Supplemental Digital Content 6: Proportion of Subjects Reaching the Immunogenicity Endpoint and GMT for Each Antigen Pre-Toddler Dose and Post-Toddler Dose

		DTaP5-HB-IPV-Hib			Control		
Time Point	**Endpoint**	n	Response	(95% CI)	n	Response	(95% CI)
Anti-PRP Response							
Pre-Toddler Dose	% ≥0.15 µg/mL	542	94.65	(92.41, 96.39)	511	64.19	(59.86, 68.35)
	% ≥1.0 µg/mL	542	57.75	(53.47, 61.95)	511	11.74	(9.08, 14.85)
	GMT	542	1.19	(1.07, 1.32)	511	0.24	(0.22, 0.26)
1 Month After Toddler Dose	% ≥0.15 µg/mL	439	99.54	(98.36, 99.94)	432	99.31	(97.98, 99.86)
	% ≥1.0 µg/mL	439	94.99	(92.51, 96.83)	432	97.69	(95.78, 98.88)
	GMT	439	6.79	(6.11, 7.54)	432	21.39	(18.77, 24.37)
Anti-HBsAg Response							
Pre-Toddler Dose	% ≥10 mIU/mL	555	91.17	(88.50, 93.40)	521	93.09	(90.56, 95.11)
	GMT	555	81.47	(72.21, 91.90)	521	121.50	(107.17, 137.74)
1 Month After Toddler Dose	% ≥10 mIU/mL	551	99.64	(98.70, 99.96)	531	99.06	(97..82, 99.69)
	GMT	551	2984.26	(2649.79, 3360.95)	531	3369.05	(2933.67, 3869.03)
Anti-Diphtheria Response							
1 Month After Toddler Dose	% ≥0.01 IU/mL	531	99.81	(98.96, 100)	508	100.00	(99.28, 100)
	% ≥0.1 IU/mL	531	93.41	(90.95, 95.37)	508	90.55	(87.67, 92.95)
	GMT	531	4.73	(4.32, 5.18)	508	3.05	(2.81, 3.32)
Anti-Tetanus Response							
1 Month After Toddler Dose	% ≥0.01 IU/mL	528	100.00	(99.30, 100)	504	100.00	(99.27, 100)
	% ≥0.1 IU/mL	528	100.00	(99.30, 100)	504	98.02	(96.38, 99.04)
	GMT	528	8.16	(7.70, 8.66)	504	3.82	(3.62, 4.03)
Anti-Pertussis PT Response							
Pre-Toddler Dose	GMT	565	12.91	(12.19, 13.68)	357	13.49	(12.73, 14.29)
1 Month After Toddler Dose	% seroresponse †	543	99.82	(98.98, 100)	523	98347	(97.01, 99.34)
	GMT	548	196.81	(186.52, 207.67)	529	90.69	(85.82, 95.84)
Anti-Pertussis FHA Response							
Pre-Toddler Dose	GMT	565	8.63	(7.99, 9.31)	537	22.85	(21.45, 24.34)

1 Month After Toddler Dose	% seroresponse [†]	542	97.23	(95.48, 98.44)	524	99.81	(98.94, 100)
	GMT	547	121.59	(115.68, 127.80)	529	196.53	(186.88, 206.67)
Anti-Pertussis PRN Response							
Pre-Toddler Dose	GMT	565	11.47	(10.60, 12.41)	537	12.09	(11.13, 13.13)
1 Month After Toddler Dose	% seroresponse [†]	543	98.90	(97.61, 99.59)	523	98.85	(97.52, 99.58)
	GMT	548	166.67	(155.40, 178.75)	529	182.08	(168.93, 196.24)
Anti-Pertussis FIM[*] Response							
Pre-Toddler Dose	GMT	565	45.97	(42.43, 49.81)	537	2.17	(2.09, 2.25)
1 Month After Toddler Dose	% seroresponse [†]	508	99.61	(98.59, 99.95)	507	4.73	(3.06, 6.96)
	GMT	548	803.76	(745.50, 866.57)	529	2.60	(2.43, 2.79)
Anti-Poliovirus Type 1 Response							
1 Month After Toddler Dose	% Nab ≥1:8 dilution	538	99.81	(98.97, 100)	524	100.00	(99.30, 100)
	GMT	538	3550.18	(3229.18, 3903.10)	524	4310.01	(3897.96, 4765.62)
Anti-Poliovirus Type 2 Response							
1 Month After Toddler Dose	% Nab ≥1:8 dilution	538	100.00	(99.32, 100)	524	100.00	(99.30, 100)
	GMT	538	4561.22	(4125.90, 5042.46)	524	5457.86	(4918.36, 6056.55)
Anti-Poliovirus Type 3 Response							
1 Month After Toddler Dose	% Nab ≥1:8 dilution	541	100.00	(99.32, 100)	523	99.81	(98.94, 100)
	GMT	541	3954.18	(3576.74, 4371.44)	523	4542.13	(4061.01, 5080.25)
Anti-Measles Response							
1 Month After Toddler Dose	% ≥255 mIU/mL	467	96.15	(93.98, 97.70)	474	96.41	(94.32, 97.90)
	GMT	467	1750.53	(1616.58, 1895.58)	474	1894.15	(1761.61, 2036.66)
Anti-Mumps Response							
1 Month After Toddler Dose	% ≥10 Ab Units/mL	467	94.86	(92.45, 96.68)	474	91.77	(88.92, 94.08)
	GMT	467	65.16	(59.72, 71.09)	474	62.30	(56.84, 68.29)
Anti-Rubella Response							
1 Month After	% ≥10 IU/mL	467	98.29	(96.65,	474	97.89	(96.15,

Toddler Dose				99.26)			98.98)
	GMT	467	41.37	(38.75, 44.17)	474	41.09	(38.46, 43.89)
Anti-Varicella Response							
1 Month After Toddler Dose	% ≥5 gpELISA Units/mL	467	97.64	(95.82, 98.82)	471	97.66	(95.86, 98.83)
	GMT	467	15.64	(14.76, 16.57)	471	16.29	(15.39, 17.24)

* 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 ≥ LLOQ, (2) If pre-vaccination antibody concentration was ≥ LLOQ, then the post-vaccination antibody concentration was ≥ pre-vaccination levels. The pre-vaccination level was defined as the antibody titer at pre-Dose 1.