Table 14.1.1.1 Population Flow Chart: Enrolled Population

Analysis Population	PNEUMOSIL n (%)	Synflorix n (%)	Prevenar 13 n (%)	Total n (%)
Enrolled Population				745
Screen Failure				85 (11.4)
Randomized	220	220	220	660
Safety Population	220	220	220	660
Person-Years[1]	216.5	215.2	216.1	647.8
Full Immunogenicity Population (FIP)	216 (98.2)	213 (96.8)	212 (96.4)	641 (97.1)
Person-Years[2]	214.4	213.2	214.7	642.4
Reasons excluded:				
No post-vaccination immunogenicity measurement(s)	4	7	8	19
Primary Per Protocol Immunogenicity Population	202 (91.8)	200 (90.9)	200 (90.9)	602 (91.2)
Person-Years[2]	208.4	207.7	209	625
Reasons excluded:				
Did not receive all three study vaccinations	8	7	6	21
Visit 6 out of window	1	0	0	1
No post-booster immunogenicity measurements	5	6	6	17

[1]Person-years of follow-up from first vaccination through last study visit.
[2]Person-years of follow-up contributed through last immunological assessment.
[3]The Secondary Per Protocol Immunogenicity Population consisted of the same subjects as the Full Immunogenicity Population, but 22 only contributed valid data at V4 or V5 (not both) and so are excluded from 1 or more per protocol analyses of relevant secondary objectives.
[4]Person-years of follow-up contributed through last immunological assessment on or before V5

Data source: ADSL

Table 14.1.1.1 Population Flow Chart: Enrolled Population

Analysis Population	PNEUMOSIL n (%)	Synflorix n (%)	Prevenar 13 n (%)	Total n (%)
Secondary Per Protocol Immunogenicity Population[3]	216 (98.2)	213 (96.8)	212 (96.4)	641 (97.1)
Person-Years[4]	197.9	197.2	198.7	593.8
Reasons not contributing to all secondary analyses:				
Out of window visit 4	0	1	0	1
No in-window immunogenicity measurement at visit 5	8	7	6	21

[1]Person-years of follow-up from first vaccination through last study visit.
[2]Person-years of follow-up contributed through last immunological assessment.
[3]The Secondary Per Protocol Immunogenicity Population consisted of the same subjects as the Full Immunogenicity Population, but 22 only contributed valid data at V4 or V5 (not both) and so are excluded from 1 or more per protocol analyses of relevant secondary objectives.
[4]Person-years of follow-up contributed through last immunological assessment on or before V5

Data source: ADSL

PATH CVIA-074 – Final Report (Confidential)
Table 14.1.2.1 Study Disposition and Visit Completion: Safety Population

	PNEUMOSIL (N= 220)		Synflorix (N= 220)		Prevenar 13 (N= 220)		Total (N= 660)	
	n	(%)	n	(%)	n	(%)	n	(%)
Final Status								
Completed Study	203	(92.3)	200	(90.9)	200	(90.9)	603	(91.4)
Discontinued Early	15	(6.8)	19	(8.6)	19	(8.6)	53	(8.0)
Subject met ineligibility criteria during the study	1	(6.7)	1	(5.3)	2	(10.5)	4	(7.5)
Subject's parent requested withdrawal	8	(53.3)	12	(63.2)	9	(47.4)	29	(54.7)
Subject/subject's parent was considered unable to comply with the protocol	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Major protocol violation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Adverse Event	0	(0.0)	0	(0.0)	1	(5.3)	1	(1.9)
Death	1	(6.7)	0	(0.0)	0	(0.0)	1	(1.9)
Sponsor decided to suspend or discontinue development of PNEUMOSIL	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Other	5	(33.3)	6	(31.6)	7	(36.8)	18	(34.0)
Lost to Follow-up	2	(0.9)	1	(0.5)	1	(0.5)	4	(0.6)
Total	220		220		220		660	
Number of Study Vaccinations Received								
1	3	(1.4)	7	(3.2)	7	(3.2)	17	(2.6)
2	9	(4.1)	7	(3.2)	7	(3.2)	23	(3.5)
3	208	(94.5)	206	(93.6)	206	(93.6)	620	(93.9)
Total vaccinations	645		639		639		1923	

Data source: ADSL
Listing source: 16.2.5

Table 14.1.2.1 Study Disposition and Visit Completion: Safety Population

	PNEUMOSIL (N= 220)		Synflorix (N= 220)		Prevenar 13 (N= 220)		Total (N= 660)	
	n	(%)	n	(%)	n	(%)	n	(%)
Clinic Visit Status								
Visit 1 (Primary Series Vaccination #1)								
Within visit window defined in protocol	220	(100)	220	(100)	220	(100)	660	(100)
Missed visit window, for an allowable reason	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Missed visit window, but the subject seen	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Missed visit	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Total	220		220		220		660	
Visit 2 (One-Month Post Visit 1, EPI Vaccination Only)								
Within visit window defined in protocol	218	(100)	215	(100)	214	(99.5)	647	(99.8)
Missed visit window, for an allowable reason	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.2)
Missed visit window, but the subject seen	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Missed visit	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Total	218		215		215		648	
Visit 3 (Primary Series Vaccination #2)								
Within visit window defined in protocol	215	(99.1)	212	(99.5)	213	(100)	640	(99.5)
Missed visit window, for an allowable reason	1	(0.5)	0	(0.0)	0	(0.0)	1	(0.2)
Missed visit window, but the subject seen	1	(0.5)	1	(0.5)	0	(0.0)	2	(0.3)
Missed visit	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Total	217		213		213		643	

Data source: ADSL
Listing source: 16.2.5

Table 14.1.2.1 Study Disposition and Visit Completion: Safety Population

	PNEUMOSIL (N= 220)		Synflorix (N= 220)		Prevenar 13 (N= 220)		Total (N= 660)	
	n	(%)	n	(%)	n	(%)	n	(%)
Visit 4 (One-Month Post Primary Series Vaccination #2)								
Within visit window defined in protocol	216	(100)	210	(98.6)	212	(100)	638	(99.5)
Missed visit window, for an allowable reason	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.2)
Missed visit window, but the subject seen	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.2)
Missed visit	0	(0.0)	1	(0.5)	0	(0.0)	1	(0.2)
Total	216		213		212		641	
Visit 5 (Booster Vaccination)								
Within visit window (9 months + 4 weeks of age)	64	(30.8)	61	(29.6)	54	(26.2)	179	(28.9)
Within visit window (9 to 18 months of age + 4 weeks)	144	(69.2)	145	(70.4)	152	(73.8)	441	(71.1)
Missed visit window, for an allowable reason	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Missed visit window, but the subject seen	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Missed visit	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Total	208		206		206		620	
Visit 6 (One-Month Post Booster Vaccination)								
Within visit window defined in protocol	199	(98.0)	199	(99.5)	200	(100)	598	(99.2)
Missed visit window, for an allowable reason	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Missed visit window, but the subject seen	4	(2.0)	1	(0.5)	0	(0.0)	5	(0.8)
Missed visit	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Total	203		200		200		603	

Data source: ADSL
Listing source: 16.2.5

Table 14.1.5.3.1 Baseline Medical Assessment and Medical History: Safety Population

	PNEUMOSIL (N= 220)	Synflorix (N= 220)	Prevenar 13 (N= 220)	Total (N= 660)
	n (%)	n (%)	n (%)	n (%)
Length (cm)				
Mean (SD)	55.44 (1.91)	55.48 (2.02)	55.29 (2.11)	55.40 (2.02)
Median (Range)	55.5 (50.7 to 59.2)	55.5 (50.0 to 62.5)	55.4 (49.5 to 61.3)	55.5 (49.5 to 62.5)
Total	220	220	220	660
Weight (kg)				
Mean (SD)	4.64 (0.55)	4.68 (0.58)	4.67 (0.65)	4.66 (0.59)
Median (Range)	4.7 (3.5 to 5.9)	4.7 (3.5 to 6.8)	4.7 (3.5 to 6.7)	4.7 (3.5 to 6.8)
Total	220	220	220	660
Weight-to-Height Z-score				
< -2SD	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.2)
>= -2SD	220 (100)	219 (99.5)	220 (100)	659 (99.8)
Mean (SD)	0.03 (1.02)	0.10 (1.01)	0.20 (1.02)	0.11 (1.02)
Median (Q1-Q3)	-0.0 (-0.6 to 0.7)	0.2 (-0.7 to 0.9)	0.2 (-0.5 to 0.9)	0.1 (-0.6 to 0.8)
Total	220	220	220	660
Vaccination History				
Birth Vaccines				
BCG	220 (100)	220 (100)	220 (100)	660 (100)
Hep B	220 (100)	220 (100)	220 (100)	660 (100)
OPV #0	220 (100)	220 (100)	220 (100)	660 (100)
Total	220	220	220	660

Data source: ADMH
Listing source: 16.2.4.2

Table 14.1.5.3.1 Baseline Medical Assessment and Medical History: Safety Population

	PNEUMOSIL (N= 220)		Synflorix (N= 220)		Prevenar 13 (N= 220)		Total (N= 660)	
	n	(%)	n	(%)	n	(%)	n	(%)
Medical History by Body System								
Pulmonary								
Normal	194	(88.2)	193	(87.7)	187	(85.0)	574	(87.0)
Abnormal	26	(11.8)	27	(12.3)	33	(15.0)	86	(13.0)
Total	220		220		220		660	
Cardiovascular								
Normal	220	(100)	220	(100)	220	(100)	660	(100)
Abnormal	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Total	220		220		220		660	
Hepatobiliary								
Normal	220	(100)	220	(100)	220	(100)	660	(100)
Abnormal	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Total	220		220		220		660	
Gastrointestinal								
Normal	212	(96.4)	215	(97.7)	214	(97.3)	641	(97.1)
Abnormal	8	(3.6)	5	(2.3)	6	(2.7)	19	(2.9)
Total	220		220		220		660	
Renal								
Normal	220	(100)	220	(100)	220	(100)	660	(100)
Abnormal	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Total	220		220		220		660	

Data source: ADMH
Listing source: 16.2.4.2

Table 14.1.5.3.1 Baseline Medical Assessment and Medical History: Safety Population

	PNEUMOSIL (N= 220)		Synflorix (N= 220)		Prevenar 13 (N= 220)		Total (N= 660)	
	n	(%)	n	(%)	n	(%)	n	(%)
Neurological								
Normal	220	(100)	220	(100)	220	(100)	660	(100)
Abnormal	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Total	220		220		220		660	
Hematological								
Normal	220	(100)	220	(100)	220	(100)	660	(100)
Abnormal	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Total	220		220		220		660	
Other								
Normal	194	(88.2)	200	(90.9)	203	(92.3)	597	(90.5)
Abnormal	26	(11.8)	20	(9.1)	17	(7.7)	63	(9.5)
Total	220		220		220		660	

Data source: ADMH
Listing source: 16.2.4.2

PATH CVIA 074 - Final Report (Confidential)
TABLE 14.2.1.1.1 Primary Objective: IgG Geometric Mean Concentrations (GMC) 4 weeks Post-Booster
Primary PP_IMM Population

	PNEUMOSIL (N=202)		Synflorix (N=200)		Prevenar 13 (N=200)		Treatment Group Comparison[1]	
							PNEUMOSIL/ Synflorix	PNEUMOSIL/ Prevenar 13
Serotype	**n[2]**	**GMC (95% CI)**	**n[2]**	**GMC (95% CI)**	**n[2]**	**GMC (95% CI)**	**GMC Ratio (95% CI)**	**GMC Ratio (95% CI)**
PnC-IgG-ELISA Type 1	201	8.45 (7.54 , 9.48)	197	2.90 (2.57 , 3.28)	200	5.87 (5.26 , 6.56)	2.91 (2.47 , 3.44)*	1.44 (1.23 , 1.69)*
PnC-IgG-ELISA Type 5	202	1.54 (1.38 , 1.73)	199	0.80 (0.72 , 0.88)	200	2.04 (1.86 , 2.24)	1.93 (1.66 , 2.25)*	0.76 (0.65 , 0.88)*
PnC-IgG-ELISA Type 6A	201	9.56 (8.26 , 11.05)	195	0.60 (0.50 , 0.71)	199	10.95 (9.57 , 12.54)	16.03 (12.84 , 20.03)*	0.87 (0.72 , 1.06)
PnC-IgG-ELISA Type 6B	202	12.46 (11.07 , 14.01)	200	4.96 (4.44 , 5.53)	200	15.54 (13.71 , 17.60)	2.51 (2.14 , 2.95)*	0.80 (0.68 , 0.95)*
PnC-IgG-ELISA Type 7F	202	6.66 (5.96 , 7.44)	200	3.15 (2.87 , 3.45)	200	6.31 (5.75 , 6.93)	2.11 (1.83 , 2.44)*	1.05 (0.91 , 1.22)
PnC-IgG-ELISA Type 9V	202	3.46 (3.08 , 3.88)	200	2.45 (2.21 , 2.72)	200	3.87 (3.47 , 4.32)	1.41 (1.21 , 1.65)*	0.89 (0.76 , 1.05)
PnC-IgG-ELISA Type 14	202	8.28 (6.97 , 9.82)	200	5.02 (4.22 , 5.97)	200	9.17 (8.06 , 10.45)	1.65 (1.29 , 2.10)*	0.90 (0.73 , 1.12)
PnC-IgG-ELISA Type 19A	200	8.82 (7.65 , 10.15)	199	2.39 (1.97 , 2.89)	199	12.21 (10.83 , 13.76)	3.69 (2.91 , 4.67)*	0.72 (0.60 , 0.87)*
PnC-IgG-ELISA Type 19F	200	11.11 (9.70 , 12.73)	194	17.31 (14.83 , 20.20)	197	14.99 (13.25 , 16.96)	0.64 (0.52 , 0.79)*	0.74 (0.62 , 0.89)*
PnC-IgG-ELISA Type 23F	202	4.95 (4.28 , 5.73)	200	2.16 (1.92 , 2.44)	198	4.97 (4.34 , 5.69)	2.29 (1.89 , 2.76)*	1.00 (0.82 , 1.22)

[1]Based on GMC Ratio (GMCR), with 95% CIs based on antilog of normal-theory limits for difference in logged means. Asterisks denote statistically significant differences.
[2]Number of subjects with reportable results for a given serotype, among N with specimens collected.

Data source: ADIMMUNO
Listing source: 16.2.6.1

PATH CVIA 074 - Final Report (Confidential)
Table 14.2.2.1.1 Secondary Objective 1: OPA Geometric Mean Titers (GMT) 4 Weeks Post-Booster
Primary PP_IMM Population

	PNEUMOSIL (N=50)		Synflorix (N=50)		Prevenar 13 (N=50)		Treatment Group Comparison[1]	
							PNEUMOSIL/ Synflorix	PNEUMOSIL/ Prevenar 13
Serotype	n[2]	GMT (95% CI)	n[2]	GMT (95% CI)	n[2]	GMT (95% CI)	GMT Ratio (95% CI)	GMT Ratio (95% CI)
MOPA 1	50	631.29 (467.98 , 851.59)	50	282.35 (190.44 , 418.60)	49	429.13 (310.99 , 592.14)	2.24 (1.37 , 3.64)*	1.47 (0.95 , 2.27)
MOPA 5	50	885.98 (662.20 , 1185.37)	50	484.66 (361.73 , 649.38)	50	703.15 (556.01 , 889.24)	1.83 (1.22 , 2.75)*	1.26 (0.87 , 1.82)
MOPA 6A	50	3651.54 (2593.53 , 5141.16)	45	53.86 (25.10 , 115.56)	50	6464.88 (5120.52 , 8162.19)	67.80 (29.55 , 155.52)*	0.56 (0.38 , 0.85)*
MOPA 6B	50	3931.21 (2969.79 , 5203.89)	50	1294.61 (929.52 , 1803.11)	50	6012.88 (4130.89 , 8752.29)	3.04 (1.98 , 4.66)*	0.65 (0.41 , 1.04)
MOPA 7F	50	7053.37 (5904.91 , 8425.18)	50	4401.18 (3593.44 , 5390.50)	50	8288.88 (6756.83 , 10168.3)	1.60 (1.23 , 2.09)*	0.85 (0.65 , 1.11)
MOPA 9V	50	1408.68 (1092.33 , 1816.64)	49	845.47 (631.39 , 1132.13)	50	2464.43 (1957.36 , 3102.85)	1.67 (1.14 , 2.44)*	0.57 (0.41 , 0.80)*
MOPA 14	50	2622.36 (1845.88 , 3725.47)	50	1381.52 (883.30 , 2160.74)	50	3131.96 (2245.73 , 4367.91)	1.90 (1.08 , 3.33)*	0.84 (0.52 , 1.35)
MOPA 19A	50	1620.76 (1200.51 , 2188.13)	50	305.46 (177.87 , 524.57)	50	3679.06 (2920.79 , 4634.19)	5.31 (2.87 , 9.79)*	0.44 (0.30 , 0.64)*
MOPA 19F	50	1384.38 (937.18 , 2044.98)	50	2541.40 (1666.99 , 3874.49)	50	2094.57 (1410.71 , 3109.94)	0.54 (0.31 , 0.96)*	0.66 (0.38 , 1.14)
MOPA 23F	50	2998.53 (2272.86 , 3955.89)	50	1427.66 (1110.72 , 1835.05)	50	5687.60 (3891.57 , 8312.54)	2.10 (1.45 , 3.04)*	0.53 (0.33 , 0.84)*

[1]95% CIs for GMT Ratios based on antilog of normal-theory limits for difference in logged means. Asterisks denote statistically significant differences.
[2]Number of subjects with reportable results for a given serotype, among N with specimens collected within visit window.

Data source: ADIMMUNO
Listing source: 16.2.6.2

PATH CVIA 074 - Final Report (Confidential)
Table 14.2.2.2.1.1 Secondary Objective 2.1: IgG Seroresponse Rates (≥0.35µg/mL) 4 Weeks Post-Booster
Primary PP_IMM Population

	PNEUMOSIL (N=202)			Synflorix (N=200)			Prevenar 13 (N=200)			Treatment Group Comparison[1]	
Serotype	**N[2]**	**n[3]**	**(%) (95% CI)**	**N[2]**	**n[3]**	**(%) (95% CI)**	**N[2]**	**n[3]**	**(%) (95% CI)**	**PNEUMOSIL - Synflorix Difference (95% CI)**	**PNEUMOSIL - Prevenar 13 Difference (95% CI)**
PnC-IgG-ELISA Type 1	201	201	(100) (98.2 , 100.0)	197	197	(100) (98.1 , 100.0)	200	199	(99.5) (97.3 , 100.0)	0.0 (-1.9 , 1.9)	0.5 (-1.4 , 2.8)
PnC-IgG-ELISA Type 5	202	197	(97.5) (94.3 , 99.2)	199	179	(89.9) (84.9 , 93.8)	200	198	(99.0) (96.4 , 99.9)	7.6 (3.0 , 12.8)*	-1.5 (-4.8 , 1.4)
PnC-IgG-ELISA Type 6A	201	197	(98.0) (95.0 , 99.5)	195	129	(66.2) (59.1 , 72.8)	199	197	(99.0) (96.4 , 99.9)	31.9 (25.2 , 39.0)*	-1.0 (-4.1 , 1.8)
PnC-IgG-ELISA Type 6B	202	202	(100) (98.2 , 100.0)	200	199	(99.5) (97.3 , 100.0)	200	199	(99.5) (97.3 , 100.0)	0.5 (-1.4 , 2.8)	0.5 (-1.4 , 2.8)
PnC-IgG-ELISA Type 7F	202	202	(100) (98.2 , 100.0)	200	199	(99.5) (97.3 , 100.0)	200	200	(100) (98.2 , 100.0)	0.5 (-1.4 , 2.8)	0.0 (-1.9 , 1.9)
PnC-IgG-ELISA Type 9V	202	200	(99.0) (96.5 , 99.9)	200	199	(99.5) (97.3 , 100.0)	200	200	(100) (98.2 , 100.0)	-0.5 (-3.1 , 1.9)	-1.0 (-3.5 , 0.9)
PnC-IgG-ELISA Type 14	202	199	(98.5) (95.7 , 99.7)	200	195	(97.5) (94.3 , 99.2)	200	199	(99.5) (97.3 , 100.0)	1.0 (-2.1 , 4.4)	-1.0 (-3.8 , 1.4)
PnC-IgG-ELISA Type 19A	200	200	(100) (98.2 , 100.0)	199	182	(91.5) (86.7 , 94.9)	199	199	(100) (98.2 , 100.0)	8.5 (5.4 , 13.3)*	0.0 (-1.9 , 1.9)
PnC-IgG-ELISA Type 19F	200	200	(100) (98.2 , 100.0)	194	194	(100) (98.1 , 100.0)	197	197	(100) (98.1 , 100.0)	0.0 (-1.9 , 1.9)	0.0 (-1.9 , 1.9)
PnC-IgG-ELISA Type 23F	202	198	(98.0) (95.0 , 99.5)	200	196	(98.0) (95.0 , 99.5)	198	195	(98.5) (95.6 , 99.7)	0.0 (-3.2 , 3.3)	-0.5 (-3.7 , 2.6)

[1]Based on differences in proportions responding, with 95% CIs based on Miettinen-Nurminen score method. Asterisks denote statistically significant differences.
[2]Number of observations contributing to analysis.
[3]Number of responders (IgG ≥ 0.35 µg/mL)

Data source: ADIMMUNO
Listing source: 16.2.6.1

PATH CVIA 074 - Final Report (Confidential)
Table 14.2.2.2.2.1 Secondary Objective 2.2: IgG Seroresponse Rates (≥1.0µg/mL) 4 Weeks Post-Booster
Primary PP_IMM Population

	PNEUMOSIL (N=202)			Synflorix (N=200)			Prevenar 13 (N=200)			Treatment Group Comparison[1]	
										PNEUMOSIL - Synflorix	PNEUMOSIL - Prevenar 13
Serotype	**N[2]**	**n[3]**	**(%) (95% CI)**	**N[2]**	**n[3]**	**(%) (95% CI)**	**N[2]**	**n[3]**	**(%) (95% CI)**	**Difference (95% CI)**	**Difference (95% CI)**
PnC-IgG-ELISA Type 1	201	198	(98.5) (95.7 , 99.7)	197	174	(88.3) (83.0 , 92.5)	200	195	(97.5) (94.3 , 99.2)	10.2 (5.7 , 15.6)*	1.0 (-2.1 , 4.4)
PnC-IgG-ELISA Type 5	202	139	(68.8) (61.9 , 75.1)	199	75	(37.7) (30.9 , 44.8)	200	175	(87.5) (82.1 , 91.7)	31.1 (21.6 , 40.1)*	-19 (-26.6 , -10.8)*
PnC-IgG-ELISA Type 6A	201	194	(96.5) (93.0 , 98.6)	195	74	(37.9) (31.1 , 45.2)	199	195	(98.0) (94.9 , 99.5)	58.6 (51.0 , 65.5)*	-1.5 (-5.3 , 2.0)
PnC-IgG-ELISA Type 6B	202	202	(100) (98.2 , 100.0)	200	193	(96.5) (92.9 , 98.6)	200	199	(99.5) (97.3 , 100.0)	3.5 (1.6 , 7.1)*	0.5 (-1.4 , 2.8)
PnC-IgG-ELISA Type 7F	202	198	(98.0) (95.0 , 99.5)	200	190	(95.0) (91.0 , 97.6)	200	199	(99.5) (97.3 , 100.0)	3.0 (-0.6 , 7.2)	-1.5 (-4.5 , 1.0)
PnC-IgG-ELISA Type 9V	202	191	(94.6) (90.5 , 97.3)	200	179	(89.5) (84.4 , 93.4)	200	191	(95.5) (91.6 , 97.9)	5.1 (-0.3 , 10.7)	-0.9 (-5.5 , 3.6)
PnC-IgG-ELISA Type 14	202	192	(95.0) (91.1 , 97.6)	200	180	(90.0) (85.0 , 93.8)	200	198	(99.0) (96.4 , 99.9)	5.0 (-0.1 , 10.6)	-4.0 (-8.0 , -0.7)*
PnC-IgG-ELISA Type 19A	200	192	(96.0) (92.3 , 98.3)	199	154	(77.4) (70.9 , 83.0)	199	198	(99.5) (97.2 , 100.0)	18.6 (12.4 , 25.3)*	-3.5 (-7.3 , -0.7)*
PnC-IgG-ELISA Type 19F	200	197	(98.5) (95.7 , 99.7)	194	188	(96.9) (93.4 , 98.9)	197	195	(99.0) (96.4 , 99.9)	1.6 (-1.6 , 5.3)	-0.5 (-3.4 , 2.3)
PnC-IgG-ELISA Type 23F	202	191	(94.6) (90.5 , 97.3)	200	166	(83.0) (77.1 , 87.9)	198	190	(96.0) (92.2 , 98.2)	11.6 (5.6 , 18.0)*	-1.4 (-6.0 , 3.0)

[1]Based on differences in proportions responding, with 95% CIs based on Miettinen-Nurminen score method. Asterisks denote statistically significant differences.
[2]Number of observations contributing to analysis.
[3]Number of responders (IgG ≥ 1.0 µg/mL)

Data source: ADIMMUNO
Listing source: 16.2.6.1

PATH CVIA 074 - Final Report (Confidential)
Table 14.2.2.2.3.1 Secondary Objective 2.3: OPA Seroresponse Rates 4 Weeks Post-Booster
Primary PP_IMM Population

	PNEUMOSIL (N=50)	Synflorix (N=50)	Prevenar 13 (N=50)	Treatment Group Comparison[1]	
				PNEUMOSIL - Synflorix	PNEUMOSIL - Prevenar13
Serotype	N[2] n[3] (%) (95% CI)	N[2] n[3] (%) (95% CI)	N[2] n[3] (%) (95% CI)	Difference (95% CI)	Difference (95% CI)
MOPA 1	50 50 (100) (92.9 , 100.0)	50 48 (96.0) (86.3 , 99.5)	49 48 (98.0) (89.2 , 100.0)	4.0 (-3.3 , 13.5)	2.0 (-5.2 , 10.8)
MOPA 5	50 50 (100) (92.9 , 100.0)	50 50 (100) (92.9 , 100.0)	50 50 (100) (92.9 , 100.0)	0.0 (-7.2 , 7.2)	0.0 (-7.2 , 7.2)
MOPA 6A	50 50 (100) (92.9 , 100.0)	45 25 (55.6) (40.0 , 70.4)	50 50 (100) (92.9 , 100.0)	44.4 (30.9 , 58.9)*	0.0 (-7.2 , 7.2)
MOPA 6B	50 50 (100) (92.9 , 100.0)	50 49 (98.0) (89.4 , 100.0)	50 49 (98.0) (89.4 , 100.0)	2.0 (-5.3 , 10.6)	2.0 (-5.3 , 10.6)
MOPA 7F	50 50 (100) (92.9 , 100.0)	50 50 (100) (92.9 , 100.0)	50 50 (100) (92.9 , 100.0)	0.0 (-7.2 , 7.2)	0.0 (-7.2 , 7.2)
MOPA 9V	50 50 (100) (92.9 , 100.0)	49 49 (100) (92.8 , 100.0)	50 50 (100) (92.9 , 100.0)	0.0 (-7.2 , 7.3)	0.0 (-7.2 , 7.2)
MOPA 14	50 50 (100) (92.9 , 100.0)	50 48 (96.0) (86.3 , 99.5)	50 50 (100) (92.9 , 100.0)	4.0 (-3.3 , 13.5)	0.0 (-7.2 , 7.2)
MOPA 19A	50 50 (100) (92.9 , 100.0)	50 45 (90.0) (78.2 , 96.7)	50 50 (100) (92.9 , 100.0)	10.0 (2.4 , 21.4)*	0.0 (-7.2 , 7.2)
MOPA 19F	50 49 (98.0) (89.4 , 100.0)	50 49 (98.0) (89.4 , 100.0)	50 49 (98.0) (89.4 , 100.0)	0.0 (-8.8 , 8.8)	0.0 (-8.8 , 8.8)
MOPA 23F	50 50 (100) (92.9 , 100.0)	50 50 (100) (92.9 , 100.0)	50 50 (100) (92.9 , 100.0)	0.0 (-7.2 , 7.2)	0.0 (-7.2 , 7.2)

[1]Based on differences in proportions responding, with 95% CIs based on Miettinen-Nurminen score method. Asterisks denote statistically significant differences.
[2]Number of observations contributing to analysis within visit window.
[3]Number of responders (titer >= 8)

Data source: ADIMMUNO
Listing source: 16.2.6.2

PATH CVIA 074 - Final Report (Confidential)
Table 14.2.2.3.1.1 Secondary Objective 3.1: IgG Seroresponse Rates (≥0.35µg/mL) 4 Weeks Post Primary Series
Secondary PP_IMM Population

	PNEUMOSIL (N=216)			Synflorix (N=213)			Prevenar 13 (N=212)			Treatment Group Comparison[1]	
Serotype	**N[2]**	**n[3]**	**(%) (95% CI)**	**N[2]**	**n[3]**	**(%) (95% CI)**	**N[2]**	**n[3]**	**(%) (95% CI)**	**PNEUMOSIL - Synflorix Difference (95% CI)**	**PNEUMOSIL - Prevenar 13 Difference (95% CI)**
PnC-IgG-ELISA Type 1	216	215	(99.5) (97.5 , 100.0)	212	204	(96.2) (92.7 , 98.4)	212	212	(100) (98.3 , 100.0)	3.3 (0.8 , 6.9)*	-0.5 (-2.6 , 1.3)
PnC-IgG-ELISA Type 5	216	209	(96.8) (93.4 , 98.7)	212	195	(92.0) (87.5 , 95.3)	212	204	(96.2) (92.7 , 98.4)	4.8 (0.4 , 9.6)*	0.5 (-3.3 , 4.4)
PnC-IgG-ELISA Type 6A	216	180	(83.3) (77.7 , 88.1)	211	27	(12.8) (8.6 , 18.1)	212	194	(91.5) (86.9 , 94.9)	70.5 (63.2 , 76.6)*	-8.2 (-14.6 , -1.9)*
PnC-IgG-ELISA Type 6B	216	183	(84.7) (79.2 , 89.2)	212	151	(71.2) (64.6 , 77.2)	210	187	(89.0) (84.0 , 92.9)	13.5 (5.7 , 21.3)*	-4.3 (-10.9 , 2.1)
PnC-IgG-ELISA Type 7F	216	215	(99.5) (97.5 , 100.0)	212	206	(97.2) (93.9 , 99.0)	212	212	(100) (98.3 , 100.0)	2.4 (-0.1 , 5.6)	-0.5 (-2.6 , 1.3)
PnC-IgG-ELISA Type 9V	216	205	(94.9) (91.1 , 97.4)	212	193	(91.0) (86.4 , 94.5)	212	208	(98.1) (95.2 , 99.5)	3.9 (-1.0 , 9.1)	-3.2 (-7.2 , 0.3)
PnC-IgG-ELISA Type 14	216	213	(98.6) (96.0 , 99.7)	212	202	(95.3) (91.5 , 97.7)	212	206	(97.2) (93.9 , 99.0)	3.3 (0.1 , 7.2)*	1.4 (-1.5 , 4.8)
PnC-IgG-ELISA Type 19A	216	211	(97.7) (94.7 , 99.2)	210	158	(75.2) (68.8 , 80.9)	212	207	(97.6) (94.6 , 99.2)	22.4 (16.5 , 28.9)*	0.0 (-3.2 , 3.4)
PnC-IgG-ELISA Type 19F	216	216	(100) (98.3 , 100.0)	209	208	(99.5) (97.4 , 100.0)	211	211	(100) (98.3 , 100.0)	0.5 (-1.3 , 2.7)	0.0 (-1.8 , 1.8)
PnC-IgG-ELISA Type 23F	216	207	(95.8) (92.2 , 98.1)	212	134	(63.2) (56.3 , 69.7)	212	190	(89.6) (84.7 , 93.4)	32.6 (25.7 , 39.7)*	6.2 (1.4 , 11.5)*

[1]Based on differences in proportions responding, with 95% CIs based on Miettinen-Nurminen score method. Asterisks denote statistically significant differences.
[2]Number of observations contributing to analysis.
[3]Number of responders (IgG ≥ 0.35 µg/mL)

Data source: ADIMMUNO
Listing source: 16.2.6.1

PATH CVIA 074 - Final Report (Confidential)
Table 14.2.2.3.2.1 Secondary Objective 3.2: IgG Geometric Mean Concentrations (GMCs) 4 Weeks Post Primary Series
Secondary PP_IMM Population

	PNEUMOSIL (N=216)		Synflorix (N=213)		Prevenar 13 (N=212)		Treatment Group Comparison[1]	
							PNEUMOSIL/ Synflorix	PNEUMOSIL/ Prevenar 13
Serotype	n[2]	GMC (95% CI)	n[2]	GMC (95% CI)	n[2]	GMC (95% CI)	GMC Ratio (95% CI)	GMC Ratio (95% CI)
PnC-IgG-ELISA Type 1	216	3.63 (3.32 , 3.98)	212	1.36 (1.23 , 1.51)	212	3.40 (3.10 , 3.74)	2.66 (2.32 , 3.05)*	1.07 (0.94 , 1.22)
PnC-IgG-ELISA Type 5	216	1.19 (1.10 , 1.28)	212	0.87 (0.79 , 0.96)	212	1.81 (1.62 , 2.01)	1.36 (1.21 , 1.54)*	0.66 (0.57 , 0.75)*
PnC-IgG-ELISA Type 6A	216	1.19 (1.00 , 1.41)	211	0.14 (0.13 , 0.16)	212	2.62 (2.24 , 3.08)	8.50 (6.93 , 10.42)*	0.45 (0.36 , 0.57)*
PnC-IgG-ELISA Type 6B	216	1.82 (1.48 , 2.23)	212	0.91 (0.75 , 1.10)	210	1.75 (1.49 , 2.07)	2.00 (1.51 , 2.65)*	1.04 (0.80 , 1.35)
PnC-IgG-ELISA Type 7F	216	3.46 (3.09 , 3.88)	212	1.73 (1.55 , 1.92)	212	4.67 (4.19 , 5.20)	2.01 (1.72 , 2.34)*	0.74 (0.63 , 0.87)*
PnC-IgG-ELISA Type 9V	216	1.93 (1.74 , 2.16)	212	1.31 (1.17 , 1.46)	212	2.56 (2.28 , 2.88)	1.48 (1.27 , 1.73)*	0.76 (0.64 , 0.89)*
PnC-IgG-ELISA Type 14	216	4.03 (3.50 , 4.64)	212	2.58 (2.18 , 3.04)	212	3.27 (2.70 , 3.96)	1.56 (1.26 , 1.94)*	1.23 (0.97 , 1.56)
PnC-IgG-ELISA Type 19A	216	1.75 (1.57 , 1.96)	210	0.65 (0.57 , 0.73)	212	4.38 (3.73 , 5.15)	2.71 (2.30 , 3.20)*	0.40 (0.33 , 0.49)*
PnC-IgG-ELISA Type 19F	216	5.45 (4.94 , 6.01)	209	8.86 (7.71 , 10.17)	211	9.06 (7.97 , 10.30)	0.62 (0.52 , 0.73)*	0.60 (0.51 , 0.71)*
PnC-IgG-ELISA Type 23F	216	2.21 (1.92 , 2.56)	212	0.57 (0.48 , 0.68)	212	1.64 (1.39 , 1.93)	3.87 (3.11 , 4.83)*	1.35 (1.09 , 1.68)*

[1]Based on GMC Ratio (GMCR), with 95% CIs based on antilog of normal-theory limits for difference in logged means. Asterisks denote statistically significant differences.
[2]Number of subjects with reportable results for a given serotype, among N with specimens collected.

Data source: ADIMMUNO
Listing source: 16.2.6.1

PATH CVIA 074 - Final Report (Confidential)
Table 14.2.2.4.1.1 Secondary Objective 4.1: OPA Seroresponse Rates 4 Weeks Post Primary Series
Secondary PP_IMM Population

	PNEUMOSIL (N=50)	Synflorix (N=50)	Prevenar 13 (N=50)	Treatment Group Comparison[1]	
				PNEUMOSIL - Synflorix	PNEUMOSIL - Prevenar13
Serotype	N[2] n[3] (%) (95% CI)	N[2] n[3] (%) (95% CI)	N[2] n[3] (%) (95% CI)	Difference (95% CI)	Difference (95% CI)
MOPA 1	50 49 (98.0) (89.4 , 100.0)	49 36 (73.5) (58.9 , 85.1)	50 48 (96.0) (86.3 , 99.5)	24.5 (12.3 , 38.7)*	2.0 (-7.0 , 11.8)
MOPA 5	50 49 (98.0) (89.4 , 100.0)	50 48 (96.0) (86.3 , 99.5)	50 50 (100) (92.9 , 100.0)	2.0 (-7.0 , 11.8)	-2.0 (-10.6 , 5.3)
MOPA 6A	50 46 (92.0) (80.8 , 97.8)	49 5 (10.2) (3.4 , 22.2)	50 49 (98.0) (89.4 , 100.0)	81.8 (67.1 , 90.3)*	-6.0 (-17.2 , 3.5)
MOPA 6B	50 48 (96.0) (86.3 , 99.5)	49 34 (69.4) (54.6 , 81.8)	50 46 (92.0) (80.8 , 97.8)	26.6 (12.8 , 41.3)*	4.0 (-6.6 , 15.5)
MOPA 7F	50 50 (100) (92.9 , 100.0)	50 50 (100) (92.9 , 100.0)	50 50 (100) (92.9 , 100.0)	0.0 (-7.2 , 7.2)	0.0 (-7.2 , 7.2)
MOPA 9V	47 47 (100) (92.5 , 100.0)	50 50 (100) (92.9 , 100.0)	50 50 (100) (92.9 , 100.0)	-0.0 (-7.6 , 7.2)	-0.0 (-7.6 , 7.2)
MOPA 14	50 47 (94.0) (83.5 , 98.8)	48 47 (97.9) (88.9 , 100.0)	50 45 (90.0) (78.2 , 96.7)	-3.9 (-14.5 , 5.7)	4.0 (-7.7 , 16.3)
MOPA 19A	49 45 (91.8) (80.4 , 97.7)	46 26 (56.5) (41.1 , 71.1)	50 48 (96.0) (86.3 , 99.5)	35.3 (18.6 , 51.1)*	-4.2 (-15.9 , 6.5)
MOPA 19F	50 48 (96.0) (86.3 , 99.5)	49 47 (95.9) (86.0 , 99.5)	50 49 (98.0) (89.4 , 100.0)	0.1 (-10.0 , 10.3)	-2.0 (-11.8 , 7.0)
MOPA 23F	48 48 (100) (92.6 , 100.0)	47 47 (100) (92.5 , 100.0)	49 49 (100) (92.8 , 100.0)	0.0 (-7.5 , 7.6)	-0.0 (-7.5 , 7.3)

[1]Based on differences in proportions responding, with 95% CIs based on Miettinen-Nurminen score method. Asterisks denote statistically significant differences.
[2]Number of observations contributing to analysis within visit window.
[3]Number of responders (titer >= 8)

Data source: ADIMMUNO
Listing source: 16.2.6.2

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Table 14.2.2.4.2.1 Secondary Objective 4.2 OPA Geometric Mean Titers (GMTs) 4 Weeks Post Primary Series
Secondary PP_IMM Population

	PNEUMOSIL (N=50)			Synflorix (N=50)			Prevenar 13 (N=50)			Treatment Group Comparison[1]	
										PNEUMOSIL/ Synflorix	PNEUMOSIL/ Prevenar 13
Serotype	n[2]	GMT	(95% CI)	n[2]	GMT	(95% CI)	n[2]	GMT	(95% CI)	GMT Ratio (95% CI)	GMT Ratio (95% CI)
MOPA 1	50	99.67	(71.83 , 138.30)	49	26.70	(17.72 , 40.22)	50	98.63	(70.61 , 137.78)	3.73 (2.23 , 6.26)*	1.01 (0.64 , 1.60)
MOPA 5	50	182.18	(134.53 , 246.70)	50	85.09	(58.98 , 122.75)	50	291.98	(221.91 , 384.18)	2.14 (1.34 , 3.42)*	0.62 (0.42 , 0.93)*
MOPA 6A	50	400.49	(238.40 , 672.79)	49	5.35	(4.04 , 7.08)	50	1524.31	(1066.28 , 2179.09)	74.89 (41.73 , 134.41)*	0.26 (0.14 , 0.49)*
MOPA 6B	50	923.86	(589.56 , 1447.73)	49	166.74	(88.71 , 313.43)	50	920.43	(573.35 , 1477.61)	5.54 (2.58 , 11.92)*	1.00 (0.53 , 1.91)
MOPA 7F	50	2069.84	(1622.83 , 2639.98)	50	1096.84	(853.88 , 1408.93)	50	3069.95	(2435.98 , 3868.91)	1.89 (1.34 , 2.66)*	0.67 (0.48 , 0.94)*
MOPA 9V	47	134.50	(87.35 , 207.10)	50	58.24	(38.29 , 88.58)	50	331.79	(241.48 , 455.89)	2.31 (1.27 , 4.18)*	0.41 (0.24 , 0.68)*
MOPA 14	50	669.79	(383.93 , 1168.50)	48	577.98	(376.06 , 888.33)	50	489.56	(224.00 , 1069.94)	1.16 (0.58 , 2.33)	1.37 (0.53 , 3.53)
MOPA 19A	49	69.15	(46.95 , 101.85)	46	22.40	(13.27 , 37.83)	50	324.64	(204.39 , 515.65)	3.09 (1.63 , 5.84)*	0.21 (0.12 , 0.39)*
MOPA 19F	50	381.46	(269.27 , 540.40)	49	690.36	(461.10 , 1033.61)	50	647.79	(460.50 , 911.24)	0.55 (0.33 , 0.93)*	0.59 (0.36 , 0.95)*
MOPA 23F	48	806.12	(584.18 , 1112.39)	47	180.97	(106.19 , 308.44)	49	748.96	(458.35 , 1223.84)	4.45 (2.40 , 8.25)*	1.08 (0.60 , 1.92)

[1]95% CIs for GMT Ratios based on antilog of normal-theory limits for difference in logged means. Asterisks denote statistically significant differences.
[2]Number of subjects with reportable results for a given serotype, among N with specimens collected within visit window.

Data source: ADIMMUNO
Listing source: 16.2.6.2

PATH CVIA 074 - Final Report (Confidential)
Table 14.2.2.5.1.1 Secondary Objective 5.1: Persistence of IgG Seroresponse Rates Prior to Booster Vaccination
Secondary PP_IMM Population

	PNEUMOSIL (N=216)			Synflorix (N=213)			Prevenar 13 (N=212)			Treatment Group Comparison[1]	
										PNEUMOSIL - Synflorix	PNEUMOSIL - Prevenar 13
Serotype	**N[2]**	**n[3]**	**(%) (95% CI)**	**N[2]**	**n[3]**	**(%) (95% CI)**	**N[2]**	**n[3]**	**(%) (95% CI)**	**Difference (95% CI)**	**Difference (95% CI)**
PnC-IgG-ELISA Type 1	207	104	(50.2) (43.2 , 57.3)	203	35	(17.2) (12.3 , 23.2)	206	110	(53.4) (46.3 , 60.4)	33.0 (24.2 , 41.3)*	-3.2 (-12.7 , 6.5)
PnC-IgG-ELISA Type 5	205	28	(13.7) (9.3 , 19.1)	201	33	(16.4) (11.6 , 22.3)	204	69	(33.8) (27.4 , 40.8)	-2.8 (-9.8 , 4.3)	-20.2 (-28.2 , -12)*
PnC-IgG-ELISA Type 6A	208	158	(76.0) (69.6 , 81.6)	205	67	(32.7) (26.3 , 39.6)	206	145	(70.4) (63.7 , 76.5)	43.3 (34.2 , 51.5)*	5.6 (-3.0 , 14.1)
PnC-IgG-ELISA Type 6B	208	187	(89.9) (85.0 , 93.6)	205	153	(74.6) (68.1 , 80.4)	206	125	(60.7) (53.7 , 67.4)	15.3 (8.0 , 22.6)*	29.2 (21.3 , 37.0)*
PnC-IgG-ELISA Type 7F	208	155	(74.5) (68.0 , 80.3)	205	134	(65.4) (58.4 , 71.9)	206	174	(84.5) (78.8 , 89.1)	9.2 (0.3 , 17.9)*	-10.0 (-17.7 , -2.2)*
PnC-IgG-ELISA Type 9V	205	72	(35.1) (28.6 , 42.1)	205	74	(36.1) (29.5 , 43.1)	204	77	(37.7) (31.1 , 44.8)	-1.0 (-10.2 , 8.3)	-2.6 (-11.9 , 6.7)
PnC-IgG-ELISA Type 14	207	144	(69.6) (62.8 , 75.8)	204	121	(59.3) (52.2 , 66.1)	205	177	(86.3) (80.9 , 90.7)	10.3 (1.0 , 19.4)*	-16.8 (-24.6 , -8.9)*
PnC-IgG-ELISA Type 19A	203	118	(58.1) (51.0 , 65.0)	204	112	(54.9) (47.8 , 61.9)	204	134	(65.7) (58.7 , 72.2)	3.2 (-6.4 , 12.8)	-7.6 (-16.9 , 1.9)
PnC-IgG-ELISA Type 19F	207	174	(84.1) (78.4 , 88.8)	205	195	(95.1) (91.2 , 97.6)	206	166	(80.6) (74.5 , 85.8)	-11.1 (-17.2 , -5.4)*	3.5 (-3.9 , 10.9)
PnC-IgG-ELISA Type 23F	208	96	(46.2) (39.2 , 53.2)	206	40	(19.4) (14.3 , 25.5)	205	51	(24.9) (19.1 , 31.4)	26.7 (17.9 , 35.2)*	21.3 (12.1 , 30.1)*

[1]Based on differences in proportions responding, with 95% CIs based on Miettinen-Nurminen score method. Asterisks denote statistically significant differences.
[2]Number of observations contributing to analysis.
[3]Number of responders (IgG $\geq$ 0.35 µg/mL)

Data source: ADIMMUNO
Listing source: 16.2.6.1

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Table 14.2.2.5.2.1 Secondary Objective 5.2: IgG Geometric Mean Concentrations Prior to Booster Vaccination
Secondary PP_IMM Population

	PNEUMOSIL (N=216)		Synflorix (N=213)		Prevenar 13 (N=212)		Treatment Group Comparison[1]	
							PNEUMOSIL/ Synflorix	PNEUMOSIL/ Prevenar 13
Serotype	**n[2]**	**GMC (95% CI)**	**n[2]**	**GMC (95% CI)**	**n[2]**	**GMC (95% CI)**	**GMC Ratio (95% CI)**	**GMC Ratio (95% CI)**
PnC-IgG-ELISA Type 1	207	0.36 (0.33 , 0.41)	203	0.16 (0.15 , 0.18)	206	0.37 (0.33 , 0.41)	2.21 (1.91 , 2.57)*	0.99 (0.85 , 1.15)
PnC-IgG-ELISA Type 5	205	0.17 (0.15 , 0.18)	201	0.16 (0.14 , 0.17)	204	0.24 (0.22 , 0.27)	1.05 (0.91 , 1.20)	0.68 (0.59 , 0.78)*
PnC-IgG-ELISA Type 6A	208	0.62 (0.55 , 0.70)	205	0.22 (0.19 , 0.25)	206	0.50 (0.45 , 0.56)	2.85 (2.39 , 3.39)*	1.24 (1.05 , 1.46)*
PnC-IgG-ELISA Type 6B	208	0.97 (0.87 , 1.08)	205	0.56 (0.50 , 0.62)	206	0.45 (0.39 , 0.50)	1.75 (1.49 , 2.05)*	2.18 (1.85 , 2.57)*
PnC-IgG-ELISA Type 7F	208	0.60 (0.53 , 0.68)	205	0.43 (0.39 , 0.48)	206	0.72 (0.64 , 0.80)	1.40 (1.19 , 1.66)*	0.84 (0.72 , 1.00)*
PnC-IgG-ELISA Type 9V	205	0.25 (0.23 , 0.28)	205	0.29 (0.26 , 0.32)	204	0.28 (0.25 , 0.31)	0.88 (0.75 , 1.03)	0.92 (0.78 , 1.08)
PnC-IgG-ELISA Type 14	207	0.71 (0.60 , 0.83)	204	0.48 (0.41 , 0.56)	205	1.16 (1.00 , 1.35)	1.47 (1.17 , 1.83)*	0.61 (0.49 , 0.76)*
PnC-IgG-ELISA Type 19A	203	0.49 (0.42 , 0.56)	204	0.40 (0.35 , 0.45)	204	0.53 (0.46 , 0.62)	1.23 (1.00 , 1.50)*	0.91 (0.74 , 1.12)
PnC-IgG-ELISA Type 19F	207	0.83 (0.73 , 0.94)	205	1.25 (1.11 , 1.40)	206	0.72 (0.63 , 0.83)	0.66 (0.56 , 0.79)*	1.14 (0.95 , 1.38)
PnC-IgG-ELISA Type 23F	208	0.32 (0.27 , 0.37)	206	0.16 (0.15 , 0.19)	205	0.17 (0.15 , 0.20)	1.92 (1.59 , 2.33)*	1.82 (1.48 , 2.22)*

[1]Based on GMC Ratio (GMCR), with 95% CIs based on antilog of normal-theory limits for difference in logged means. Asterisks denote statistically signifant differences.
[2]Number of subjects with reportable results for a given serotype, among N with specimens collected.

Data source: ADIMMUNO
Listing source: 16.2.6.1

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TABLE 14.2.2.6.1.1 Secondary Objective 6.1: Persistence of OPA Seroresponse Rates Prior to Booster Vaccination
Secondary PP_IMM Population

	PNEUMOSIL (N=50)	Synflorix (N=50)	Prevenar 13 (N=50)	Treatment Group Comparison[1]	
				PNEUMOSIL - Synflorix	PNEUMOSIL - Prevenar 13
Serotype	N[2] n[3] (%) (95% CI)	N n (%) (95% CI)	N n (%) (95% CI)	Difference (95% CI)	Difference (95% CI)
MOPA 1	49 11 (22.4) (11.8 , 36.6)	50 8 (16.0) (7.2 , 29.1)	47 12 (25.5) (13.9 , 40.3)	6.5 (-9.4 , 22.4)	-3.1 (-20.4 , 14.2)
MOPA 5	48 28 (58.3) (43.2 , 72.4)	49 24 (49.0) (34.4 , 63.7)	49 31 (63.3) (48.3 , 76.6)	9.4 (-10.5 , 28.5)	-4.9 (-24.0 , 14.4)
MOPA 6A	47 36 (76.6) (62.0 , 87.7)	50 7 (14.0) (5.8 , 26.7)	47 30 (63.8) (48.5 , 77.3)	62.6 (44.8 , 75.7)*	12.8 (-5.9 , 30.7)
MOPA 6B	48 42 (87.5) (74.8 , 95.3)	48 30 (62.5) (47.3 , 76.1)	48 26 (54.2) (39.2 , 68.6)	25.0 (7.9 , 41.3)*	33.3 (15.6 , 49.5)*
MOPA 7F	49 49 (100) (92.8 , 100.0)	49 49 (100) (92.8 , 100.0)	48 48 (100) (92.6 , 100.0)	0.0 (-7.3 , 7.3)	0.0 (-7.3 , 7.5)
MOPA 9V	44 44 (100) (92.0 , 100.0)	43 43 (100) (91.8 , 100.0)	45 45 (100) (92.1 , 100.0)	0.0 (-8.1 , 8.3)	0.0 (-8.1 , 7.9)
MOPA 14	49 37 (75.5) (61.1 , 86.7)	48 25 (52.1) (37.2 , 66.7)	48 35 (72.9) (58.2 , 84.7)	23.4 (4.3 , 41.1)*	2.6 (-15.0 , 20.1)
MOPA 19A	48 17 (35.4) (22.2 , 50.5)	49 20 (40.8) (27.0 , 55.8)	49 31 (63.3) (48.3 , 76.6)	-5.4 (-24.3 , 13.9)	-27.9 (-45.6 , -7.9)*
MOPA 19F	48 29 (60.4) (45.3 , 74.2)	49 39 (79.6) (65.7 , 89.8)	49 18 (36.7) (23.4 , 51.7)	-19.2 (-36.5 , -0.9)*	23.7 (3.7 , 41.8)*
MOPA 23F	43 43 (100) (91.8 , 100.0)	42 42 (100) (91.6 , 100.0)	42 42 (100) (91.6 , 100.0)	0.0 (-8.3 , 8.5)	0.0 (-8.3 , 8.5)

[1]Based on differences in proportions responding, with 95% CIs based on Miettinen-Nurminen score method. Asterisks denote statistically significant differences.
[2]Number of observations contributing to analysis within visit window.
[3]Number of responders (titer >= 8)

Data source: ADIMMUNO
Listing source: 16.2.6.2

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Table 14.2.2.6.2.1 Secondary Objective 6.2: OPA Geometric Mean Titers Prior to Booster Vaccination
Secondary PP_IMM Population

	PNEUMOSIL (N=50)		Synflorix (N=50)		Prevenar 13 (N=50)		Treatment Group Comparison[1]	
							PNEUMOSIL/ Synflorix	PNEUMOSIL/ Prevenar 13
Serotype	n[2]	GMT (95% CI)	n[2]	GMT (95% CI)	n[2]	GMT (95% CI)	GMT Ratio (95% CI)	GMT Ratio (95% CI)
MOPA 1	49	5.57 (4.56 , 6.80)	50	5.19 (4.27 , 6.30)	47	5.45 (4.57 , 6.49)	1.07 (0.81 , 1.41)	1.02 (0.79 , 1.33)
MOPA 5	48	12.53 (9.03 , 17.37)	49	12.01 (8.28 , 17.43)	49	16.03 (10.95 , 23.45)	1.04 (0.64 , 1.70)	0.78 (0.48 , 1.28)
MOPA 6A	47	42.59 (26.46 , 68.55)	50	6.41 (4.49 , 9.15)	47	40.66 (22.34 , 74.00)	6.64 (3.71 , 11.88)*	1.05 (0.49 , 2.23)
MOPA 6B	48	121.60 (78.09 , 189.36)	48	40.08 (25.20 , 63.72)	48	32.27 (19.77 , 52.68)	3.03 (1.61 , 5.71)*	3.77 (1.96 , 7.23)*
MOPA 7F	49	1756.80 (1234.91 , 2499.24)	49	1725.63 (1206.66 , 2467.79)	48	1688.30 (1160.23 , 2456.74)	1.02 (0.62 , 1.67)	1.04 (0.63 , 1.73)
MOPA 9V	44	27.60 (15.80 , 48.21)	43	27.95 (17.48 , 44.67)	45	48.64 (29.08 , 81.36)	0.99 (0.48 , 2.03)	0.57 (0.27 , 1.20)
MOPA 14	49	60.53 (32.55 , 112.55)	48	17.67 (10.31 , 30.29)	48	62.77 (33.95 , 116.08)	3.42 (1.52 , 7.72)*	0.96 (0.41 , 2.28)
MOPA 19A	48	13.43 (7.80 , 23.11)	49	12.88 (8.25 , 20.12)	49	28.20 (16.96 , 46.89)	1.04 (0.52 , 2.08)	0.48 (0.23 , 0.99)*
MOPA 19F	48	24.09 (13.90 , 41.77)	49	57.66 (33.74 , 98.52)	49	12.27 (7.34 , 20.50)	0.42 (0.20 , 0.89)*	1.96 (0.93 , 4.13)
MOPA 23F	43	65.62 (38.19 , 112.74)	42	41.99 (23.29 , 75.68)	42	81.42 (44.08 , 150.40)	1.56 (0.71 , 3.43)	0.81 (0.36 , 1.80)

[1]95% CIs for GMT Ratios based on antilog of normal-theory limits for difference in logged means. Asterisks denote statistically significant differences.
[2]Number of subjects with reportable results for a given serotype, among N with specimens collected within visit window.

Data source: ADIMMUNO
Listing source: 16.2.6.2

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Table 14.2.2.7.1.1 Secondary Objective 7.1: IgG Booster Responses by Treatment Group
Primary PP_IMM Population

PNEUMOSIL	4-Weeks Post Primary Series (N=202) n[2] GMC (95% CI)	4-Weeks Post Booster (N=202) n[2] GMC (95% CI)	Booster Response[1] GMC Ratio (95% CI)
PnC-IgG-ELISA type 1	201 3.65 (3.32 , 4.02)	201 8.45 (7.54 , 9.48)	2.31 (2.10 , 2.55)
PnC-IgG-ELISA type 5	202 1.20 (1.10 , 1.30)	202 1.54 (1.38 , 1.73)	1.29 (1.15 , 1.44)
PnC-IgG-ELISA type 6A	201 1.22 (1.01 , 1.46)	201 9.56 (8.26 , 11.05)	7.86 (6.54 , 9.44)
PnC-IgG-ELISA type 6B	202 1.86 (1.50 , 2.30)	202 12.46 (11.07 , 14.01)	6.71 (5.48 , 8.21)
PnC-IgG-ELISA type 7F	202 3.48 (3.09 , 3.92)	202 6.66 (5.96 , 7.44)	1.91 (1.69 , 2.17)
PnC-IgG-ELISA type 9V	202 1.97 (1.76 , 2.20)	202 3.46 (3.08 , 3.88)	1.76 (1.55 , 1.98)
PnC-IgG-ELISA type 14	202 4.17 (3.61 , 4.82)	202 8.28 (6.97 , 9.82)	1.98 (1.69 , 2.33)
PnC-IgG-ELISA type 19A	200 1.77 (1.57 , 1.99)	200 8.82 (7.65 , 10.15)	4.98 (4.33 , 5.74)
PnC-IgG-ELISA type 19F	200 5.60 (5.06 , 6.20)	200 11.11 (9.70 , 12.73)	1.98 (1.74 , 2.26)
PnC-IgG-ELISA type 23F	202 2.21 (1.90 , 2.58)	202 4.95 (4.28 , 5.73)	2.24 (1.95 , 2.58)

[1]Ratio of GMC 4-weeks post booster to 4-weeks post-primary series, with 95% CIs based on antilog of normal-theory limits for difference in logged means, restricted to subjects contributing data to both timepoints.
[2]Number of subjects with reportable results for a given serotype at both timepoints, among N with specimens collected at both timepoints.

Data source: ADIMMUNO
Listing source: 16.2.6.1

Table 14.2.2.7.1.1 Secondary Objective 7.1: IgG Booster Responses by Treatment Group
Primary PP_IMM Population

Synflorix	4-Weeks Post Primary Series (N=200) n[2] GMC (95% CI)	4-Weeks Post Booster (N=200) n[2] GMC (95% CI)	Booster Response[1] GMC Ratio (95% CI)
PnC-IgG-ELISA type 1	197 1.39 (1.25 , 1.55)	197 2.90 (2.57 , 3.28)	2.09 (1.86 , 2.34)
PnC-IgG-ELISA type 5	199 0.88 (0.80 , 0.97)	199 0.80 (0.72 , 0.88)	0.90 (0.81 , 1.01)
PnC-IgG-ELISA type 6A	195 0.14 (0.12 , 0.16)	195 0.60 (0.50 , 0.71)	4.30 (3.61 , 5.12)
PnC-IgG-ELISA type 6B	200 0.93 (0.77 , 1.13)	200 4.96 (4.44 , 5.53)	5.32 (4.46 , 6.35)
PnC-IgG-ELISA type 7F	200 1.72 (1.54 , 1.92)	200 3.15 (2.87 , 3.45)	1.84 (1.64 , 2.05)
PnC-IgG-ELISA type 9V	200 1.32 (1.17 , 1.48)	200 2.45 (2.21 , 2.72)	1.86 (1.65 , 2.09)
PnC-IgG-ELISA type 14	200 2.59 (2.19 , 3.08)	200 5.02 (4.22 , 5.97)	1.93 (1.61 , 2.33)
PnC-IgG-ELISA type 19A	197 0.65 (0.57 , 0.74)	197 2.40 (1.98 , 2.91)	3.69 (3.08 , 4.42)
PnC-IgG-ELISA type 19F	192 9.10 (7.90 , 10.48)	192 17.85 (15.36 , 20.74)	1.96 (1.68 , 2.29)
PnC-IgG-ELISA type 23F	200 0.59 (0.50 , 0.70)	200 2.16 (1.92 , 2.44)	3.67 (3.10 , 4.36)

[1]Ratio of GMC 4-weeks post booster to 4-weeks post-primary series, with 95% CIs based on antilog of normal-theory limits for difference in logged means, restricted to subjects contributing data to both timepoints.
[2]Number of subjects with reportable results for a given serotype at both timepoints, among N with specimens collected at both timepoints.

Data source: ADIMMUNO
Listing source: 16.2.6.1

Table 14.2.2.7.1.1 Secondary Objective 7.1: IgG Booster Responses by Treatment Group
Primary PP_IMM Population

Prevenar 13	4-Weeks Post Primary Series (N=200) n[2] GMC (95% CI)	4-Weeks Post Booster (N=200) n[2] GMC (95% CI)	Booster Response[1] GMC Ratio (95% CI)
PnC-IgG-ELISA type 1	200 3.37 (3.05 , 3.71)	200 5.87 (5.26 , 6.56)	1.74 (1.54 , 1.97)
PnC-IgG-ELISA type 5	200 1.77 (1.58 , 1.98)	200 2.04 (1.86 , 2.24)	1.15 (1.02 , 1.30)
PnC-IgG-ELISA type 6A	199 2.65 (2.25 , 3.12)	199 10.95 (9.57 , 12.54)	4.14 (3.49 , 4.91)
PnC-IgG-ELISA type 6B	198 1.74 (1.47 , 2.07)	198 15.55 (13.72 , 17.63)	8.92 (7.47 , 10.66)
PnC-IgG-ELISA type 7F	200 4.64 (4.17 , 5.17)	200 6.31 (5.75 , 6.93)	1.36 (1.22 , 1.52)
PnC-IgG-ELISA type 9V	200 2.50 (2.21 , 2.82)	200 3.87 (3.47 , 4.32)	1.55 (1.34 , 1.79)
PnC-IgG-ELISA type 14	200 3.27 (2.69 , 3.98)	200 9.17 (8.06 , 10.45)	2.80 (2.29 , 3.43)
PnC-IgG-ELISA type 19A	199 4.54 (3.85 , 5.35)	199 12.21 (10.83 , 13.76)	2.69 (2.25 , 3.22)
PnC-IgG-ELISA type 19F	196 8.96 (7.85 , 10.23)	196 15.07 (13.32 , 17.05)	1.68 (1.46 , 1.94)
PnC-IgG-ELISA type 23F	198 1.66 (1.40 , 1.96)	198 4.97 (4.34 , 5.69)	3.00 (2.55 , 3.52)

[1]Ratio of GMC 4-weeks post booster to 4-weeks post-primary series, with 95% CIs based on antilog of normal-theory limits for difference in logged means, restricted to subjects contributing data to both timepoints.
[2]Number of subjects with reportable results for a given serotype at both timepoints, among N with specimens collected at both timepoints.

Data source: ADIMMUNO
Listing source: 16.2.6.1

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Table 14.2.2.7.2.1 Secondary Objective 7.2: OPA Booster Response by Treatment Group
Primary PP_IMM Population

PNEUMOSIL	4-Weeks Post Primary Series (N=50) n[2] GMT (95% CI)	4-Weeks Post Booster (N=50) n[2] GMT (95% CI)	Booster Response[1] GMT Ratio (95% CI)
MOPA 1	50 99.67 (71.83 , 138.30)	50 631.29 (467.98 , 851.59)	6.70 (5.07 , 8.86)
MOPA 5	50 182.18 (134.53 , 246.70)	50 885.98 (662.20 , 1185.37)	4.91 (3.71 , 6.49)
MOPA 6A	50 400.49 (238.40 , 672.79)	50 3651.54 (2593.53 , 5141.16)	10.36 (6.54 , 16.41)
MOPA 6B	50 923.86 (589.56 , 1447.73)	50 3931.21 (2969.79 , 5203.89)	4.62 (2.84 , 7.53)
MOPA 7F	50 2069.84 (1622.83 , 2639.98)	50 7053.37 (5904.91 , 8425.18)	3.51 (2.67 , 4.62)
MOPA 9V	47 134.50 (87.35 , 207.10)	50 1408.68 (1092.33 , 1816.64)	10.24 (6.36 , 16.50)
MOPA 14	50 669.79 (383.93 , 1168.50)	50 2622.36 (1845.88 , 3725.47)	4.27 (2.38 , 7.64)
MOPA 19A	49 69.15 (46.95 , 101.85)	50 1620.76 (1200.51 , 2188.13)	23.79 (15.61 , 36.25)
MOPA 19F	50 381.46 (269.27 , 540.40)	50 1384.38 (937.18 , 2044.98)	3.74 (2.47 , 5.65)
MOPA 23F	48 806.12 (584.18 , 1112.39)	50 2998.53 (2272.86 , 3955.89)	3.81 (2.69 , 5.40)

[1]Ratio of GMT 4-weeks post booster to 4-weeks post-primary series, with 95% CIs based on antilog of normal-theory limits for difference in logged means.
[2]Number of subjects with reportable results for a given serotype, among N with specimens collected.

Data source: ADIMMUNO
Listing source: 16.2.6.2

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Table 14.2.2.7.2.1 Secondary Objective 7.2: OPA Booster Response by Treatment Group
Primary PP_IMM Population

Synflorix	4-Weeks Post Primary Series (N=50) n[2] GMT (95% CI)	4-Weeks Post Booster (N=50) n[2] GMT (95% CI)	Booster Response[1] GMT Ratio (95% CI)
MOPA 1	49 26.70 (17.72 , 40.22)	50 282.35 (190.44 , 418.60)	9.35 (6.50 , 13.46)
MOPA 5	50 85.09 (58.98 , 122.75)	50 484.66 (361.73 , 649.38)	5.36 (3.78 , 7.61)
MOPA 6A	49 5.35 (4.04 , 7.08)	45 53.86 (25.10 , 115.56)	10.12 (4.98 , 20.53)
MOPA 6B	49 166.74 (88.71 , 313.43)	50 1294.61 (929.52 , 1803.11)	7.70 (4.40 , 13.46)
MOPA 7F	50 1096.84 (853.88 , 1408.93)	50 4401.18 (3593.44 , 5390.50)	4.03 (2.93 , 5.54)
MOPA 9V	50 58.24 (38.29 , 88.58)	49 845.47 (631.39 , 1132.13)	14.90 (9.12 , 24.35)
MOPA 14	48 577.98 (376.06 , 888.33)	50 1381.52 (883.30 , 2160.74)	2.25 (1.32 , 3.83)
MOPA 19A	46 22.40 (13.27 , 37.83)	50 305.46 (177.87 , 524.57)	12.25 (6.86 , 21.87)
MOPA 19F	49 690.36 (461.10 , 1033.61)	50 2541.40 (1666.99 , 3874.49)	3.30 (2.32 , 4.68)
MOPA 23F	47 180.97 (106.19 , 308.44)	50 1427.66 (1110.72 , 1835.05)	8.71 (5.63 , 13.45)

[1]Ratio of GMT 4-weeks post booster to 4-weeks post-primary series, with 95% CIs based on antilog of normal-theory limits for difference in logged means.
[2]Number of subjects with reportable results for a given serotype, among N with specimens collected.

Data source: ADIMMUNO
Listing source: 16.2.6.2

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Table 14.2.2.7.2.1 Secondary Objective 7.2: OPA Booster Response by Treatment Group
Primary PP_IMM Population

Prevenar 13	4-Weeks Post Primary Series (N=50) n[2] GMT (95% CI)	4-Weeks Post Booster (N=50) n[2] GMT (95% CI)	Booster Response[1] GMT Ratio (95% CI)
MOPA 1	50 98.63 (70.61 , 137.78)	49 429.13 (310.99 , 592.14)	4.45 (2.94 , 6.74)
MOPA 5	50 291.98 (221.91 , 384.18)	50 703.15 (556.01 , 889.24)	2.46 (1.86 , 3.25)
MOPA 6A	50 1524.31 (1066.28 , 2179.09)	50 6464.88 (5120.52 , 8162.19)	3.89 (2.70 , 5.61)
MOPA 6B	50 920.43 (573.35 , 1477.61)	50 6012.88 (4130.89 , 8752.29)	6.54 (4.03 , 10.60)
MOPA 7F	50 3069.95 (2435.98 , 3868.91)	50 8288.88 (6756.83 , 10168.3)	2.71 (2.08 , 3.53)
MOPA 9V	50 331.79 (241.48 , 455.89)	50 2464.43 (1957.36 , 3102.85)	7.64 (5.58 , 10.45)
MOPA 14	50 489.56 (224.00 , 1069.94)	50 3131.96 (2245.73 , 4367.91)	5.73 (2.84 , 11.60)
MOPA 19A	50 324.64 (204.39 , 515.65)	50 3679.06 (2920.79 , 4634.19)	11.63 (7.59 , 17.81)
MOPA 19F	50 647.79 (460.50 , 911.24)	50 2094.57 (1410.71 , 3109.94)	3.55 (2.35 , 5.39)
MOPA 23F	49 748.96 (458.35 , 1223.84)	50 5687.60 (3891.57 , 8312.54)	7.41 (4.32 , 12.72)

[1]Ratio of GMT 4-weeks post booster to 4-weeks post-primary series, with 95% CIs based on antilog of normal-theory limits for difference in logged means.
[2]Number of subjects with reportable results for a given serotype, among N with specimens collected.

Data source: ADIMMUNO
Listing source: 16.2.6.2

Table 14.3.2 Unsolicited Treatment Emergent Adverse Events at any Time during Follow-up by System Organ Class and Preferred Term: Safety Population

	PNEUMOSIL (N= 220)		Synflorix (N= 220)		Prevenar 13 (N= 220)		Total (N= 660)	
System Organ Class / Preferred Term[1]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Infections and infestations	**448**	**189 (85.9)**	**442**	**177 (80.5)**	**410**	**174 (79.1)**	**1300**	**540 (81.8)**
Upper respiratory tract infection	151	111 (50.5)	172	112 (50.9)	130	99 (45.0)	453	322 (48.8)
Furuncle	70	52 (23.6)	48	40 (18.2)	46	39 (17.7)	164	131 (19.8)
Conjunctivitis	32	29 (13.2)	44	42 (19.1)	36	36 (16.4)	112	107 (16.2)
Gastroenteritis	31	28 (12.7)	28	23 (10.5)	35	29 (13.2)	94	80 (12.1)
Rash pustular	18	18 (8.2)	19	16 (7.3)	24	22 (10.0)	61	56 (8.5)
Skin candida	25	22 (10.0)	13	11 (5.0)	18	17 (7.7)	56	50 (7.6)
Pneumonia	11	11 (5.0)	14	11 (5.0)	18	18 (8.2)	43	40 (6.1)
Body tinea	13	13 (5.9)	12	12 (5.5)	15	14 (6.4)	40	39 (5.9)
Bronchiolitis	13	12 (5.5)	10	9 (4.1)	15	14 (6.4)	38	35 (5.3)
Otitis media	11	8 (3.6)	8	8 (3.6)	10	9 (4.1)	29	25 (3.8)
Febrile infection	8	7 (3.2)	10	8 (3.6)	9	9 (4.1)	27	24 (3.6)
Impetigo	9	9 (4.1)	11	11 (5.0)	7	7 (3.2)	27	27 (4.1)
Oral candidiasis	8	6 (2.7)	7	7 (3.2)	5	5 (2.3)	20	18 (2.7)
Tinea capitis	6	6 (2.7)	7	6 (2.7)	4	4 (1.8)	17	16 (2.4)
Tinea infection	7	7 (3.2)	1	1 (0.5)	7	7 (3.2)	15	15 (2.3)
Cutaneous larva migrans	6	6 (2.7)	1	1 (0.5)	7	7 (3.2)	14	14 (2.1)
Abscess	2	2 (0.9)	5	5 (2.3)	2	2 (0.9)	9	9 (1.4)

[1] Based on MedDRA dictionary version 23. Includes solicited events if ongoing 6 days after study vaccination.

Data source: ADAE
Listing source: 16.2.7.1

Table 14.3.2 Unsolicited Treatment Emergent Adverse Events at any Time during Follow-up by System Organ Class and Preferred Term: Safety Population

	PNEUMOSIL (N= 220)		Synflorix (N= 220)		Prevenar 13 (N= 220)		Total (N= 660)	
System Organ Class / Preferred Term[1]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Otitis media acute	3	3 (1.4)	5	5 (2.3)	1	1 (0.5)	9	9 (1.4)
Nasopharyngitis	4	4 (1.8)	1	1 (0.5)	1	1 (0.5)	6	6 (0.9)
Periorbital cellulitis	0	0 (0.0)	4	4 (1.8)	2	2 (0.9)	6	6 (0.9)
Tinea versicolour	1	1 (0.5)	4	4 (1.8)	0	0 (0.0)	5	5 (0.8)
Urinary tract infection	2	2 (0.9)	0	0 (0.0)	3	3 (1.4)	5	5 (0.8)
Abscess limb	1	1 (0.5)	2	2 (0.9)	1	1 (0.5)	4	4 (0.6)
Cellulitis	1	1 (0.5)	0	0 (0.0)	3	3 (1.4)	4	4 (0.6)
Otitis externa	1	1 (0.5)	1	1 (0.5)	2	2 (0.9)	4	4 (0.6)
Varicella	3	3 (1.4)	1	1 (0.5)	0	0 (0.0)	4	4 (0.6)
Infected dermal cyst	0	0 (0.0)	3	1 (0.5)	0	0 (0.0)	3	1 (0.2)
Pustule	1	1 (0.5)	1	1 (0.5)	1	1 (0.5)	3	3 (0.5)
Vaccination site abscess	1	1 (0.5)	1	1 (0.5)	1	1 (0.5)	3	3 (0.5)
Acarodermatitis	1	1 (0.5)	0	0 (0.0)	1	1 (0.5)	2	2 (0.3)
Dysentery	1	1 (0.5)	1	1 (0.5)	0	0 (0.0)	2	2 (0.3)
Molluscum contagiosum	1	1 (0.5)	0	0 (0.0)	1	1 (0.5)	2	2 (0.3)
Subcutaneous abscess	0	0 (0.0)	1	1 (0.5)	1	1 (0.5)	2	2 (0.3)
Viral rash	0	0 (0.0)	1	1 (0.5)	1	1 (0.5)	2	2 (0.3)
Angular cheilitis	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	1	1 (0.2)

[1] Based on MedDRA dictionary version 23. Includes solicited events if ongoing 6 days after study vaccination.

Data source: ADAE
Listing source: 16.2.7.1

Table 14.3.2 Unsolicited Treatment Emergent Adverse Events at any Time during Follow-up by System Organ Class and Preferred Term: Safety Population

	PNEUMOSIL (N= 220)		Synflorix (N= 220)		Prevenar 13 (N= 220)		Total (N= 660)	
System Organ Class / Preferred Term[1]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Breast abscess	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)	1	1 (0.2)
Candida nappy rash	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	1	1 (0.2)
Dermatophytosis	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)	1	1 (0.2)
Gingival abscess	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	1	1 (0.2)
Helminthic infection	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)	1	1 (0.2)
Hordeolum	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	1	1 (0.2)
Mastitis	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	1	1 (0.2)
Meningitis bacterial	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	1	1 (0.2)
Paronychia	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	1	1 (0.2)
Pharyngitis	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	1	1 (0.2)
Respiratory tract infection	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	1	1 (0.2)
Vaccination site infection	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	1	1 (0.2)
Vaccination site pustule	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	1	1 (0.2)
Vulval cellulitis	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	1	1 (0.2)
Gastrointestinal disorders	**78**	**61 (27.7)**	**84**	**67 (30.5)**	**63**	**52 (23.6)**	**225**	**180 (27.3)**
Diarrhoea	65	52 (23.6)	68	58 (26.4)	55	45 (20.5)	188	155 (23.5)
Vomiting	8	8 (3.6)	9	9 (4.1)	6	6 (2.7)	23	23 (3.5)
Diarrhoea haemorrhagic	1	1 (0.5)	3	3 (1.4)	2	2 (0.9)	6	6 (0.9)

[1] Based on MedDRA dictionary version 23. Includes solicited events if ongoing 6 days after study vaccination.

Data source: ADAE
Listing source: 16.2.7.1

Table 14.3.2 Unsolicited Treatment Emergent Adverse Events at any Time during Follow-up by System Organ Class and Preferred Term: Safety Population

	PNEUMOSIL (N= 220)		Synflorix (N= 220)		Prevenar 13 (N= 220)		Total (N= 660)	
System Organ Class / Preferred Term[1]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Infantile colic	3	3 (1.4)	2	2 (0.9)	0	0 (0.0)	5	5 (0.8)
Incarcerated umbilical hernia	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	1	1 (0.2)
Intussusception	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	1	1 (0.2)
Stomatitis	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	1	1 (0.2)
Skin and subcutaneous tissue disorders	**70**	**57 (25.9)**	**62**	**57 (25.9)**	**51**	**48 (21.8)**	**183**	**162 (24.5)**
Rash papular	32	25 (11.4)	31	29 (13.2)	16	15 (6.8)	79	69 (10.5)
Dermatitis diaper	14	14 (6.4)	11	10 (4.5)	14	13 (5.9)	39	37 (5.6)
Dermatitis	8	8 (3.6)	4	4 (1.8)	2	2 (0.9)	14	14 (2.1)
Rash macular	7	7 (3.2)	4	4 (1.8)	2	2 (0.9)	13	13 (2.0)
Rash vesicular	4	4 (1.8)	6	5 (2.3)	2	2 (0.9)	12	11 (1.7)
Rash maculo-papular	3	3 (1.4)	2	2 (0.9)	5	5 (2.3)	10	10 (1.5)
Dermatitis atopic	0	0 (0.0)	1	1 (0.5)	3	2 (0.9)	4	3 (0.5)
Exfoliative rash	2	2 (0.9)	0	0 (0.0)	1	1 (0.5)	3	3 (0.5)
Rash	0	0 (0.0)	2	2 (0.9)	0	0 (0.0)	2	2 (0.3)
Seborrhoeic dermatitis	0	0 (0.0)	1	1 (0.5)	1	1 (0.5)	2	2 (0.3)
Dermatitis contact	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)	1	1 (0.2)
Eczema	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)	1	1 (0.2)
Intertrigo	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)	1	1 (0.2)

[1] Based on MedDRA dictionary version 23. Includes solicited events if ongoing 6 days after study vaccination.

Data source: ADAE
Listing source: 16.2.7.1

Table 14.3.2 Unsolicited Treatment Emergent Adverse Events at any Time during Follow-up by System Organ Class and Preferred Term: Safety Population

	PNEUMOSIL (N= 220)		Synflorix (N= 220)		Prevenar 13 (N= 220)		Total (N= 660)	
System Organ Class / Preferred Term[1]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Pityriasis	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)	1	1 (0.2)
Skin erosion	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)	1	1 (0.2)
Injury, poisoning and procedural complications	**10**	**9 (4.1)**	**8**	**8 (3.6)**	**9**	**9 (4.1)**	**27**	**26 (3.9)**
Thermal burn	8	7 (3.2)	7	7 (3.2)	6	6 (2.7)	21	20 (3.0)
Skin laceration	2	2 (0.9)	0	0 (0.0)	1	1 (0.5)	3	3 (0.5)
Eye injury	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)	1	1 (0.2)
Skin abrasion	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)	1	1 (0.2)
Tooth injury	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	1	1 (0.2)
Respiratory, thoracic and mediastinal disorders	**9**	**9 (4.1)**	**4**	**4 (1.8)**	**3**	**3 (1.4)**	**16**	**16 (2.4)**
Cough	9	9 (4.1)	4	4 (1.8)	3	3 (1.4)	16	16 (2.4)
General disorders and administration site conditions	**1**	**1 (0.5)**	**6**	**6 (2.7)**	**5**	**5 (2.3)**	**12**	**12 (1.8)**
Pyrexia	0	0 (0.0)	3	3 (1.4)	4	4 (1.8)	7	7 (1.1)
Vaccination site swelling	1	1 (0.5)	0	0 (0.0)	1	1 (0.5)	2	2 (0.3)
Developmental delay	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	1	1 (0.2)
Peripheral swelling	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	1	1 (0.2)
Vaccination site induration	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	1	1 (0.2)
Eye disorders	**8**	**6 (2.7)**	**2**	**2 (0.9)**	**1**	**1 (0.5)**	**11**	**9 (1.4)**
Conjunctivitis allergic	5	4 (1.8)	1	1 (0.5)	0	0 (0.0)	6	5 (0.8)

[1] Based on MedDRA dictionary version 23. Includes solicited events if ongoing 6 days after study vaccination.

Data source: ADAE
Listing source: 16.2.7.1

Table 14.3.2 Unsolicited Treatment Emergent Adverse Events at any Time during Follow-up by System Organ Class and Preferred Term: Safety Population

	PNEUMOSIL (N= 220)		Synflorix (N= 220)		Prevenar 13 (N= 220)		Total (N= 660)	
System Organ Class / Preferred Term[1]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Blepharitis	2	2 (0.9)	1	1 (0.5)	1	1 (0.5)	4	4 (0.6)
Vernal keratoconjunctivitis	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	1	1 (0.2)
Blood and lymphatic system disorders	**2**	**2 (0.9)**	**2**	**2 (0.9)**	**2**	**2 (0.9)**	**6**	**6 (0.9)**
Anaemia	1	1 (0.5)	1	1 (0.5)	0	0 (0.0)	2	2 (0.3)
Lymphadenitis	0	0 (0.0)	1	1 (0.5)	1	1 (0.5)	2	2 (0.3)
Lymphadenopathy	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)	1	1 (0.2)
Thrombocytosis	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	1	1 (0.2)
Cardiac disorders	**0**	**0 (0.0)**	**2**	**2 (0.9)**	**3**	**3 (1.4)**	**5**	**5 (0.8)**
Tachycardia	0	0 (0.0)	2	2 (0.9)	2	2 (0.9)	4	4 (0.6)
Pulmonary valve stenosis	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)	1	1 (0.2)
Congenital, familial and genetic disorders	**1**	**1 (0.5)**	**2**	**2 (0.9)**	**2**	**2 (0.9)**	**5**	**5 (0.8)**
Atrioventricular septal defect	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)	1	1 (0.2)
Cystic lymphangioma	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	1	1 (0.2)
Dermoid cyst	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	1	1 (0.2)
Hydrocele	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)	1	1 (0.2)
Sickle cell anaemia	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	1	1 (0.2)
Metabolism and nutrition disorders	**1**	**1 (0.5)**	**1**	**1 (0.5)**	**2**	**2 (0.9)**	**4**	**4 (0.6)**
Malnutrition	1	1 (0.5)	1	1 (0.5)	1	1 (0.5)	3	3 (0.5)

[1] Based on MedDRA dictionary version 23. Includes solicited events if ongoing 6 days after study vaccination.

Data source: ADAE
Listing source: 16.2.7.1

Table 14.3.2 Unsolicited Treatment Emergent Adverse Events at any Time during Follow-up by System Organ Class and Preferred Term: Safety Population

	PNEUMOSIL (N= 220)		Synflorix (N= 220)		Prevenar 13 (N= 220)		Total (N= 660)	
System Organ Class / Preferred Term[1]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Weight gain poor	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)	1	1 (0.2)
Nervous system disorders	**1**	**1 (0.5)**	**0**	**0 (0.0)**	**2**	**2 (0.9)**	**3**	**3 (0.5)**
Infant irritability	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)	1	1 (0.2)
Lethargy	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)	1	1 (0.2)
Seizure	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	1	1 (0.2)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**1**	**1 (0.5)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**1**	**1 (0.2)**
Lipoma	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	1	1 (0.2)
Reproductive system and breast disorders	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**1**	**1 (0.5)**	**1**	**1 (0.2)**
Balanoposthitis	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)	1	1 (0.2)
Total	**630**	**198 (90.0)**	**615**	**197 (89.5)**	**554**	**189 (85.9)**	**1799**	**584 (88.5)**

[1] Based on MedDRA dictionary version 23. Includes solicited events if ongoing 6 days after study vaccination.

Data source: ADAE
Listing source: 16.2.7.1

Table 14.3.3 Unsolicited Serious Treatment Emergent Adverse Events at any Time during Follow-up by System Organ Class and Preferred Term: Safety Population

	PNEUMOSIL (N= 220)		Synflorix (N= 220)		Prevenar 13 (N= 220)		Total (N= 660)	
System Organ Class / Preferred Term[1]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Infections and infestations	**11**	**10 (4.5)**	**9**	**9 (4.1)**	**7**	**7 (3.2)**	**27**	**26 (3.9)**
Gastroenteritis	5	5 (2.3)	2	2 (0.9)	0	0 (0.0)	7	7 (1.1)
Bronchiolitis	3	3 (1.4)	1	1 (0.5)	2	2 (0.9)	6	6 (0.9)
Periorbital cellulitis	0	0 (0.0)	3	3 (1.4)	2	2 (0.9)	5	5 (0.8)
Cellulitis	1	1 (0.5)	0	0 (0.0)	2	2 (0.9)	3	3 (0.5)
Pneumonia	0	0 (0.0)	2	2 (0.9)	1	1 (0.5)	3	3 (0.5)
Infected dermal cyst	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	1	1 (0.2)
Meningitis bacterial	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	1	1 (0.2)
Vulval cellulitis	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	1	1 (0.2)
Congenital, familial and genetic disorders	**1**	**1 (0.5)**	**1**	**1 (0.5)**	**1**	**1 (0.5)**	**3**	**3 (0.5)**
Atrioventricular septal defect	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)	1	1 (0.2)
Dermoid cyst	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	1	1 (0.2)
Sickle cell anaemia	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	1	1 (0.2)
Gastrointestinal disorders	**1**	**1 (0.5)**	**1**	**1 (0.5)**	**0**	**0 (0.0)**	**2**	**2 (0.3)**
Incarcerated umbilical hernia	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	1	1 (0.2)
Intussusception	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	1	1 (0.2)
Nervous system disorders	**1**	**1 (0.5)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**1**	**1 (0.2)**
Seizure	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	1	1 (0.2)
Total	**14**	**12 (5.5)**	**11**	**10 (4.5)**	**8**	**7 (3.2)**	**33**	**29 (4.4)**

[1] Based on MedDRA dictionary version 23. Includes solicited events if ongoing 6 days after study vaccination.

Data source: ADAE
Listing source: 16.2.7.1 and 16.2.7.3

Table 14.3.5.1 Unsolicited Treatment Emergent Adverse Events at any Time during Follow-up by Severity and Relatedness: Safety Population

	PNEUMOSIL (N= 220)											
	Mild				Moderate				Severe+[1]			
	Related		Not Related		Related		Not Related		Related		Not Related	
System Organ Class / Preferred Term[2]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Infections and infestations	**0**	**0 (0.0)**	**420**	**187 (85.0)**	**0**	**0 (0.0)**	**19**	**19 (8.6)**	**0**	**0 (0.0)**	**9**	**9 (4.1)**
Upper respiratory tract infection	0	0 (0.0)	147	110 (50.0)	0	0 (0.0)	4	4 (1.8)	0	0 (0.0)	0	0 (0.0)
Furuncle	0	0 (0.0)	68	51 (23.2)	0	0 (0.0)	2	2 (0.9)	0	0 (0.0)	0	0 (0.0)
Conjunctivitis	0	0 (0.0)	31	28 (12.7)	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)
Gastroenteritis	0	0 (0.0)	24	23 (10.5)	0	0 (0.0)	3	3 (1.4)	0	0 (0.0)	4	4 (1.8)
Skin candida	0	0 (0.0)	24	21 (9.5)	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)
Rash pustular	0	0 (0.0)	17	17 (7.7)	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)
Body tinea	0	0 (0.0)	13	13 (5.9)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Bronchiolitis	0	0 (0.0)	9	9 (4.1)	0	0 (0.0)	2	2 (0.9)	0	0 (0.0)	2	2 (0.9)
Otitis media	0	0 (0.0)	11	8 (3.6)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)

[1] Includes severe or medically significant but not life threatening and death.
[2] Based on MedDRA dictionary version 23. Includes solicited events if ongoing 6 days after study vaccination.

Data source: ADAE
Listing source: 16.2.7.1

Table 14.3.5.1 Unsolicited Treatment Emergent Adverse Events at any Time during Follow-up by Severity and Relatedness: Safety Population

	PNEUMOSIL (N= 220)											
	Mild				Moderate				Severe+[1]			
	Related		Not Related		Related		Not Related		Related		Not Related	
System Organ Class / Preferred Term[2]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Pneumonia	0	0 (0.0)	8	8 (3.6)	0	0 (0.0)	3	3 (1.4)	0	0 (0.0)	0	0 (0.0)
Impetigo	0	0 (0.0)	9	9 (4.1)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Febrile infection	0	0 (0.0)	8	7 (3.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Oral candidiasis	0	0 (0.0)	8	6 (2.7)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Tinea infection	0	0 (0.0)	7	7 (3.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Cutaneous larva migrans	0	0 (0.0)	6	6 (2.7)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Tinea capitis	0	0 (0.0)	6	6 (2.7)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Nasopharyngitis	0	0 (0.0)	4	4 (1.8)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Otitis media acute	0	0 (0.0)	3	3 (1.4)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Varicella	0	0 (0.0)	3	3 (1.4)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)

[1] Includes severe or medically significant but not life threatening and death.
[2] Based on MedDRA dictionary version 23. Includes solicited events if ongoing 6 days after study vaccination.

Data source: ADAE
Listing source: 16.2.7.1

Table 14.3.5.1 Unsolicited Treatment Emergent Adverse Events at any Time during Follow-up by Severity and Relatedness: Safety Population

	PNEUMOSIL (N= 220)											
	Mild				Moderate				Severe+[1]			
	Related		Not Related		Related		Not Related		Related		Not Related	
System Organ Class / Preferred Term[2]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Abscess	0	0 (0.0)	2	2 (0.9)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Urinary tract infection	0	0 (0.0)	2	2 (0.9)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Abscess limb	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)
Acarodermatitis	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Cellulitis	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)
Dysentery	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Hordeolum	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Mastitis	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Meningitis bacterial	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)
Molluscum contagiosum	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)

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	PNEUMOSIL (N= 220)											
	Mild				Moderate				Severe+[1]			
	Related		Not Related		Related		Not Related		Related		Not Related	
System Organ Class / Preferred Term[2]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Otitis externa	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Pustule	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Respiratory tract infection	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)
Tinea versicolour	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Vaccination site abscess	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Vaccination site infection	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Vulval cellulitis	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)
Gastrointestinal disorders	**0**	**0 (0.0)**	**77**	**61 (27.7)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**1**	**1 (0.5)**
Diarrhoea	0	0 (0.0)	65	52 (23.6)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Vomiting	0	0 (0.0)	8	8 (3.6)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)

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Table 14.3.5.1 Unsolicited Treatment Emergent Adverse Events at any Time during Follow-up by Severity and Relatedness: Safety Population

	PNEUMOSIL (N= 220)											
	Mild				Moderate				Severe+[1]			
	Related		Not Related		Related		Not Related		Related		Not Related	
System Organ Class / Preferred Term[2]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Infantile colic	0	0 (0.0)	3	3 (1.4)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Diarrhoea haemorrhagic	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Intussusception	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)
Skin and subcutaneous tissue disorders	**1**	**1 (0.5)**	**68**	**56 (25.5)**	**0**	**0 (0.0)**	**1**	**1 (0.5)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**
Rash papular	1	1 (0.5)	31	25 (11.4)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Dermatitis diaper	0	0 (0.0)	14	14 (6.4)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Dermatitis	0	0 (0.0)	7	7 (3.2)	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)
Rash macular	0	0 (0.0)	7	7 (3.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Rash vesicular	0	0 (0.0)	4	4 (1.8)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Rash maculo-papular	0	0 (0.0)	3	3 (1.4)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)

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Listing source: 16.2.7.1

Table 14.3.5.1 Unsolicited Treatment Emergent Adverse Events at any Time during Follow-up by Severity and Relatedness: Safety Population

	PNEUMOSIL (N= 220)											
	Mild				Moderate				Severe+[1]			
	Related		Not Related		Related		Not Related		Related		Not Related	
System Organ Class / Preferred Term[2]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Exfoliative rash	0	0 (0.0)	2	2 (0.9)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Injury, poisoning and procedural complications	**0**	**0 (0.0)**	**10**	**9 (4.1)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**
Thermal burn	0	0 (0.0)	8	7 (3.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Skin laceration	0	0 (0.0)	2	2 (0.9)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Respiratory, thoracic and mediastinal disorders	**0**	**0 (0.0)**	**9**	**9 (4.1)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**
Cough	0	0 (0.0)	9	9 (4.1)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Eye disorders	**0**	**0 (0.0)**	**8**	**6 (2.7)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**
Conjunctivitis allergic	0	0 (0.0)	5	4 (1.8)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Blepharitis	0	0 (0.0)	2	2 (0.9)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Vernal keratoconjunctivitis	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)

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[2] Based on MedDRA dictionary version 23. Includes solicited events if ongoing 6 days after study vaccination.

Data source: ADAE
Listing source: 16.2.7.1

Table 14.3.5.1 Unsolicited Treatment Emergent Adverse Events at any Time during Follow-up by Severity and Relatedness: Safety Population

	PNEUMOSIL (N= 220)											
	Mild				Moderate				Severe+[1]			
	Related		Not Related		Related		Not Related		Related		Not Related	
System Organ Class / Preferred Term[2]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Blood and lymphatic system disorders	**0**	**0 (0.0)**	**2**	**2 (0.9)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**
Anaemia	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Thrombocytosis	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Congenital, familial and genetic disorders	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**1**	**1 (0.5)**
Sickle cell anaemia	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)
General disorders and administration site conditions	**0**	**0 (0.0)**	**1**	**1 (0.5)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**
Vaccination site swelling	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Metabolism and nutrition disorders	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**1**	**1 (0.5)**
Malnutrition	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**1**	**1 (0.5)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**

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[2] Based on MedDRA dictionary version 23. Includes solicited events if ongoing 6 days after study vaccination.

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Table 14.3.5.1 Unsolicited Treatment Emergent Adverse Events at any Time during Follow-up by Severity and Relatedness: Safety Population

	PNEUMOSIL (N= 220)											
	Mild				Moderate				Severe+[1]			
	Related		Not Related		Related		Not Related		Related		Not Related	
System Organ Class / Preferred Term[2]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Lipoma	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)
Nervous system disorders	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**1**	**1 (0.5)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**
Seizure	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)
Total	**1**	**1 (0.5)**	**595**	**196 (89.1)**	**0**	**0 (0.0)**	**22**	**22 (10.0)**	**0**	**0 (0.0)**	**12**	**11 (5.0)**

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Table 14.3.5.1 Unsolicited Treatment Emergent Adverse Events at any Time during Follow-up by Severity and Relatedness: Safety Population

	Synflorix (N= 220)											
	Mild				Moderate				Severe+[1]			
	Related		Not Related		Related		Not Related		Related		Not Related	
System Organ Class / Preferred Term[2]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Infections and infestations	**0**	**0 (0.0)**	**417**	**176 (80.0)**	**0**	**0 (0.0)**	**16**	**15 (6.8)**	**1**	**1 (0.5)**	**8**	**8 (3.6)**
Upper respiratory tract infection	0	0 (0.0)	171	111 (50.5)	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)
Furuncle	0	0 (0.0)	48	40 (18.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Conjunctivitis	0	0 (0.0)	42	40 (18.2)	0	0 (0.0)	2	2 (0.9)	0	0 (0.0)	0	0 (0.0)
Gastroenteritis	0	0 (0.0)	23	19 (8.6)	0	0 (0.0)	3	3 (1.4)	0	0 (0.0)	2	2 (0.9)
Rash pustular	0	0 (0.0)	19	16 (7.3)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Pneumonia	0	0 (0.0)	7	7 (3.2)	0	0 (0.0)	5	4 (1.8)	0	0 (0.0)	2	2 (0.9)
Skin candida	0	0 (0.0)	12	10 (4.5)	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)
Body tinea	0	0 (0.0)	12	12 (5.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Impetigo	0	0 (0.0)	11	11 (5.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)

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	Synflorix (N= 220)											
	Mild				Moderate				Severe+[1]			
	Related		Not Related		Related		Not Related		Related		Not Related	
System Organ Class / Preferred Term[2]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Bronchiolitis	0	0 (0.0)	8	7 (3.2)	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	1	1 (0.5)
Febrile infection	0	0 (0.0)	10	8 (3.6)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Otitis media	0	0 (0.0)	7	7 (3.2)	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)
Oral candidiasis	0	0 (0.0)	7	7 (3.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Tinea capitis	0	0 (0.0)	7	6 (2.7)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Abscess	0	0 (0.0)	5	5 (2.3)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Otitis media acute	0	0 (0.0)	5	5 (2.3)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Periorbital cellulitis	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	2	2 (0.9)
Tinea versicolour	0	0 (0.0)	4	4 (1.8)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Infected dermal cyst	0	0 (0.0)	2	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)

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	Related		Not Related		Related		Not Related		Related		Not Related	
System Organ Class / Preferred Term[2]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Abscess limb	0	0 (0.0)	2	2 (0.9)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Angular cheilitis	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Candida nappy rash	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Cutaneous larva migrans	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Dysentery	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Gingival abscess	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)
Nasopharyngitis	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Otitis externa	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Paronychia	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Pharyngitis	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)

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	Mild				Moderate				Severe+[1]			
	Related		Not Related		Related		Not Related		Related		Not Related	
System Organ Class / Preferred Term[2]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Pustule	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Subcutaneous abscess	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Tinea infection	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Vaccination site abscess	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)
Vaccination site pustule	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Varicella	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Viral rash	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Gastrointestinal disorders	**0**	**0 (0.0)**	**83**	**67 (30.5)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**1**	**1 (0.5)**
Diarrhoea	0	0 (0.0)	68	58 (26.4)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Vomiting	0	0 (0.0)	9	9 (4.1)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)

[1] Includes severe or medically significant but not life threatening and death.
[2] Based on MedDRA dictionary version 23. Includes solicited events if ongoing 6 days after study vaccination.

Data source: ADAE
Listing source: 16.2.7.1

Table 14.3.5.1 Unsolicited Treatment Emergent Adverse Events at any Time during Follow-up by Severity and Relatedness: Safety Population

	Synflorix (N= 220)											
	Mild				Moderate				Severe+[1]			
	Related		Not Related		Related		Not Related		Related		Not Related	
System Organ Class / Preferred Term[2]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Diarrhoea haemorrhagic	0	0 (0.0)	3	3 (1.4)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Infantile colic	0	0 (0.0)	2	2 (0.9)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Incarcerated umbilical hernia	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)
Stomatitis	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Skin and subcutaneous tissue disorders	**0**	**0 (0.0)**	**62**	**57 (25.9)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**
Rash papular	0	0 (0.0)	31	29 (13.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Dermatitis diaper	0	0 (0.0)	11	10 (4.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Rash vesicular	0	0 (0.0)	6	5 (2.3)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Dermatitis	0	0 (0.0)	4	4 (1.8)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Rash macular	0	0 (0.0)	4	4 (1.8)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)

[1] Includes severe or medically significant but not life threatening and death.
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Table 14.3.5.1 Unsolicited Treatment Emergent Adverse Events at any Time during Follow-up by Severity and Relatedness: Safety Population

	Synflorix (N= 220)											
	Mild				Moderate				Severe+[1]			
	Related		Not Related		Related		Not Related		Related		Not Related	
System Organ Class / Preferred Term[2]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Rash	0	0 (0.0)	2	2 (0.9)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Rash maculo-papular	0	0 (0.0)	2	2 (0.9)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Dermatitis atopic	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Seborrhoeic dermatitis	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Injury, poisoning and procedural complications	**0**	**0 (0.0)**	**8**	**8 (3.6)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**
Thermal burn	0	0 (0.0)	7	7 (3.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Tooth injury	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
General disorders and administration site conditions	**1**	**1 (0.5)**	**4**	**4 (1.8)**	**0**	**0 (0.0)**	**1**	**1 (0.5)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**
Pyrexia	0	0 (0.0)	3	3 (1.4)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Developmental delay	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)

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[2] Based on MedDRA dictionary version 23. Includes solicited events if ongoing 6 days after study vaccination.

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Table 14.3.5.1 Unsolicited Treatment Emergent Adverse Events at any Time during Follow-up by Severity and Relatedness: Safety Population

	Synflorix (N= 220)											
	Mild				Moderate				Severe+[1]			
	Related		Not Related		Related		Not Related		Related		Not Related	
System Organ Class / Preferred Term[2]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Peripheral swelling	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Vaccination site induration	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Respiratory, thoracic and mediastinal disorders	**0**	**0 (0.0)**	**4**	**4 (1.8)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**
Cough	0	0 (0.0)	4	4 (1.8)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Blood and lymphatic system disorders	**0**	**0 (0.0)**	**1**	**1 (0.5)**	**0**	**0 (0.0)**	**1**	**1 (0.5)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**
Anaemia	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Lymphadenitis	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)
Cardiac disorders	**0**	**0 (0.0)**	**2**	**2 (0.9)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**
Tachycardia	0	0 (0.0)	2	2 (0.9)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Congenital, familial and genetic disorders	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**2**	**2 (0.9)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**

[1] Includes severe or medically significant but not life threatening and death.
[2] Based on MedDRA dictionary version 23. Includes solicited events if ongoing 6 days after study vaccination.

Data source: ADAE
Listing source: 16.2.7.1

Table 14.3.5.1 Unsolicited Treatment Emergent Adverse Events at any Time during Follow-up by Severity and Relatedness: Safety Population

	Synflorix (N= 220)											
	Mild				Moderate				Severe+[1]			
	Related		Not Related		Related		Not Related		Related		Not Related	
System Organ Class / Preferred Term[2]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Cystic lymphangioma	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)
Dermoid cyst	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)
Eye disorders	**0**	**0 (0.0)**	**2**	**2 (0.9)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**
Blepharitis	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Conjunctivitis allergic	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Metabolism and nutrition disorders	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**1**	**1 (0.5)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**
Malnutrition	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)
Total	**1**	**1 (0.5)**	**583**	**195 (88.6)**	**0**	**0 (0.0)**	**21**	**20 (9.1)**	**1**	**1 (0.5)**	**9**	**9 (4.1)**

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[2] Based on MedDRA dictionary version 23. Includes solicited events if ongoing 6 days after study vaccination.

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Listing source: 16.2.7.1

Table 14.3.5.1 Unsolicited Treatment Emergent Adverse Events at any Time during Follow-up by Severity and Relatedness: Safety Population

	Prevenar 13 (N= 220)											
	Mild				Moderate				Severe+[1]			
	Related		Not Related		Related		Not Related		Related		Not Related	
System Organ Class / Preferred Term[2]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Infections and infestations	**0**	**0 (0.0)**	**388**	**169 (76.8)**	**0**	**0 (0.0)**	**16**	**15 (6.8)**	**0**	**0 (0.0)**	**6**	**6 (2.7)**
Upper respiratory tract infection	0	0 (0.0)	126	95 (43.2)	0	0 (0.0)	4	4 (1.8)	0	0 (0.0)	0	0 (0.0)
Furuncle	0	0 (0.0)	44	37 (16.8)	0	0 (0.0)	2	2 (0.9)	0	0 (0.0)	0	0 (0.0)
Conjunctivitis	0	0 (0.0)	35	35 (15.9)	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)
Gastroenteritis	0	0 (0.0)	35	29 (13.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Rash pustular	0	0 (0.0)	24	22 (10.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Pneumonia	0	0 (0.0)	13	13 (5.9)	0	0 (0.0)	4	4 (1.8)	0	0 (0.0)	1	1 (0.5)
Skin candida	0	0 (0.0)	17	16 (7.3)	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)
Body tinea	0	0 (0.0)	15	14 (6.4)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Bronchiolitis	0	0 (0.0)	12	11 (5.0)	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	2	2 (0.9)

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Table 14.3.5.1 Unsolicited Treatment Emergent Adverse Events at any Time during Follow-up by Severity and Relatedness: Safety Population

	Prevenar 13 (N= 220)											
	Mild				Moderate				Severe+[1]			
	Related		Not Related		Related		Not Related		Related		Not Related	
System Organ Class / Preferred Term[2]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Otitis media	0	0 (0.0)	10	9 (4.1)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Febrile infection	0	0 (0.0)	9	9 (4.1)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Cutaneous larva migrans	0	0 (0.0)	7	7 (3.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Impetigo	0	0 (0.0)	7	7 (3.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Tinea infection	0	0 (0.0)	7	7 (3.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Oral candidiasis	0	0 (0.0)	5	5 (2.3)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Tinea capitis	0	0 (0.0)	4	4 (1.8)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Cellulitis	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	1	1 (0.5)
Urinary tract infection	0	0 (0.0)	3	3 (1.4)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Abscess	0	0 (0.0)	2	2 (0.9)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)

[1] Includes severe or medically significant but not life threatening and death.
[2] Based on MedDRA dictionary version 23. Includes solicited events if ongoing 6 days after study vaccination.

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Table 14.3.5.1 Unsolicited Treatment Emergent Adverse Events at any Time during Follow-up by Severity and Relatedness: Safety Population

	Prevenar 13 (N= 220)											
	Mild				Moderate				Severe+[1]			
	Related		Not Related		Related		Not Related		Related		Not Related	
System Organ Class / Preferred Term[2]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Otitis externa	0	0 (0.0)	2	2 (0.9)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Periorbital cellulitis	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	2	2 (0.9)
Abscess limb	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)
Acarodermatitis	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Breast abscess	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Dermatophytosis	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Helminthic infection	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Molluscum contagiosum	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Nasopharyngitis	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Otitis media acute	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)

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	Related		Not Related		Related		Not Related		Related		Not Related	
System Organ Class / Preferred Term[2]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Pustule	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Subcutaneous abscess	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Vaccination site abscess	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Viral rash	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Gastrointestinal disorders	**0**	**0 (0.0)**	**62**	**51 (23.2)**	**0**	**0 (0.0)**	**1**	**1 (0.5)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**
Diarrhoea	0	0 (0.0)	54	44 (20.0)	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)
Vomiting	0	0 (0.0)	6	6 (2.7)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Diarrhoea haemorrhagic	0	0 (0.0)	2	2 (0.9)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Skin and subcutaneous tissue disorders	**0**	**0 (0.0)**	**51**	**48 (21.8)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**
Rash papular	0	0 (0.0)	16	15 (6.8)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)

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	Prevenar 13 (N= 220)											
	Mild				Moderate				Severe+[1]			
	Related		Not Related		Related		Not Related		Related		Not Related	
System Organ Class / Preferred Term[2]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Dermatitis diaper	0	0 (0.0)	14	13 (5.9)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Rash maculo-papular	0	0 (0.0)	5	5 (2.3)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Dermatitis atopic	0	0 (0.0)	3	2 (0.9)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Dermatitis	0	0 (0.0)	2	2 (0.9)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Rash macular	0	0 (0.0)	2	2 (0.9)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Rash vesicular	0	0 (0.0)	2	2 (0.9)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Dermatitis contact	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Eczema	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Exfoliative rash	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Intertrigo	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)

[1] Includes severe or medically significant but not life threatening and death.
[2] Based on MedDRA dictionary version 23. Includes solicited events if ongoing 6 days after study vaccination.

Data source: ADAE
Listing source: 16.2.7.1

Table 14.3.5.1 Unsolicited Treatment Emergent Adverse Events at any Time during Follow-up by Severity and Relatedness: Safety Population

	Prevenar 13 (N= 220)											
	Mild				Moderate				Severe+[1]			
	Related		Not Related		Related		Not Related		Related		Not Related	
System Organ Class / Preferred Term[2]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Pityriasis	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Seborrhoeic dermatitis	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Skin erosion	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Injury, poisoning and procedural complications	**0**	**0 (0.0)**	**9**	**9 (4.1)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**
Thermal burn	0	0 (0.0)	6	6 (2.7)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Eye injury	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Skin abrasion	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Skin laceration	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
General disorders and administration site conditions	**0**	**0 (0.0)**	**5**	**5 (2.3)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**
Pyrexia	0	0 (0.0)	4	4 (1.8)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)

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Table 14.3.5.1 Unsolicited Treatment Emergent Adverse Events at any Time during Follow-up by Severity and Relatedness: Safety Population

	Prevenar 13 (N= 220)											
	Mild				Moderate				Severe+[1]			
	Related		Not Related		Related		Not Related		Related		Not Related	
System Organ Class / Preferred Term[2]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Vaccination site swelling	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Cardiac disorders	**0**	**0 (0.0)**	**3**	**3 (1.4)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**
Tachycardia	0	0 (0.0)	2	2 (0.9)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Pulmonary valve stenosis	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Respiratory, thoracic and mediastinal disorders	**0**	**0 (0.0)**	**3**	**3 (1.4)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**
Cough	0	0 (0.0)	3	3 (1.4)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Blood and lymphatic system disorders	**0**	**0 (0.0)**	**2**	**2 (0.9)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**
Lymphadenitis	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Lymphadenopathy	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Congenital, familial and genetic disorders	**0**	**0 (0.0)**	**1**	**1 (0.5)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**1**	**1 (0.5)**

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[2] Based on MedDRA dictionary version 23. Includes solicited events if ongoing 6 days after study vaccination.

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Table 14.3.5.1 Unsolicited Treatment Emergent Adverse Events at any Time during Follow-up by Severity and Relatedness: Safety Population

	Prevenar 13 (N= 220)											
	Mild				Moderate				Severe+[1]			
	Related		Not Related		Related		Not Related		Related		Not Related	
System Organ Class / Preferred Term[2]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Atrioventricular septal defect	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)
Hydrocele	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Metabolism and nutrition disorders	**0**	**0 (0.0)**	**1**	**1 (0.5)**	**0**	**0 (0.0)**	**1**	**1 (0.5)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**
Malnutrition	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)
Weight gain poor	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Nervous system disorders	**0**	**0 (0.0)**	**2**	**2 (0.9)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**
Infant irritability	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Lethargy	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Eye disorders	**0**	**0 (0.0)**	**1**	**1 (0.5)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**
Blepharitis	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)

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[2] Based on MedDRA dictionary version 23. Includes solicited events if ongoing 6 days after study vaccination.

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Listing source: 16.2.7.1

Table 14.3.5.1 Unsolicited Treatment Emergent Adverse Events at any Time during Follow-up by Severity and Relatedness: Safety Population

	Prevenar 13 (N= 220)											
	Mild				Moderate				Severe+[1]			
	Related		Not Related		Related		Not Related		Related		Not Related	
System Organ Class / Preferred Term[2]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Reproductive system and breast disorders	**0**	**0 (0.0)**	**1**	**1 (0.5)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**
Balanoposthitis	0	0 (0.0)	1	1 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Total	**0**	**0 (0.0)**	**529**	**186 (84.5)**	**0**	**0 (0.0)**	**18**	**17 (7.7)**	**0**	**0 (0.0)**	**7**	**6 (2.7)**

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Listing source: 16.2.7.1

Table 14.3.5.1 Unsolicited Treatment Emergent Adverse Events at any Time during Follow-up by Severity and Relatedness: Safety Population

	Total (N= 660)											
	Mild				Moderate				Severe+[1]			
	Related		Not Related		Related		Not Related		Related		Not Related	
System Organ Class / Preferred Term[2]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Infections and infestations	**0**	**0 (0.0)**	**1225**	**532 (80.6)**	**0**	**0 (0.0)**	**51**	**49 (7.4)**	**1**	**1 (0.2)**	**23**	**23 (3.5)**
Upper respiratory tract infection	0	0 (0.0)	444	316 (47.9)	0	0 (0.0)	9	9 (1.4)	0	0 (0.0)	0	0 (0.0)
Furuncle	0	0 (0.0)	160	128 (19.4)	0	0 (0.0)	4	4 (0.6)	0	0 (0.0)	0	0 (0.0)
Conjunctivitis	0	0 (0.0)	108	103 (15.6)	0	0 (0.0)	4	4 (0.6)	0	0 (0.0)	0	0 (0.0)
Gastroenteritis	0	0 (0.0)	82	71 (10.8)	0	0 (0.0)	6	6 (0.9)	0	0 (0.0)	6	6 (0.9)
Rash pustular	0	0 (0.0)	60	55 (8.3)	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)
Skin candida	0	0 (0.0)	53	47 (7.1)	0	0 (0.0)	3	3 (0.5)	0	0 (0.0)	0	0 (0.0)
Pneumonia	0	0 (0.0)	28	28 (4.2)	0	0 (0.0)	12	11 (1.7)	0	0 (0.0)	3	3 (0.5)
Body tinea	0	0 (0.0)	40	39 (5.9)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Bronchiolitis	0	0 (0.0)	29	27 (4.1)	0	0 (0.0)	4	4 (0.6)	0	0 (0.0)	5	5 (0.8)

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Table 14.3.5.1 Unsolicited Treatment Emergent Adverse Events at any Time during Follow-up by Severity and Relatedness: Safety Population

	Total (N= 660)											
	Mild				Moderate				Severe+[1]			
	Related		Not Related		Related		Not Related		Related		Not Related	
System Organ Class / Preferred Term[2]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Otitis media	0	0 (0.0)	28	24 (3.6)	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)
Febrile infection	0	0 (0.0)	27	24 (3.6)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Impetigo	0	0 (0.0)	27	27 (4.1)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Oral candidiasis	0	0 (0.0)	20	18 (2.7)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Tinea capitis	0	0 (0.0)	17	16 (2.4)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Tinea infection	0	0 (0.0)	15	15 (2.3)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Cutaneous larva migrans	0	0 (0.0)	14	14 (2.1)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Abscess	0	0 (0.0)	9	9 (1.4)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Otitis media acute	0	0 (0.0)	8	8 (1.2)	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)
Nasopharyngitis	0	0 (0.0)	6	6 (0.9)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)

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	Total (N= 660)											
	Mild				Moderate				Severe+[1]			
	Related		Not Related		Related		Not Related		Related		Not Related	
System Organ Class / Preferred Term[2]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Periorbital cellulitis	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	4	4 (0.6)
Tinea versicolour	0	0 (0.0)	5	5 (0.8)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Urinary tract infection	0	0 (0.0)	5	5 (0.8)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Abscess limb	0	0 (0.0)	2	2 (0.3)	0	0 (0.0)	2	2 (0.3)	0	0 (0.0)	0	0 (0.0)
Cellulitis	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	2	2 (0.3)
Otitis externa	0	0 (0.0)	4	4 (0.6)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Varicella	0	0 (0.0)	4	4 (0.6)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Infected dermal cyst	0	0 (0.0)	2	1 (0.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.2)
Pustule	0	0 (0.0)	3	3 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Vaccination site abscess	0	0 (0.0)	2	2 (0.3)	0	0 (0.0)	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)

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	Total (N= 660)											
	Mild				Moderate				Severe+[1]			
	Related		Not Related		Related		Not Related		Related		Not Related	
System Organ Class / Preferred Term[2]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Acarodermatitis	0	0 (0.0)	2	2 (0.3)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Dysentery	0	0 (0.0)	2	2 (0.3)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Molluscum contagiosum	0	0 (0.0)	2	2 (0.3)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Subcutaneous abscess	0	0 (0.0)	2	2 (0.3)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Viral rash	0	0 (0.0)	2	2 (0.3)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Angular cheilitis	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Breast abscess	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Candida nappy rash	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Dermatophytosis	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Gingival abscess	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)

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	Mild				Moderate				Severe+[1]			
	Related		Not Related		Related		Not Related		Related		Not Related	
System Organ Class / Preferred Term[2]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Helminthic infection	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Hordeolum	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Mastitis	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Meningitis bacterial	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.2)
Paronychia	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Pharyngitis	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Respiratory tract infection	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)
Vaccination site infection	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Vaccination site pustule	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Vulval cellulitis	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.2)

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	Mild				Moderate				Severe+[1]			
	Related		Not Related		Related		Not Related		Related		Not Related	
System Organ Class / Preferred Term[2]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Gastrointestinal disorders	**0**	**0 (0.0)**	**222**	**179 (27.1)**	**0**	**0 (0.0)**	**1**	**1 (0.2)**	**0**	**0 (0.0)**	**2**	**2 (0.3)**
Diarrhoea	0	0 (0.0)	187	154 (23.3)	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)
Vomiting	0	0 (0.0)	23	23 (3.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Diarrhoea haemorrhagic	0	0 (0.0)	6	6 (0.9)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Infantile colic	0	0 (0.0)	5	5 (0.8)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Incarcerated umbilical hernia	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.2)
Intussusception	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.2)
Stomatitis	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Skin and subcutaneous tissue disorders	**1**	**1 (0.2)**	**181**	**161 (24.4)**	**0**	**0 (0.0)**	**1**	**1 (0.2)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**
Rash papular	1	1 (0.2)	78	69 (10.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)

[1] Includes severe, medically significant but not life threatening, and death.
[2] Based on MedDRA dictionary version 23. Includes solicited events if ongoing 6 days after study vaccination.

Data source: ADAE
Listing source: 16.2.7.1

Table 14.3.5.1 Unsolicited Treatment Emergent Adverse Events at any Time during Follow-up by Severity and Relatedness: Safety Population

	Total (N= 660)											
	Mild				Moderate				Severe+[1]			
	Related		Not Related		Related		Not Related		Related		Not Related	
System Organ Class / Preferred Term[2]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Dermatitis diaper	0	0 (0.0)	39	37 (5.6)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Dermatitis	0	0 (0.0)	13	13 (2.0)	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)
Rash macular	0	0 (0.0)	13	13 (2.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Rash vesicular	0	0 (0.0)	12	11 (1.7)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Rash maculo-papular	0	0 (0.0)	10	10 (1.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Dermatitis atopic	0	0 (0.0)	4	3 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Exfoliative rash	0	0 (0.0)	3	3 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Rash	0	0 (0.0)	2	2 (0.3)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Seborrhoeic dermatitis	0	0 (0.0)	2	2 (0.3)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Dermatitis contact	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)

[1] Includes severe, medically significant but not life threatening, and death.
[2] Based on MedDRA dictionary version 23. Includes solicited events if ongoing 6 days after study vaccination.

Data source: ADAE
Listing source: 16.2.7.1

Table 14.3.5.1 Unsolicited Treatment Emergent Adverse Events at any Time during Follow-up by Severity and Relatedness: Safety Population

	Total (N= 660)											
	Mild				Moderate				Severe+[1]			
	Related		Not Related		Related		Not Related		Related		Not Related	
System Organ Class / Preferred Term[2]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Eczema	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Intertrigo	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Pityriasis	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Skin erosion	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Injury, poisoning and procedural complications	**0**	**0 (0.0)**	**27**	**26 (3.9)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**
Thermal burn	0	0 (0.0)	21	20 (3.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Skin laceration	0	0 (0.0)	3	3 (0.5)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Eye injury	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Skin abrasion	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Tooth injury	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)

[1] Includes severe, medically significant but not life threatening, and death.
[2] Based on MedDRA dictionary version 23. Includes solicited events if ongoing 6 days after study vaccination.

Data source: ADAE
Listing source: 16.2.7.1

Table 14.3.5.1 Unsolicited Treatment Emergent Adverse Events at any Time during Follow-up by Severity and Relatedness: Safety Population

	Total (N= 660)											
	Mild				Moderate				Severe+[1]			
	Related		Not Related		Related		Not Related		Related		Not Related	
System Organ Class / Preferred Term[2]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Respiratory, thoracic and mediastinal disorders	**0**	**0 (0.0)**	**16**	**16 (2.4)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**
Cough	0	0 (0.0)	16	16 (2.4)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
General disorders and administration site conditions	**1**	**1 (0.2)**	**10**	**10 (1.5)**	**0**	**0 (0.0)**	**1**	**1 (0.2)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**
Pyrexia	0	0 (0.0)	7	7 (1.1)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Vaccination site swelling	0	0 (0.0)	2	2 (0.3)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Developmental delay	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)
Peripheral swelling	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Vaccination site induration	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Eye disorders	**0**	**0 (0.0)**	**11**	**9 (1.4)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**
Conjunctivitis allergic	0	0 (0.0)	6	5 (0.8)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)

[1] Includes severe, medically significant but not life threatening, and death.
[2] Based on MedDRA dictionary version 23. Includes solicited events if ongoing 6 days after study vaccination.

Data source: ADAE
Listing source: 16.2.7.1

Table 14.3.5.1 Unsolicited Treatment Emergent Adverse Events at any Time during Follow-up by Severity and Relatedness: Safety Population

	Total (N= 660)											
	Mild				Moderate				Severe+[1]			
	Related		Not Related		Related		Not Related		Related		Not Related	
System Organ Class / Preferred Term[2]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Blepharitis	0	0 (0.0)	4	4 (0.6)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Vernal keratoconjunctivitis	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Blood and lymphatic system disorders	**0**	**0 (0.0)**	**5**	**5 (0.8)**	**0**	**0 (0.0)**	**1**	**1 (0.2)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**
Anaemia	0	0 (0.0)	2	2 (0.3)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Lymphadenitis	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)
Lymphadenopathy	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Thrombocytosis	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Cardiac disorders	**0**	**0 (0.0)**	**5**	**5 (0.8)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**
Tachycardia	0	0 (0.0)	4	4 (0.6)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Pulmonary valve stenosis	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)

[1] Includes severe, medically significant but not life threatening, and death.
[2] Based on MedDRA dictionary version 23. Includes solicited events if ongoing 6 days after study vaccination.

Data source: ADAE
Listing source: 16.2.7.1

Table 14.3.5.1 Unsolicited Treatment Emergent Adverse Events at any Time during Follow-up by Severity and Relatedness: Safety Population

	Total (N= 660)											
	Mild				Moderate				Severe+[1]			
	Related		Not Related		Related		Not Related		Related		Not Related	
System Organ Class / Preferred Term[2]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Congenital, familial and genetic disorders	**0**	**0 (0.0)**	**1**	**1 (0.2)**	**0**	**0 (0.0)**	**2**	**2 (0.3)**	**0**	**0 (0.0)**	**2**	**2 (0.3)**
Atrioventricular septal defect	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.2)
Cystic lymphangioma	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)
Dermoid cyst	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)
Hydrocele	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Sickle cell anaemia	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.2)
Metabolism and nutrition disorders	**0**	**0 (0.0)**	**1**	**1 (0.2)**	**0**	**0 (0.0)**	**2**	**2 (0.3)**	**0**	**0 (0.0)**	**1**	**1 (0.2)**
Malnutrition	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	2	2 (0.3)	0	0 (0.0)	1	1 (0.2)
Weight gain poor	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Nervous system disorders	**0**	**0 (0.0)**	**2**	**2 (0.3)**	**0**	**0 (0.0)**	**1**	**1 (0.2)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**

[1] Includes severe, medically significant but not life threatening, and death.
[2] Based on MedDRA dictionary version 23. Includes solicited events if ongoing 6 days after study vaccination.

Data source: ADAE
Listing source: 16.2.7.1

Table 14.3.5.1 Unsolicited Treatment Emergent Adverse Events at any Time during Follow-up by Severity and Relatedness: Safety Population

	Total (N= 660)											
	Mild				Moderate				Severe+[1]			
	Related		Not Related		Related		Not Related		Related		Not Related	
System Organ Class / Preferred Term[2]	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Infant irritability	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Lethargy	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Seizure	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**1**	**1 (0.2)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**
Lipoma	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)
Reproductive system and breast disorders	**0**	**0 (0.0)**	**1**	**1 (0.2)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**	**0**	**0 (0.0)**
Balanoposthitis	0	0 (0.0)	1	1 (0.2)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Total	**2**	**2 (0.3)**	**1707**	**577 (87.4)**	**0**	**0 (0.0)**	**61**	**59 (8.9)**	**1**	**1 (0.2)**	**28**	**26 (3.9)**

[1] Includes severe, medically significant but not life threatening, and death.
[2] Based on MedDRA dictionary version 23. Includes solicited events if ongoing 6 days after study vaccination.

Data source: ADAE
Listing source: 16.2.7.1

Table 14.3.8.1 Reactogenicity Events: Day 0 through Day 6 Following Any Vaccination: Safety Population

	PNEUMOSIL (N= 220)		Synflorix (N= 220)		Prevenar 13 (N= 220)		Overall (N= 660)		PNEUMOSIL -Synflorix (95% CI)[1]	PNEUMOSIL -Prevenar 13 (95% CI)[1]	p-value[2]
	n	(%)	n	(%)	n	(%)	n	(%)			
LOCAL REACTIONS											
Any Grade 1 or higher local reaction	72	(32.7)	84	(38.2)	63	(28.6)	219	(33.2)	-5.5 (-14.3,3.5)	4.1 (-4.5,12.7)	0.0957
Any Grade 3 or higher local reaction	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)			
Tenderness											
Grade 1 or higher	70	(31.8)	83	(37.7)	61	(27.7)	214	(32.4)	-5.9 (-14.7,3.0)	4.1 (-4.5,12.6)	0.0713
Grade 3 or higher	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)			
Erythema/Redness											
Grade 1 or higher	1	(0.5)	3	(1.4)	1	(0.5)	5	(0.8)	-0.9 (-3.5,1.3)	0.0 (-2.1,2.1)	0.6274
Grade 3 or higher	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)			
Induration/Swelling											
Grade 1 or higher	3	(1.4)	5	(2.3)	1	(0.5)	9	(1.4)	-0.9 (-4.0,1.9)	0.9 (-1.3,3.5)	0.3146
Grade 3 or higher	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)			
SYSTEMIC REACTIONS											
Any Grade 1 or higher systemic reaction	160	(72.7)	167	(75.9)	160	(72.7)	487	(73.8)	-3.2 (-11.3,5.0)	0.0 (-8.3,8.3)	0.6790
Any Grade 3 or higher systemic reaction	3	(1.4)	0	(0.0)	2	(0.9)	5	(0.8)			
Fever											
Grade 1 or higher	98	(44.5)	105	(47.7)	108	(49.1)	311	(47.1)	-3.2 (-12.4,6.1)	-4.5 (-13.8,4.8)	0.6178
Grade 3 or higher	3	(1.4)	0	(0.0)	2	(0.9)	5	(0.8)			

[1] Confidence intervals based on Miettinen-Nurminen Score confidence intervals for differences in proportions of subjects with event.
[2] For test of no overall difference in proportions, based on Cochran-Mantel-Haenszel (stratified on field site) or Fisher's Exact test (if fewer than 5 events for at least one treatment group).

Data source: ADRCTGRD
Listing source: 16.2.7.7 and 16.2.7.8

Table 14.3.8.1 Reactogenicity Events: Day 0 through Day 6 Following Any Vaccination: Safety Population

	PNEUMOSIL (N= 220)		Synflorix (N= 220)		Prevenar 13 (N= 220)		Overall (N= 660)		PNEUMOSIL -Synflorix (95% CI)[1]	PNEUMOSIL -Prevenar 13 (95% CI)[1]	p-value[2]
	n	(%)	n	(%)	n	(%)	n	(%)			
Cutaneous Rash											
Grade 1 or higher	16	(7.3)	7	(3.2)	6	(2.7)	29	(4.4)	4.1 (-0.1,8.7)	4.5 (0.5,9.1)	0.0358
Grade 3 or higher	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)			
Irritability											
Grade 1 or higher	105	(47.7)	110	(50.0)	101	(45.9)	316	(47.9)	-2.3 (-11.6,7.1)	1.8 (-7.5,11.1)	0.6929
Grade 3 or higher	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)			
Drowsiness											
Grade 1 or higher	12	(5.5)	15	(6.8)	18	(8.2)	45	(6.8)	-1.4 (-6.1,3.3)	-2.7 (-7.7,2.1)	0.5263
Grade 3 or higher	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)			
Decreased Appetite											
Grade 1 or higher	25	(11.4)	18	(8.2)	28	(12.7)	71	(10.8)	3.2 (-2.4,8.9)	-1.4 (-7.6,4.8)	0.2889
Grade 3 or higher	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)			

[1] Confidence intervals based on Miettinen-Nurminen Score confidence intervals for differences in proportions of subjects with event.
[2] For test of no overall difference in proportions, based on Cochran-Mantel-Haenszel (stratified on field site) or Fisher's Exact test (if fewer than 5 events for at least one treatment group).

Data source: ADRCTGRD
Listing source: 16.2.7.7 and 16.2.7.8