pre-Vaccination 1	GMT	56 5	7.71 (6.86, 8.66)	57 9	8.05 (7.20, 9.00)
1 Month Postdose 3	% serorespon se [†]	49 8	(95.33, 97.19 98.45)	48 7	(0.71, 1.64 3.221)
		53	(327.75,	50	
	GMT	4	353.61 381.51)	9	2.94 (2.75, 3.14)
Anti-Poliovirus Type 1 Response					
1 Month Postdose 3	% Nab $\geq$ 1:8 dilution	54 7	100.00 (99.33, 100)	52 8	99.81 (98.95, 100)
		54	(156.56,	52	(189.39,
	GMT	7	176.49 198.95)	8	214.99 244.04)
Anti-Poliovirus Type 2 Response					
1 Month Postdose 3	% Nab $\geq$ 1:8 dilution	54 7	99.82 (98.99, 100)	53 0	(98.64, 99.62 99.95)
		54	(135.33,	53	(145.13,
	GMT	7	153.91 175.03)	0	165.61 188.98)
Anti-Poliovirus Type 3 Response					
1 Month Postdose 3	% Nab $\geq$ 1:8 dilution	54 5	100.00 (99.33, 100)	52 5	100.00 (99.30, 100)
		54	(305.13,	52	(307.71,
	GMT	5	346.49 393.47)	5	352.14 402.98)
* FIM is not contained in the Control vaccine [†] The pertussis seroresponse was defined as follows: (1) If pre-vaccination antibody concentration was < LLOQ, then the post-vaccination antibody concentration was $\geq$ LLOQ, (2) If pre-vaccination antibody concentration was $\geq$ LLOQ, then the post-vaccination antibody concentration was $\geq$ pre-vaccination levels. The pre-vaccination level was defined as the antibody titer at pre-Dose 1.					