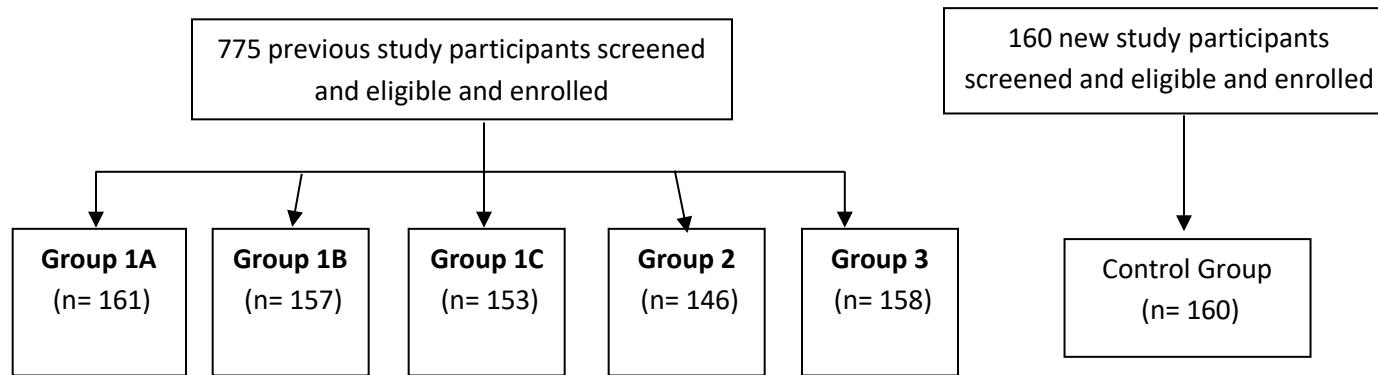


1. PARTICIPANT FLOW

The disposition of subjects for this study is summarized in the figure below:

Figure 1.



2. DEMOGRAPHIC AND OTHER BASELINE CHARACTERISTICS

Demographic and anthropometry characteristics including age, sex (male/female), ethnicity (Kassena, Nankana, or Other), height (cm) and weight (kg) are summarized in Table 2.

There were more females than males in Group 1A, 2 and 3; more males than females in Group 1B, 1C and the control group; though this difference was not considered statistically significant. The mean age across all arms from the original PsA-TT-004 study was 6.8 years (SEM=0.01) while the mean age for the control group was 4.2 years (SEM=0.01); majority of participants were of Kassena ethnicity, and the mean height, and weight were similar in all groups.

Table 2: Demographic Characteristics for All Participants by Study Group

Characteristic	Group 1A (N= 161)	Group 1B (N= 157)	Group 1C (N = 153)	Group 2 (N= 146)	Group 3 (N= 158)	Control Group (N = 160)	Total
Sex n (%)							
Male	72 (44.72%)	80 (50.96%)	84 (54.90%)	72 (49.32%)	76 (48.10%)	81 (50.63%)	465
Female	89 (55.28%)	77 (49.04%)	69 (45.10%)	74 (50.68%)	82 (51.90%)	79 (49.38%)	470
Ethnicity n (%)							
Kassena	101 (62.73%)	96 (61.15%)	99 (64.71%)	88 (60.27%)	98 (62.03%)	82 (51.25%)	564
Nankana	57 (35.40%)	58 (36.94%)	53 (34.64%)	55 (37.67%)	59 (37.34%)	70 (43.75%)	352
Other	3 (1.86%)	3 (1.91%)	1 (0.65%)	3 (2.05%)	1 (0.63%)	8 (5.00%)	19

3. PRIMARY OUTCOME MEASURE

Meningococcal A antibody persistence will be assessed in terms of geometric mean titer (GMT) of meningococcal A antibody titers as measured by rSBA assay for each study group (groups 1A, 1B, 1C, 2, and 3 from the original PsA-TT-004 study and a new control group)

Table 3a. Geometric Mean Titer (GMT) of MenA rSBA Titer for All Participants – Visit 1

Statistic	Group 1A N = 161	Group 1B N = 157	Group 1C N = 153	Group 2 N = 146	Group 3 N = 158	Control Group N = 160
n (missing)	161 (0)	157 (0)	153 (0)	146 (0)	158 (0)	160 (0)
GMT at Visit 1	1360.5	1457.8	1640.3	1540.3	1386.0	1126.4
95% CI of GMT	(1110.5, 1666.9)	(1198.0, 1773.9)	(1313.2, 2048.8)	(1288.6, 1841.3)	(1068.6, 1797.6)	(888.9, 1427.3)

4. SECONDARY OUTCOME MEASURE

Table 4a. Number and percentage of Subjects with at least 4-fold Response in MenA rSBA Titer in relation to Baseline among All Participants – Visit 1

Statistic	Group 1A N = 161	Group 1B N = 157	Group 1C N = 153	Group 2 N = 146	Group 3 N = 158	P-value
n (missing)	156 (5)	152 (5)	148 (5)	144 (2)	156 (2)	
Number of subjects with >= 4-fold response (%)	154 (98.7)	150 (98.7)	145 (98.0)	141 (97.9)	138 (88.5)	
95% CI of Percentage	(95.4, 99.8)	(95.3, 99.8)	(94.2, 99.6)	(94.0, 99.6)	(82.4, 93.0)	

Note1: n is the number of subjects with SBA titer at both previous baseline of PsA-TT-004 study and current visit.

Note2: The comparisons are made by Fisher's exact test.

Table 4b. Number and Percentage of Subjects with at least 4-fold Response in MenA rSBA Titer in relation to Baseline among All Participants – Visit 1

Statistic	Group 1A N = 161	Group 1B N = 157	Group 1C N = 153	Group 2 N = 146	Group 3 N = 158
n (missing)	156 (5)	152 (5)	148 (5)	144 (2)	156 (2)
Number of subjects with >= 4-fold response (%)	154 (98.7)	150 (98.7)	145 (98.0)	141 (97.9)	138 (88.5)
95% CI of Percentage	(95.4, 99.8)	(95.3, 99.8)	(94.2, 99.6)	(94.0, 99.6)	(82.4, 93.0)

Note1: n is the number of subjects with SBA titer at both previous baseline of PsA-TT-004 study and current visit.

Table 4c. Number and percentage of Subjects with MenA rSBA Titer above Different Thresholds among All Participants – Visit 1

Statistic	Group 1A N = 161	Group 1B N = 157	Group 1C N = 153	Group 2 N = 146	Group 3 N = 158	Control Group N = 160
n (missing)	161 (0)	157 (0)	153 (0)	146 (0)	158 (0)	160 (0)
Number of subjects with MenA Titer >= 1:8 (%)	159 (98.8)	156 (99.4)	150 (98.0)	146 (100.0)	152 (96.2)	156 (97.5)
95% CI of Percentage	(95.6, 99.8)	(96.5, 100.0)	(94.4, 99.6)	(97.5, 100.0)	(91.9, 98.6)	(93.7, 99.3)
n (missing)	161 (0)	157 (0)	153 (0)	146 (0)	158 (0)	160 (0)
Subjects with MenA Titer >= 1:128 (%)	159 (98.8)	155 (98.7)	150 (98.0)	145 (99.3)	152 (96.2)	155 (96.9)
95% CI of Percentage	(95.6, 99.8)	(95.5, 99.8)	(94.4, 99.6)	(96.2, 100.0)	(91.9, 98.6)	(92.9, 99.0)

Note1: n is the number of subjects with SBA titer.

Table 4d. Geometric Mean Concentration (GMC) of MenA-Specific IgG Concentration for All Participants – Visit 1

Statistic	Group 1A N = 161	Group 1B N = 157	Group 1C N = 153	Group 2 N = 146	Group 3 N = 158	Control Group N = 160
n (missing)	161 (0)	157 (0)	153 (0)	146 (0)	158 (0)	160 (0)
GMC at Visit 1	2.5	2.8	2.5	3.6	4.9	1.8
95% CI of GMC	(2.3, 2.8)	(2.6, 3.1)	(2.2, 2.8)	(3.2, 4.0)	(4.3, 5.5)	(1.6, 2.1)

Note: The ratio of GMT is a ratio of GMT between Visit 1 and Last Visit of PsA-TT-004 study obtained by a paired t-test procedure.

Table 4e. Number and percentage of Subjects with Different Seroresponses in MenA-specific IgG Concentration in relation to Baseline among All Participants – Visit 1

Statistic	Group 1A N = 161	Group 1B N = 157	Group 1C N = 153	Group 2 N = 146	Group 3 N = 158
n (missing)	135 (26)	137 (20)	134 (19)	142 (4)	153 (5)
Number of subjects with >= 2-fold response (%)	106 (78.5)	104 (75.9)	101 (75.4)	141 (99.3)	151 (98.7)
95% CI of Percentage	(70.6, 85.1)	(67.9, 82.8)	(67.2, 82.4)	(96.1, 100.0)	(95.4, 99.8)
n (missing)	135 (26)	137 (20)	134 (19)	142 (4)	153 (5)
Number of subjects with >= 4-fold response (%)	73 (54.1)	79 (57.7)	79 (59.0)	139 (97.9)	147 (96.1)
95% CI of Percentage	(45.3, 62.7)	(48.9, 66.1)	(50.1, 67.4)	(94.0, 99.6)	(91.7, 98.5)

Note1: n is the number of subjects with MenA-specific IgG concentration at both previous baseline of PsA-TT-004 study and current visit.

Table 4f. Number and percentage of Subjects with MenA-specific IgG Concentration above Different Thresholds among All Participants – Visit 1

Statistic	Group 1A N = 161	Group 1B N = 157	Group 1C N = 153	Group 2 N = 146	Group 3 N = 158	Control Group N = 160
n (missing)	161 (0)	157 (0)	153 (0)	146 (0)	158 (0)	160 (0)
Number of subjects with IgG Concentration >= 1 mcg/ml (%)	154 (95.7)	151 (96.2)	139 (90.8)	143 (97.9)	152 (96.2)	113 (70.6)
95% CI of Percentage	(91.2, 98.2)	(91.9, 98.6)	(85.1, 94.9)	(94.1, 99.6)	(91.9, 98.6)	(62.9, 77.6)
n (missing)	161 (0)	157 (0)	153 (0)	146 (0)	158 (0)	160 (0)
Number of subjects with IgG Concentration >= 2 mcg/ml (%)	99 (61.5)	109 (69.4)	87 (56.9)	116 (79.5)	136 (86.1)	64 (40.0)
95% CI of Percentage	(53.5, 69.0)	(61.6, 76.5)	(48.6, 64.8)	(72.0, 85.7)	(79.7, 91.1)	(32.3, 48.0)

Note1: n is the number of subjects with MenA-specific IgG concentration.

Figure 4g. Reverse Cumulative Distribution Curves of MenA rSBA Titer for All Participants – Visit 1

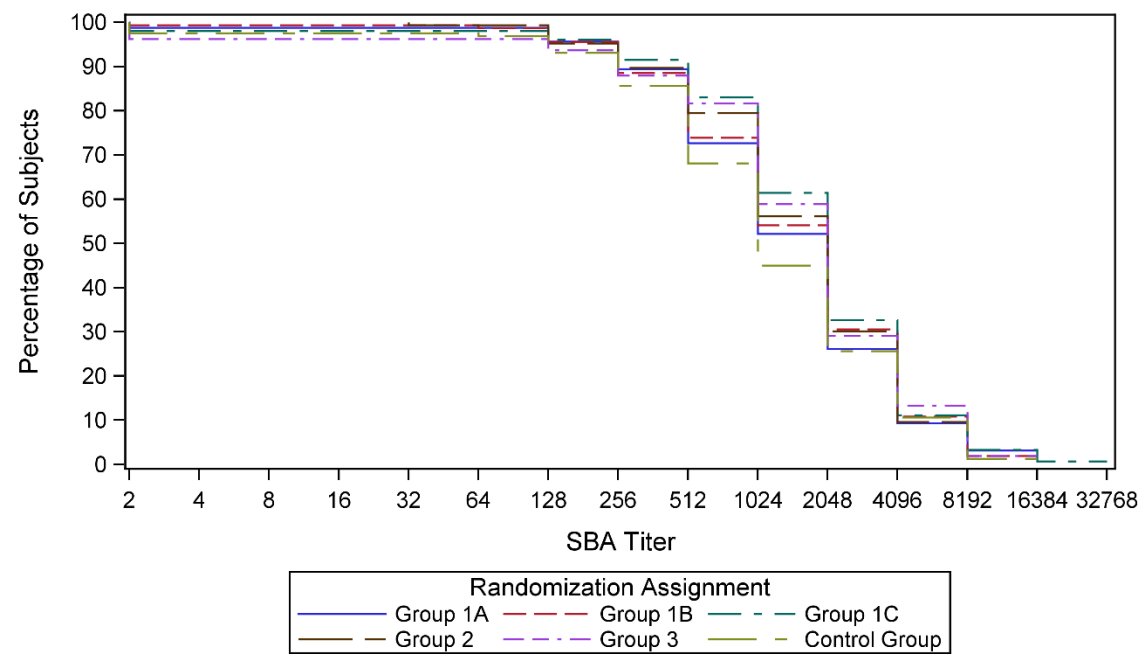
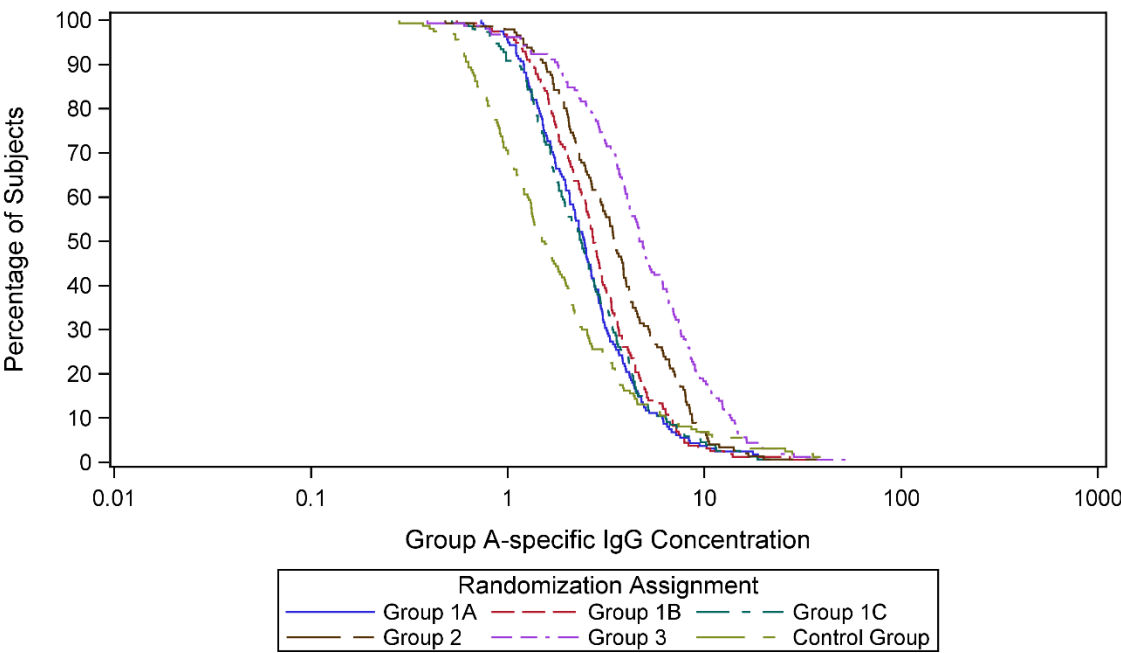


Figure 4h. Reverse Cumulative Distribution Curves of MenA-Specific IgG Concentration for All Participants – Visit 1



5. ADVERSE EVENTS

No Adverse events were reported associated with the study or study procedures