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<b>Study No.:</b> 213503/013 (DTPa-IPV-013)
<b>Title:</b> Open randomized clinical study to assess the immunogenicity and reactogenicity of co-administration of SB Biologicals' DTPa-IPV vaccine and SB Biologicals' Hib vaccine, either mixed in one syringe and given in one single injection, or given in two simultaneous injections into opposite limbs, as a booster vaccination to healthy children, previously primed with a three dose primary vaccination course using the same vaccines DTPa-IPV: GlaxoSmithKline (GSK) (formerly SmithKline Beecham [SB]) Biologicals' combined tetravalent diphtheria, tetanus, acellular <i>B. pertussis</i> and inactivated poliovirus vaccine. Hib: GSK Biologicals' <i>Haemophilus influenzae</i> type b conjugate vaccine.
<b>Rationale:</b> The purpose of the study was to assess the immunogenicity and safety of booster vaccination with DTPa-IPV and Hib vaccines when administered either combined or separately in healthy children aged 15 to 19 months previously primed with a three dose primary vaccination of the same vaccines
<b>Phase:</b> II
<b>Study Period:</b> 18 November 1995 to 17 March 1996.
<b>Study Design:</b> Open, randomised and multicentric study.
<b>Centres:</b> 4 centres in Canada.
<b>Indication:</b> Booster vaccination of healthy children against diphtheria, tetanus, pertussis, polio and Hib diseases.
<b>Treatment:</b> The study groups were as followed: <ul style="list-style-type: none"> <li>• DTPa-IPV/Hib Group: received the combined DTPa-IPV/Hib vaccine administered in the left deltoid.</li> <li>• DTPa-IPV + Hib Group: received simultaneous administration of DTPa-IPV vaccine in the left deltoid and Hib vaccine in the right deltoid.</li> </ul> Both the study groups received a single booster dose and vaccines were administered intramuscularly.
<b>Objectives:</b> To evaluate the immunological memory induced by the study vaccines during primary vaccination, as assessed through a booster response to all antigens following a fourth dose in the second year of life.
<b>Primary Outcome/Efficacy Variable:</b> <i>Immunogenicity</i> One month after the booster vaccination in all subjects: <ul style="list-style-type: none"> <li>• Anti-diphtheria and anti-tetanus antibody concentration <math>\geq 0.1</math> IU/mL and geometric mean concentrations (GMCs).</li> <li>• Anti-polyribosyl ribitol phosphate (Anti-PRP) antibody concentrations <math>\geq 0.15</math> <math>\mu</math>g/mL, <math>\geq 0.5</math> <math>\mu</math>g/mL and <math>\geq 1.0</math> <math>\mu</math>g/mL and GMCs.</li> <li>• Vaccine response to pertussis toxoid (PT), filamentous haemagglutinin (FHA) and pertactin (PRN) concentrations <math>\geq 5</math> EL.U/mL and GMCs.</li> </ul> <i>Vaccine response was defined as:</i> <ul style="list-style-type: none"> <li>-For initially seronegative subjects (concentrations <math>&lt; 5</math> EL. U/mL), a post-vaccination antibody concentration equal to or above the assay cut-off.</li> <li>-For initially seropositive subjects (concentrations <math>\geq 5</math> EL. U/mL), a post-vaccination antibody concentration at least twice the concentration present prior to vaccination.</li> </ul> <ul style="list-style-type: none"> <li>• Vaccine response to polio virus type 1, type 2 and type 3 titres <math>\geq 8</math> and geometric mean titres (GMTs).</li> </ul> <i>Vaccine response was defined as:</i>

- For initially seronegative subjects, the appearance of antibody.
- For initially seropositive subjects, a post-vaccination titre at least twice the titre present prior to vaccination.

**Secondary Outcome/Efficacy Variable(s):**

*Immunogenicity*

One year after primary vaccination (pre-booster vaccination):

- Anti-diphtheria and anti-tetanus toxoid antibody concentration  $\geq 0.1$  IU/mL and GMCs.
- Anti-PT, anti-FHA and anti-PRN antibody concentrations  $\geq 5$  EL.U/mL and GMCs.
- Anti-polio virus type 1, type 2 and type 3 titres  $\geq 8$  and GMTs.
- Anti-PRP antibody concentrations  $\geq 0.15$   $\mu$ g/mL,  $\geq 0.5$   $\mu$ g/mL and  $\geq 1.0$   $\mu$ g/mL and GMCs.

*Safety*

- Occurrence and intensity of solicited local symptoms during the 4-day (Day 0-Day 3) follow-up period after booster vaccination.
- Occurrence, intensity and relationship of solicited general symptoms during the 4-day (Day 0-Day 3) follow-up period after booster vaccination.
- Occurrence and relationship of unsolicited symptoms within 31-days post vaccination.
- Occurrence of serious adverse events (SAEs) during the entire study period after booster vaccination

**Statistical Methods:**

The analyses were performed on the Total Vaccinated Cohort and According-to-Protocol (ATP) cohort for immunogenicity

- The Total Vaccinated cohort included all vaccinated subjects who were included in the Total vaccinated cohort in the primary study DTPa-IPV-04.
- The ATP cohort for immunogenicity included all evaluable subjects (i.e. those meeting all eligibility criteria, complying with the procedures defined in the protocol, with no elimination criteria during the study) from the primary study DTPa-IPV-04 for whom data concerning immunogenicity measures were available.

*Analysis of Immunogenicity*

The percentages of subjects with antibody concentrations or titers above a specified level were calculated with 95% confidence interval (CI) per group for each vaccine antigen, as well as vaccine response rates to each of the pertussis and polio antigens. GMTs/GMCs with 95% CI were tabulated for all vaccine antigens. Antibody titres below the cut-off were given an arbitrary value of one-half the assay cut-off for GMT calculations.

*Analysis of safety*

The percentage of subjects with each individual solicited local and general symptom during the 4-day (Day 03) solicited follow-up period after the booster vaccination was tabulated with exact 95% CI by vaccine group. The same tabulation was performed for grade 3 symptoms and for general symptoms with relation to vaccination. The percentage of subjects with at least one report of unsolicited adverse events (AEs) classified according to World Health Organization (WHO) preferred terms and reported up to 31 days (Day 0 -30) after vaccination was tabulated. The occurrence of SAEs during the entire study period was tabulated according to WHO preferred terms.

**Study Population:** Healthy children aged 15 to 19 months who had received complete primary vaccination course of 3 doses of DTPa-IPV and Hib vaccines. Written informed consent was obtained from parents or guardians of each infant.

<b>Number of Subjects:</b>	<b>DTPa-IPV/Hib Group</b>	<b>DTPa-IPV + Hib Group</b>
Planned, N	100	100

Randomised, N (Total Vaccinated Cohort)		65	64						
Completed, n (%)		64 (98.5)	64 (100)						
Total Number Subjects Withdrawn, n (%)		1 (1.5)	0 (0.0)						
Withdrawn due to Adverse Events n (%)		0 (0.0)	0 (0.0)						
Withdrawn due to Lack of Efficacy n (%)		Not applicable	Not Applicable						
Withdrawn for other reasons n (%)		1 (1.5)	0 (0.0)						
<b>Demographics</b>		<b>DTPa-IPV/Hib Group</b>	<b>DTPa-IPV + Hib Group</b>						
N (Total Vaccinated Cohort)		65	64						
Females: Males		32:33	34:30						
Mean Age, months (SD)		17.94 (0.53)	17.88 (0.49)						
Race, n (%)		Not available	Not available						
<b>Primary Efficacy Results: Immune response to diphtheria toxoid (ATP cohort for immunogenicity)</b>									
Group	Timing	N	S+	%	≥1	%	GMC (IU/mL)	95% CI Lower	95% CI Upper
DTPa-IPV/Hib	PIII	59	59	100	45	76.3	1.767	1.351	2.312
	Pre	63	31	49.2	1	1.6	0.110	0.088	0.137
	PIV(d30)	64	64	100	62	96.9	5.283	4.240	6.583
DTPa-IPV + Hib	PIII	60	59	98.3	49	81.7	1.823	1.446	2.299
	Pre	64	32	50.0	1	1.6	0.106	0.085	0.132
	PIV(d30)	64	64	100	63	98.4	5.406	4.329	6.752
<p>N = number of subjects tested  S+ = number of subjects with concentrations ≥ 0.1 IU/mL  % = percentage of subjects with concentrations ≥ 0.1 IU/mL  ≥1 = number of subjects with concentrations ≥1.0 IU/mL.  95% CI lower, upper = lower and upper 95% confidence intervals  PIII = blood sample taken approximately one month after the third dose of the primary vaccination course  Pre = prevaccination blood sample  PIV (d30) = blood sample taken approx one month after the booster dose = day 30.</p>									
<b>Primary Efficacy Results: Immune response to tetanus toxoid(ATP cohort for immunogenicity)</b>									
Group	Timing	N	S+	%	≥1	%	GMC (IU/mL)	95% CI Lower	95% CI Upper
DTPa-IPV/Hib	PIII	59	59	100	51	86.4	2.457	1.996	3.024
	Pre	63	49	77.8	1	1.6	0.179	0.144	0.224
	PIV(d30)	63	63	100	62	98.4	7.113	5.791	8.736
DTPa-IPV + Hib	PIII	60	60	100	36	60.0	1.388	1.107	1.741
	Pre	64	42	65.6	2	3.1	0.152	0.118	0.196
	PIV(d30)	64	64	100	62	96.9	6.337	4.915	8.169
<p>N = number of subjects tested  S+ = number of subjects with concentrations ≥ 0.1 IU/mL  % = percentage of subjects with concentrations ≥ 0.1 IU/mL  ≥1 = number of subjects with concentrations ≥1.0 IU/mL.  95% CI lower, upper = lower and upper 95% confidence intervals  PIII = blood sample taken approximately one month after the third dose of the primary vaccination course  Pre = prevaccination blood sample  PIV (d30) = blood sample taken approximately one month after the booster dose = day 30.</p>									
<b>Primary Efficacy Results: Vaccine response to pertussis antigens(ATP cohort for immunogenicity)</b>									

Antibody	Prevaccination status	DTPa-IPV/Hib Group			DTPa-IPV + Hib Group		
		N	n	VR & 95% CI	N	n	VR & 95% CI
Anti-PT	S-	31	31	100	23	23	100
	S+	33	32	97.0	40	39	97.5
	Total	64	63	98.4 [ 90.5 ; 99.9 ]	63	62	98.4 [ 90.3 ; 99.9 ]
Anti-FHA	S-	3	3	100	2	2	100
	S+	60	58	96.7	61	61	100
	Total	63	61	96.8 [ 88.0 ; 99.4 ]	63	63	100 [ 92.8 ; 100 ]
Anti-PRN	S-	4	4	100	10	10	100
	S+	60	59	98.3	54	54	100
	Total	64	63	98.4 [ 90.5 ; 99.9 ]	64	64	100 [ 92.9 ; 100 ]

N = number of subjects tested

n = number of responders

S+ = number of subjects with antibody concentrations  $\geq 5$  EL.U/mL

S- = number of subjects with antibody concentrations  $< 5$  EL.U/mL

VR (%) = Vaccine response

95% CI lower, upper = lower and upper 95% confidence intervals

Vaccine response definition:

For initially seronegative subjects (concentrations  $< 5$  EL. U/mL) - post-vaccination antibody concentration  $\geq$  assay cut-off.

For initially seropositive subjects (concentrations  $\geq 5$  EL. U/mL) - a post-vaccination concentration of at least twice the prevaccination concentration.

**Primary Efficacy Results:** Seropositivity rates and GMCs of anti-PT antibodies(ATP cohort for immunogenicity)

Group	Timing	N	S+	%	GMC (EL.U/mL)	95% CI Lower	95% CI Upper
DTPa-IPV/Hib	PIII	59	59	100	53.8	44.9	64.5
	Pre	64	33	51.6	5.6	4.4	7.1
	PIV(d30)	64	64	100	112.5	91.4	138.6
DTPa-IPV + Hib	PIII	60	60	100	55.2	48.7	62.6
	Pre	64	41	64.1	6.3	4.9	8.0
	PIV(d30)	63	63	100	121.9	102.6	144.8

N = number of subjects tested

S+ = number of subjects with concentrations  $\geq 5$  EL.U/mL

% = percentage of subjects with concentrations  $\geq 5$  EL.U/mL

95% CI lower, upper = lower and upper 95% confidence intervals

PIII = blood sample taken approximately one month after the third dose of the primary vaccination course;

Pre = prevaccination blood sample;

PIV (d30) = blood sample taken approximately one month after the booster dose = day 30.

**Primary Efficacy Results:** Seropositivity rates and GMCs of anti-FHA antibodies(ATP cohort for immunogenicity)

Group	Timing	N	S+	%	GMC (EL.U/mL)	95% CI Lower	95% CI Upper
DTPa-IPV/Hib	PIII	59	59	100	181.9	154.4	214.4
	Pre	63	60	95.2	27.3	20.3	36.8
	PIV(d30)	63	63	100	608.7	508.1	729.1

<b>DTPa-IPV + Hib</b>	P111	60	60	100	180.9	153.1	213.6
	Pre	63	61	96.8	26.0	20.2	33.3
	PIV(d30)	63	63	100	618.4	513.3	744.9

N = number of subjects tested  
S+ = number of subjects with concentrations  $\geq 5$  EL.U/mL  
% = percentage of subjects with concentrations  $\geq 5$  EL.U/mL  
95% CI lower, upper = lower and upper 95% confidence intervals  
P111 = blood sample taken approximately one month after the third dose of the primary vaccination course;  
Pre = prevaccination blood sample;  
PIV (d30) = blood sample taken approximately one month after the booster dose = day 30.

**Primary Efficacy Results:** Seropositivity rates and GMCs of anti-PRN antibodies(ATP cohort for immunogenicity)

Group	Timing	N	S+	%	GMC (EL.U/mL)	95% CI Lower	95% CI Upper
<b>DTPa-IPV/Hib</b>	P111	59	59	100	161.9	134.4	195.1
	Pre	64	60	93.8	18.7	14.3	24.5
	PIV(d30)	64	64	100	784.5	618.9	994.6
<b>DTPa-IPV + Hib</b>	P111	60	60	100	125.1	99.3	157.6
	Pre	64	54	84.4	13.0	9.9	17.2
	PIV(d30)	64	64	100	601.5	465.7	776.9

N = number of subjects tested  
S+ = number with concentrations  $\geq 5$  EL.U/mL  
% = percentage of subjects with concentrations  $\geq 5$  EL.U/mL  
95% CI lower, upper = lower and upper 95% confidence intervals  
P111 = blood sample taken approximately one month after the third dose of the primary vaccination course;  
Pre = prevaccination blood sample;  
PIV (d30) = blood sample taken approximately one month after the booster dose = day 30.

**Primary Efficacy Results:** Vaccine response to poliovirus types 1, 2 and 3 antigens (ATP cohort for immunogenicity)

Antibody	Prevacc. status	DTPa-IPV/Hib Group			DTPa-IPV + Hib Group		
		N	n	VR & 95% CI	N	n	VR & 95% CI
<b>Anti-polio type 1</b>	S-	5	5	100	6	6	100
	S+	29	29	100	28	27	96.4
	Total	34	34	100 [ 87.4; 100 ]	34	33	97.1
<b>Anti-polio type 2</b>	S-	3	3	100	4	4	100
	S+	31	31	100	30	30	100
	Total	34	34	100 [ 87.4; 100 ]	34	34	100
<b>Anti-polio type 3</b>	S-	0	-	-	5	5	100
	S+	34	34	100	28	27	96.4
	Total	34	34	100 [ 87.4; 100 ]	33	32	97.0

N = Number of subjects tested  
n = number of responders  
S+ = antibody concentration  $\geq 8$  VN dil  
S- = antibody concentration  $< 8$  VN dil  
VR(%) = Vaccine response

95% CI = lower and upper 95% confidence intervals of the vaccine response

Vaccine response definition:

For initially seronegative subjects (titres < 8 VN dil): post-vaccination antibody titre ≥ assay cut-off.

For initially seropositive subjects (titres ≥ 8 VN dil): a post-vaccination titre ≥ 2 x prevaccination titre

**Primary Efficacy Results:** Seropositivity rates and GMTs of poliovirus type 1 antibodies(ATP cohort for immunogenicity)

Group	Timing	N	S+	%	GMT	95% CI Lower	95% CI Upper
DTPa-IPV/Hib	PIII	38	37	97.4	154.9	97.8	245.4
	Pre	37	32	86.5	41.0	24.8	67.7
	PIV(d30)	34	34	100	2288.7	1558.5	3360.8
DTPa-IPV + Hib	PIII	33	32	97.0	154.5	98.1	243.3
	Pre	34	28	82.4	36.3	21.2	62.4
	PIV(d30)	34	34	100	1848.3	1151.5	2966.7

N = number of subjects tested

S+ = number of subjects with titres ≥ 8 VN dil

95% CI lower, upper = lower and upper 95% confidence intervals

PIII = blood sample taken approximately one month after the third dose of the primary vaccination course

Pre = prevaccination blood sample

PIV (d30), = blood sample taken approx one month after the booster dose = day 30.

**Primary Efficacy Results:** Seropositivity rates and GMTs of poliovirus type 2 antibodies(ATP cohort for immunogenicity)

Group	Timing	N	S+	%	GMT	95% CI Lower	95% CI Upper
DTPa-IPV/Hib	PIII	38	36	94.7	127.7	72.9	223.8
	Pre	37	33	89.2	45.8	26.9	78.1
	PIV(d30)	34	34	100	2383.6	1581.3	3593.0
DTPa-IPV + Hib	PIII	33	32	97.0	139.3	89.2	217.5
	Pre	34	30	88.2	36.9	24.1	56.3
	PIV(d30)	34	34	100	2044.3	1309.2	3192.3

N = number of subjects tested

S+ = number of subjects with titres ≥ 8 VN dil

95% CI lower, upper = lower and upper 95% confidence intervals

PIII = blood sample taken approximately one month after the third dose of the primary vaccination course

Pre = prevaccination blood sample

PIV (d30), = blood sample taken approximately one month after the booster dose = day 30.

**Primary Efficacy Results:** Seropositivity rates and GMTs of poliovirus type 3 antibodies(ATP cohort for immunogenicity)

Group	Timing	N	S+	%	GMT	95% CI Lower	95% CI Upper
DTPa-IPV/Hib	PIII	38	38	100	419.0	307.6	570.9
	Pre	37	37	100	84.3	58.1	122.3
	PIV(d30)	34	34	100	3848.7	2868.6	5163.7
DTPa-IPV + Hib	PIII	33	33	100	393.5	242.5	638.5
	Pre	33	28	84.8	42.2	23.6	75.4
	PIV(d30)	33	33	100	2268.4	1293.2	3979.2

N = number of subjects tested

S+ = number of subjects with titres ≥ 8 VN dil

95% CI lower, upper = lower and upper 95% confidence intervals

PIII = blood sample taken approximately one month after the third dose of the primary vaccination course

Pre = prevaccination blood sample PIV (d30), = blood sample taken approximately one month after the booster dose = day 30.								
<b>Primary Efficacy Results:</b> Distribution of anti-PRP concentrations (ATP cohort for immunogenicity)								
Group	Timing	N	≥0.15 µg/mL	%	≥0.50 µg/mL	%	≥1 µg/mL	%
DTPa-IPV/Hib	PIII	63	61	96.8	52	82.5	44	69.8
	Pre	64	46	71.9	19	29.7	13	20.3
	PIV(d30)	64	64	100	64	100	64	100
DTPa-IPV + Hib	PIII	64	62	96.9	56	89.1	51	79.7
	Pre	63	45	71.4	17	27.0	8	12.7
	PIV(d30)	64	64	100	64	100	64	100
N = number of subjects tested % = Percentage PIII = blood sample taken approximately one month after the third dose of the primary vaccination course Pre = prevaccination blood sample PIV (d30), = blood sample taken approximately one month after the booster dose = day 30.								
<b>Primary Efficacy Results:</b> GMCs of anti-PRP antibodies(ATP cohort for immunogenicity)								
Group	Timing	N	S+	%	GMC (g/mL)	95% CI Lower	95% CI Upper	
DTPa-IPV/Hib	PIII	63	61	96.8	1.705	1.220	2.383	
	Pre	64	46	71.9	0.323	0.236	0.442	
	PIV(d30)	64	64	100	32.892	24.119	44.857	
DTPa-IPV + Hib	PIII	64	62	96.9	3.125	2.152	4.538	
	Pre	63	45	71.4	0.254	0.196	0.330	
	PIV(d30)	64	64	100	47.779	36.891	61.881	
N = number of subjects tested S+ = number of subjects with concentrations ≥ 0.15 µg/mL % =Percentage of subjects with concentrations ≥ 0.15 µg/mL 95% CI lower, upper = lower and upper 95% confidence intervals PIII = blood sample taken approximately one month after the third dose of the primary vaccination course Pre = prevaccination blood sample PIV (d30), = blood sample taken approximately one month after the booster dose = day 30.								
<b>Secondary Outcome Variable(s):</b> Overall incidence and intensity of local solicited symptoms up to 4 days after the booster dose (days 0-3) (Total Vaccinated Cohort)								
Symptom		DTPa-IPV/Hib Group (N=65)		DTPa-IPV + Hib Group (N=64)				
		n	%	n	%			
Pain	Any	30	46.2	26	40.6			
	Grade 3	1	1.5	1	1.6			
Redness	Any	37	56.9	32	50.0			
	> 20 mm	22	33.8	17	26.6			
Swelling	Any	25	38.5	22	34.4			
	> 20 mm	14	21.5	9	14.1			
N = total number of symptom sheets returned n = number of reports of a given symptom Any = occurrence of any local solicited symptom regardless of intensity grade Grade 3 = severe (symptom which prevented infant's normal daily activities)								
<b>Secondary Outcome Variable(s):</b> Overall incidence, intensity and relationship of general solicited symptoms up to 4 days after the booster dose (days 0-3) (Total Vaccinated Cohort)								

Symptom		DTPa-IPV/Hib Group (N=65)		DTPa-IPV + Hib Group (N=64)	
		n	%	n	%
Diarrhoea	Any	11	16.9	13	20.3
	Grade 3	1	1.5	0	-
	Related	10	15.4	12	18.8
Loss of Appetite	Any	24	36.9	18	28.1
	Grade 3	3	4.6	2	3.1
	Related	22	33.8	18	28.1
Restlessness	Any	25	38.5	23	35.9
	Grade 3	1	1.5	2	3.1
	Related	25	38.5	23	35.9
Temperature	≥38.0°C	26	40.0	16	25.0
	>39.5°C	1	1.5	4	6.3
	Related	24	36.9	16	25.0
Unusual crying	Any	16	24.6	11	17.2
	Grade 3	1	1.5	1	1.6
	Related	16	24.6	11	17.2
Vomiting	Any	5	7.7	1	1.6
	Grade 3	1	1.5	1	1.6
	Related	4	6.2	1	1.6

N = total number of symptom sheets returned for a given vaccine dose

n = total number of symptom sheets reporting a particular symptom following a given dose

Any = occurrence of any general symptom regardless of intensity grade and relationship

Grade 3 = .severe (adverse experience which prevented infant's normal daily activities)

Related= Related or Probably related

**Safety results:** Number (%) of subjects with unsolicited AEs (Total Vaccinated Cohort)

Most frequent adverse events - On-Therapy (occurring within day 0-30 following vaccination)	DTPa-IPV/Hib Group N=65	DTPa-IPV + Hib Group N=64
Subjects with any AE(s), n (%)	41 (63.1)	37 (57.8)
Subjects with related AE(s), n (%)	16 (24.6)	16 (25.0)
Upper respiratory tract infection	9 (13.8)	15 (23.4)
Otitis media	12 (18.5)	9 (14.1)
Injection site reaction	10 (15.4)	7 (10.9)
Fever	6 (9.2)	6 (9.4)
Anorexia	6 (9.2)	4 (6.3)
Diarrhea	4 (6.2)	6 (9.4)
Tooth ache	4 (6.2)	5 (7.8)
Nervousness	4 (6.2)	2 (3.1)
Vomiting	2 (3.1)	4 (6.3)
Injury	2 (3.1)	2 (3.1)
Rhinitis	2 (3.1)	2 (3.1)
Conjunctivitis	-	2 (3.1)
Coughing	-	2 (3.1)
Injection site pain	2 (3.1)	-

-: Adverse Events absent or not meeting the counting rules

Detail rule: More than 30 subjects per treatment group and <= 3 groups: the most frequent 10 events in each group

**Safety results:** Number (%) of subjects with serious adverse events (Total Vaccinated Cohort)

Serious adverse event, n (%) [n considered by the investigator to be related to study medication]		
All SAEs	DTPa-IPV/Hib Group N=65	DTPa-IPV + Hib Group N=64
Subjects with any SAE(s), n (%) [n related]	0 (0.0) [0]	0 (0.0) [0]
Fatal SAEs	DTPa-IPV/Hib Group N=65	DTPa-IPV + Hib Group N=64
Subjects with fatal SAE(s), n (%) [n related]	0 (0.0) [0]	0 (0.0) [0]

**Conclusion:** One month after booster vaccination, all subjects had anti-diphtheria and anti-tetanus antibody concentrations  $\geq 0.1$  IU/mL. Vaccine response to PT, FHA and PRN was mounted by 98.4%, 96.8% and 98.4% subjects in DTPa-IPV/Hib Group and by 98.4%, 100% and 100% subjects in DTPa-IPV + Hib Group, respectively. Vaccine response to poliovirus 1, 2, and 3 was 100% in DTPa-IPV/Hib Group and 97.1%, 100% and 97%, respectively, in DTPa-IPV + Hib Group. All subjects had anti-PRP antibody concentrations  $\geq 1.0$   $\mu\text{g/mL}$ . At least one unsolicited AE was reported by 41 and 37 subjects in the DTPa-IPV/Hib Group and in the DTPa-IPV + Hib Group, respectively. No SAEs were reported.

**Publications:** None.

Date updated: 26 August 2009