

Supplemental Digital Content 4: Vaccine-Related Serious Adverse Event Listing (Protocols 004, 005, 006, 007, 008, and PRI01C)

Protocol	Dose	Relative Day of Onset	Gender	Age (days)*	Adverse Event	Duration	Intensity	Vaccine Administered
DTaP5-HB-IPV-Hib Group								
4	2	1	M	77	Hypotonia	2 days	Unknown	DTaP5-HB-IPV-Hib, Prevnar
5	1	1	M	61	Apparent life threatening event	7 days	Severe	DTaP5-HB-IPV-Hib, Prevnar 13, RotaTeq
6	1	1	M	61	Pyrexia	<24 hours	Moderate	DTaP5-HB-IPV-Hib Lot B, Prevnar 13, RotaTeq
6	1	1	F	62	Pyrexia	2 days	Moderate	DTaP5-HB-IPV-Hib Lot C, Prevnar 13, RotaTeq
6	1	2	M	56	Pyrexia	Continuing	Severe	DTaP5-HB-IPV-Hib Lot C, Prevnar 13, RotaTeq
7	3	6	M	70	Febrile convulsion	<24 hours	Moderate	DTaP5-HB-IPV-Hib, Prevnar 13, RotaTeq
7	Toddler	151	F	61	Polymphocytic leukaemia	Continuing	Severe	ProQuad, Prevenar 13
8	Toddler	5	F	53	Idiopathic thrombocytopenic purpura	20 days	Moderate	DTaP5-HB-IPV-Hib, Prevnar 13
PRI01C	2	3	F	62	Abdominal pain	2 days	Severe	DTaP5-HB-IPV-Hib, MCC-TT, MCC-CRM
					Crying	2 days	Severe	DTaP5-HB-IPV-Hib, MCC-TT, MCC-CRM
Control Group								
4	Toddler	5	M	56	Febrile convulsion	<24 hours	Unknown	Pentacel, Prevnar
6	Toddler	1	F	66	Pyrexia	4 days	Severe	Pentacel, Prevnar 13
6	Toddler	1	F	66	Febrile convulsion	<24 hours	Severe	Pentacel, Prevnar 13
7	1	1	F	65	Pyrexia	2 days	Moderate	Infanrix-hexa, Prevnar 13, RotaTeq
					Swollen tongue	2 days	Mild	Infanrix-hexa, Prevnar 13, RotaTeq
8	1	9	F	65	Kawasaki's disease	366 days	Severe	Infanrix-hexa, Prevnar 13, RotaTeq
8	Toddler	30	M	58	Injection site abscess	44 days	Severe	Infanrix-hexa, Prevnar 13
8	2	3	M	69	Convulsion	47 days	Mild	Infanrix-hexa, Prevnar 13, Rotarix

*At time of enrollment; MCC-TT = Meningococcal serogroup C conjugated to tetanus toxoid; MCC-CRM = Meningococcal serogroup C conjugate to diphtheria toxin mutant protein