

1. PARTICIPANT FLOW

The disposition of subject for this study is summarized in the table below:

Study Disposition	Group 1A n	Group 1B n	Group 2A n	Group 2B n	Control Group n	Total n
Visit 1						
Participants Enrolled	165	165	165	165	165	825
Participants Completed Visit 1 Procedures and had blood collected	165	165	165	165	165	825
Participants Selected for Visit 2 and 3	56	56	56	56	56	280
Visit 2						
Participants Discontinued between Visit 1 and 2	3	2	3	0	2	10
Lost to follow up	0	0	1	0	0	1
Migrated/moved from study area	0	0	0	0	1	1
Consent withdrawal	3	2	2	0	1	8
Participants Completed Visit 2 Procedures and had blood collected	53	54	53	56	54	270
Visit 3						
Participants Discontinued between Visit 2 and 3	2	1	1	0	1	5
Migrated/moved from study area	2	1	1	0	1	5
Participants Completed Visit 3 Procedures and had blood collected	51	53	52	56	53	265

2. DEMOGRAPHIC AND OTHER BASELINE CHARACTERISTICS

Table 2: Demographic Characteristics by Study Group

Characteristic	Group 1A (N= 165)	Group 1B (N= 165)	Group 2A (N= 165)	Group 2B (N= 165)	Control Group (N= 165)	All (N= 825)	P-value
Sex n (%)							0.0361
Male	80 (48.5)	82 (49.7)	99 (60.0)	71 (43.0)	79 (47.9)	411 (49.8)	
Female	85 (51.5)	83 (50.3)	66 (40.0)	94 (57.0)	86 (52.1)	414 (50.2)	
Ethnicity n (%)							0.0307
Bambara	57 (34.5)	53 (32.1)	43 (26.1)	60 (36.4)	44 (26.7)	257 (31.2)	
Mandika/Malinke	46 (27.9)	41 (24.8)	42 (25.5)	33 (20.0)	35 (21.2)	197 (23.9)	
Fula/Peulh	20 (12.1)	24 (14.5)	32 (19.4)	22 (13.3)	31 (18.8)	129 (15.6)	
Sarahule/Sarakole	6 (3.6)	22 (13.3)	15 (9.1)	17 (10.3)	25 (15.2)	85 (10.3)	
Other	36 (21.8)	25 (15.2)	33 (20.0)	33 (20.0)	30 (18.2)	157 (19.0)	
Age (years)							< 0.0001
Mean (SEM)	5.2 (0.02)	5.2 (0.02)	5.2 (0.02)	5.2 (0.02)	5.4 (0.02)	5.3 (0.01)	
Median	5.3	5.3	5.3	5.3	5.4	5.3	
Range (Min – Max)	4.7 - 5.8	4.7 - 5.7	4.8 - 5.8	4.7 - 5.7	4.9 - 5.9	4.7 - 5.9	
Height (cm)							0.407
Mean (SEM)	109.0 (0.37)	109.2 (0.37)	110.0 (0.35)	109.7 (0.55)	109.7 (0.35)	109.5 (0.18)	
Median	109	109	109.5	109	110	109.5	
Range (Min – Max)	97.3 - 127.0	97.5 - 124.0	99.0 - 122.5	96.0 - 177.0	99.0 - 120.6	96.0 - 177.0	
Weight (kg)							0.0626
Mean (SEM)	17.8 (0.17)	17.9 (0.18)	18.3 (0.22)	17.7 (0.16)	17.7 (0.15)	17.9 (0.08)	
Median	17.6	17.7	17.9	17.6	17.5	17.7	
Range (Min – Max)	11.9 - 27.6	11.7 - 26.0	13.0 - 36.7	12.1 - 25.9	13.9 - 22.9	-36.7	

3. PRIMARY OUTCOME MEASURE:

Geometric mean titer (GMT) for MenA-specific serum antibody as measured by serum bactericidal antibody assay using rabbit complement (rSBA) approximately four years following primary immunization.

Table 3: GMT for MenA-specific serum bactericidal antibody measured by rSBA using Strain F8238 and Strain A3125 – Visit 1; ATP Set

	Group 1A GMT (95% CI)	Group 1B GMT (95% CI)	Group 2A GMT (95% CI)	Group 2B GMT (95% CI)	Control Group GMT (95% CI)
Strain F8238					
Last Visit	12627.16 (11098.03 – 14366.98)	10584.73 (9137.12 – 12261.69)	2526.69 (2009.76 – 3176.56)	3104.19 (2518.48 – 3826.11)	–
Visit 1	1109.08 (832.29 – 1477.93)	1011.18 (746.63 – 1369.46)	618.54 (444.89 – 859.97)	561.57 (388.79 – 811.14)	176.14 (111.31 – 278.73)
Strain A3125					
Visit 1	299.05 (221.27 – 404.17)	313.19 (236.02 – 415.59)	107.30 (76.42 – 150.64)	64.81 (43.24 – 97.13)	7.97 (5.62 – 11.30)

4. SECONDARY OUTCOME MEASURES:

4.1.1 The percentage of participants with a MenA antibody titer $\geq 1:8$, and $\geq 1:128$, as measured by rSBA assay

Table 4.1.1: The percentage and 95% CI of subjects with MenA rSBA titer $\geq 1:8$ threshold and titer $\geq 1:128$ thresholds using Strain F8238 and A3125 at Visit 1, Visit 2 and Visit 3; ATP Set

	Group 1A % (95% CI)	Group 1B % (95% CI)	Group 2A % (95% CI)	Group 2B % (95% CI)	Control Group % (95% CI)
Strain F8238					
$\geq 1:8$ threshold					
Visit 1	95.2 (90.7–97.9)	93.9 (89.1–97.1)	89.7 (84.0–93.9)	86.7 (80.5–91.5)	70.9 (63.3–77.7)
Visit 2	100.0 (93.0–100.0)	100 (93.4–100.0)	100 (93.3–100.0)	100.0 (93.6 –100.0)	100.0 (93.4–100.0)
Visit 3	100.0 (93.0–100.0)	100 (93.3–100.0)	100 (93.3–100.0)	100.0 (93.6 –100.0)	100.0 (93.3–100.0)
$\geq 1:128$ threshold					
Visit 1	92.1 (86.9, 95.7)	90.9 (85.4–94.8)	87.3 (81.2–91.9)	84.8 (78.5 –89.9)	70.3 (62.7–77.2)
Visit 2	100.0 (93.0–100.0)	100 (93.4–100.0)	100 (93.3–100.0)	100.0 (93.6 –100.0)	100.0 (93.4–100.0)
Visit 3	100.0 (93.0–100.0)	100 (93.3–100.0)	100 (93.3–100.0)	100.0 (93.6 –100.0)	100.0 (93.3–100.0)
Strain A3125					
$\geq 1:8$ threshold					
Visit 1	92.1 (86.9–95.7)	92.7 (87.6–96.2)	81.8 (75.1–87.4)	65.5 (57.7–72.7)	27.9 (21.2–35.4)
Visit 2	100.0 (93.0–100.0)	100.0 (93.4–100.0)	100.0 (93.3–100.0)	100.0 (93.6 –100.0)	100.0 (93.4–100.0)
Visit 3	100.0 (93.0–100.0)	100.0 (93.3–100.0)	100.0 (93.2–100.0)	100.0 (93.6 –100.0)	100.0 (93.3–100.0)
$\geq 1:128$ threshold					
Visit 1	79.4 (72.4, 85.3)	83.6 (77.1–88.9)	67.9 (60.2–74.9)	57.0 (49.0–64.6)	24.8 (18.5–32.2)
Visit 2	100.0 (93.0–100.0)	100.0 (93.4–100.0)	100.0 (93.3–100.0)	100.0 (93.6 –100.0)	100.0 (93.4–100.0)
Visit 3	100.0 (93.0–100.0)	100.0 (93.3–100.0)	100.0 (93.2–100.0)	100.0 (93.6 –100.0)	100.0 (93.3–100.0)

4.1.2 The geometric mean concentrations (GMC) for serogroup A-specific IgG concentrations, as measured by ELISA

Table 4.1.2: MenA-specific Serum IgG Geometric Mean Concentration by ELISA, at Last Visit of PsA-TT-007, Visit 1, Visit 2 and Visit 3, and Ratios comparisons between Former Participants vs. Control Group, Visit 2 and Visit 3 compared to Visit 1; ATP Set

	Group 1A	Group 1B	Group 2A	Group 2B	Control Group
GMC	GMC (95% CI)	GMC (95% CI)	GMC (95% CI)	GMC (95% CI)	GMC (95% CI)
Last Visit	35.83 (31.49–40.75)	23.83 (20.83–27.25)	1.15 (0.99–1.34)	0.93 (0.82–1.07)	–
Visit 1	1.65 (1.45–1.86)	1.33 (1.18–1.50)	1.03 (0.92–1.15)	0.94 (0.84–1.05)	0.71 (0.63–0.80)
Visit 2	94.18 (72.85–121.74)	94.72 (77.67–115.53)	98.57 (79.91–121.60)	85.13 (67.10–108.00)	69.67 (54.14–89.66)
Visit 3	16.85 (12.36–22.98)	15.10 (12.10–18.84)	18.12 (14.23–23.07)	16.34 (12.73–20.97)	10.06 (7.58–13.34)
GMC Ratio	GMC Ratio (95% CI)	GMC Ratio (95% CI)	GMC Ratio (95% CI)	GMC Ratio (95% CI)	GMC Ratio (95% CI)
Visit 1 vs. Last Visit (Study vs Control)	2.32 (1.95–2.76)	1.87 (1.58–2.22)	1.45 (1.23–1.71)	1.33 (1.13–1.57)	–
Visit 2 (Previously Vaccinated vs. Control)	1.35 (0.95–1.93)	1.36 (0.99–1.87)	1.41 (1.02–1.96)	1.22 (0.87–1.72)	–
Visit 3 (Previously Vaccinated vs. Control)	1.68 (1.11–2.53)	1.50 (1.05–2.14)	1.80 (1.25–2.60)	1.62 (1.12–2.36)	–
Visit 2 vs. Visit 1	56.04 (41.75–75.22)	72.55 (58.30–90.29)	95.91 (74.54–123.40)	89.10 (69.50–114.23)	96.82 (72.16–129.92)
Visit 3 vs. Visit 1	9.97 (7.55–13.17)	11.81 (9.63–14.48)	17.63 (13.59–22.87)	17.10 (13.37–21.88)	14.01 (10.36–18.93)

4.1.3 The percentage of participants with serogroup A-specific IgG concentration $\geq 2 \mu\text{g/ml}$, and $\geq 1 \mu\text{g/ml}$, as measured by ELISA

Table 4.1.3: The percentage and 95% CI of subjects with MenA-specific Serum IgG by ELISA Proportion above Threshold $\geq 1 \mu\text{g/mL}$ and $2 \mu\text{g/mL}$ at Visit 1, Visit 2 and Visit 3; ATP Set

	Group 1A % (95% CI)	Group 1B % (95% CI)	Group 2A % (95% CI)	Group 2B % (95% CI)	Control Group % (95% CI)
$\geq 1 \mu\text{g/mL}$					
Visit 1	71.5 (64.0–78.3)	59.4 (51.5–67.0)	49.1 (41.2–57.0)	46.1 (38.3–54.0)	23.6 (17.4–30.9)
Visit 2	100.0 (93.0–100.0)	100.0 (93.4–100.0)	100.0 (93.3–100.0)	100.0 (93.6–100.0)	100.0 (93.4–100.0)
Visit 3	100.0 (93.0–100.0)	100.0 (93.3–100.0)	100.0 (93.3–100.0)	100.0 (93.6–100.0)	100.0 (93.3–100.0)
$\geq 2 \mu\text{g/mL}$					
Visit 1	32.7 (25.6–40.5)	27.3 (20.6–34.7)	18.2 (12.6–24.9)	14.5 (9.5–20.9)	12.1 (7.6–18.1)
Visit 2	100.0 (93.0–100.0)	100.0 (93.4–100.0)	100.0 (93.3–100.0)	100.0 (93.6–100.0)	100.0 (93.4–100.0)
Visit 3	100.0 (93.0–100.0)	100.0 (93.3–100.0)	100.0 (93.3–100.0)	100.0 (93.6–100.0)	100.0 (89.9–100.0)

4.1.4 The reverse cumulative distribution curves for MenA antibody titers as measured by rSBA assay, and for MenA-specific IgG concentrations as measured by ELISA

Figure 4.1.4a Reverse Cumulative Distribution Curves of MenA rSBA Titers using Strain F8238–Visit 1; ATP Set

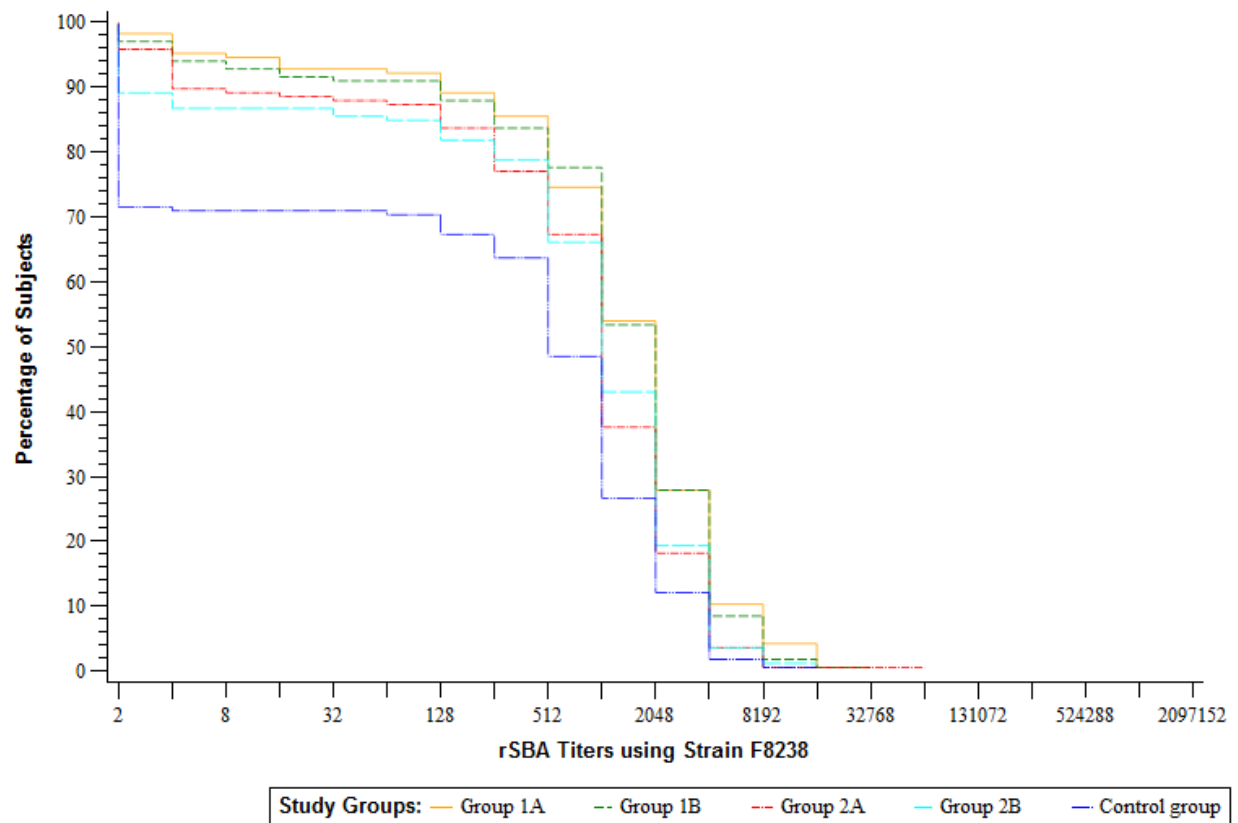


Figure 4.1.4b Reverse Cumulative Distribution Curves of MenA rSBA Titers using Strain F8238 – Visit 2; ATP Set

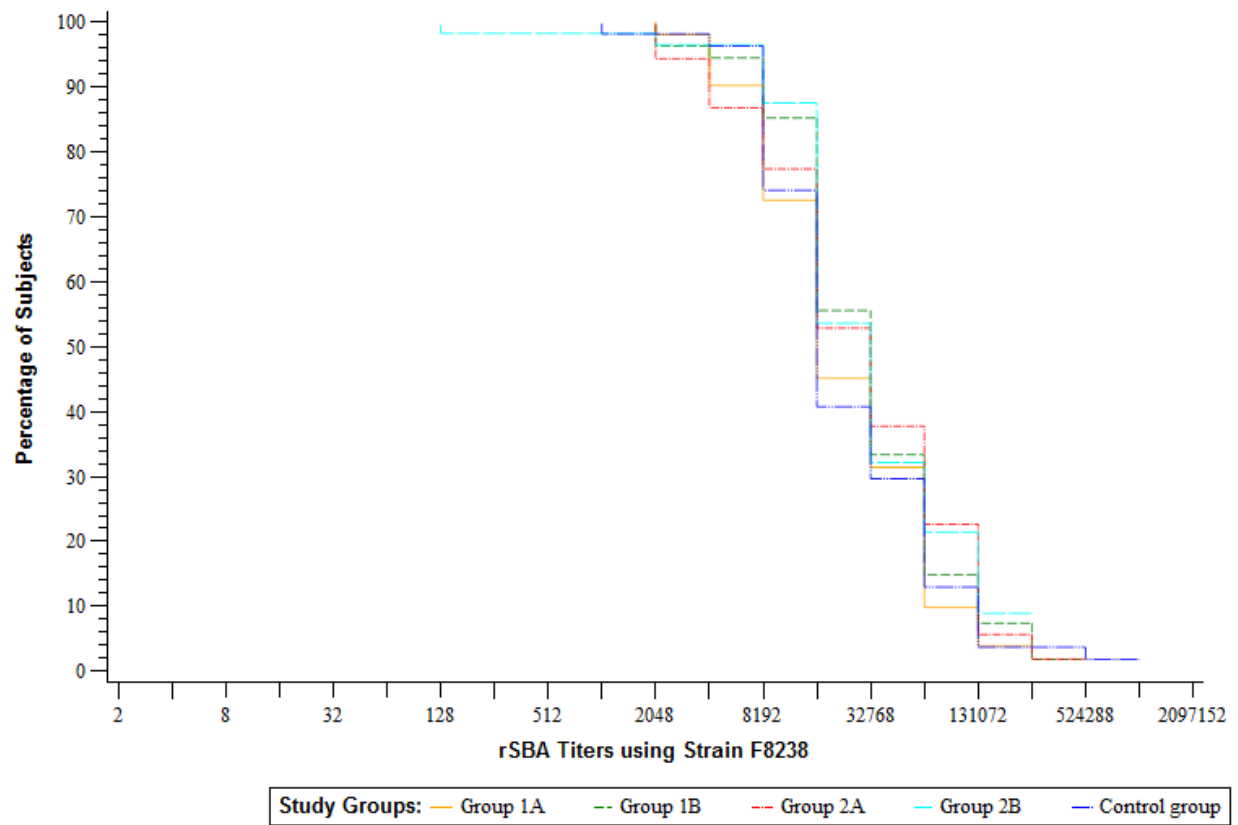
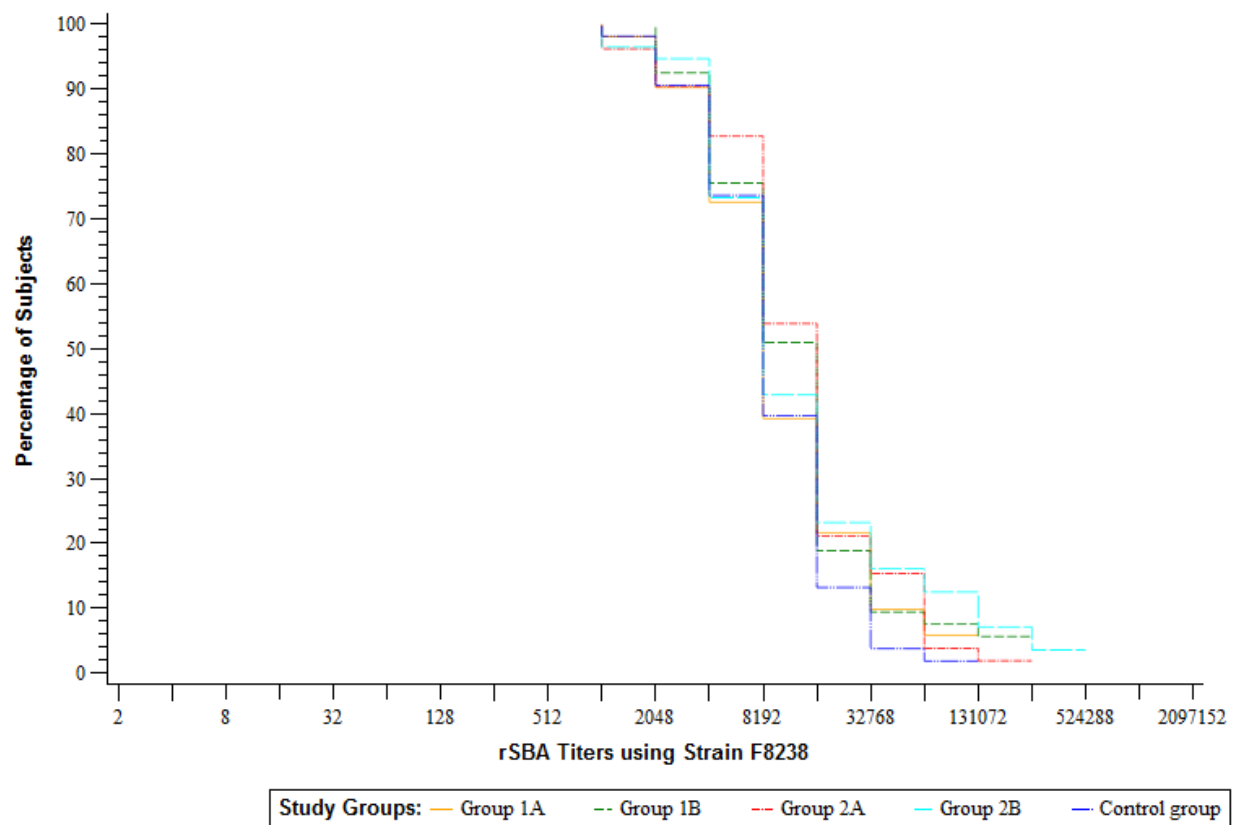


Figure 4.1.4c Reverse Cumulative Distribution Curves of MenA rSBA Titers using Strain F8238- Visit 3; ATP Set



4.1.5 The geometric mean titer for MenA-specific serum antibody, measured by rSBA assay.

Table 4.1.5 GMT for MenA-specific serum bactericidal antibody measured by rSBA using Strain F8238 and Strain A3125- Visit 2 & 3; ATP Set

	Group 1A GMT (95% CI)	Group 1B GMT (95% CI)	Group 2A GMT (95% CI)	Group 2B GMT (95% CI)	Control Group GMT (95% CI)
Strain F8238					
Visit 2	23328.47 (17020.63– 31973.99)	30339.06 (22178.96– 41501.43)	28377.36 (19644.30– 40992.78)	30422.63 (21403.58– 43242.12)	24706.32 (17765.80– 34358.28)
Visit 3	10605.68 (7783.54–14451.06)	12449.27 (9071.96–17083.88)	12888.94 (9407.55–17658.66)	13275.04 (9143.88–19272.64)	9459.49 (7349.78–12174.79)
Strain A3125					
Visit 2	11506.78 (9348.83– 14162.83)	12040.06 (10229.29–14171.38)	13290.55 (10955.71– 16122.98)	11729.53 (9973.50–13794.73)	8735.00 (7209.66– 10583.06)
Visit 3	4444.01 (3194.81–6181.67)	4430.36 (3542.13–5541.31)	5137.76 (4002.19–6595.53)	4751.89 (3485.14–6479.07)	4855.09 (3787.68–6223.31)

- 4.1.6 The percentage of participants demonstrating a ≥ 4 -fold rise (i.e., seroconversion) in MenA antibody titers, when compared to the pre-campaign (persistence) timepoint titer, as measured by rSBA assay.

Table 4.1.6 The percentage and 95% CI of subjects with MenA-specific rSBA GMT 4-fold Seroresponse Rates in Relation to Pre-Campaign (Visit 1) at Visit 2 and Visit 3 for Strains F8238 and A3125; ATP Set

	Group 1A % (95% CI)	Group 1B % (95% CI)	Group 2A % (95% CI)	Group 2B % (95% CI)	Control Group % (95% CI)
F8238					
Visit 2	88.2 (76.1–95.6)	96.3 (87.3–99.5)	92.5 (81.8–97.9)	96.4 (87.7–99.6)	94.4 (84.6–98.8)
Visit 3	72.5 (58.3–84.1)	81.1 (68.0–90.6)	88.5 (76.6–95.6)	89.3 (78.1–96.0)	86.8 (74.7–94.5)
A3125					
Visit 2	92.2 (81.1–97.8)	92.2 (81.1–97.8)	100.0 (93.4–100.0)	96.4 (87.7–99.6)	98.1 (90.1–100.0)
Visit 3	74.5 (60.4–85.7)	86.8 (74.7–94.5)	94.2 (84.1–98.8)	92.9 (82.7–98.0)	94.3 (84.3–98.8)

- 4.1.7 The ratio of GMC for MenA-specific IgG concentration in relation to the pre-campaign (persistence) time point, as measured by ELISA.

Table 4.1.7 MenA-specific Serum IgG Geometric Mean Concentration by ELISA, Ratios comparisons Visit 2 and Visit 3 compared to Visit 1; ATP Set

GMC Ratio	Group 1A GMC Ratio (95% CI)	Group 1B GMC Ratio (95% CI)	Group 2A GMC Ratio (95% CI)	Group 2B GMC Ratio (95% CI)	Control Group GMC Ratio (95% CI)
Visit 2 vs. Visit 1	56.04 (41.75–75.22)	72.55 (58.30–90.29)	95.91 (74.54–123.40)	89.10 (69.50–114.23)	96.82 (72.16–129.92)
Visit 3 vs. Visit 1	9.97 (7.55–13.17)	11.81 (9.63–14.48)	17.63 (13.59–22.87)	17.10 (13.37–21.88)	14.01 (10.36–18.93)

- 4.1.8 The percentage of participants who demonstrate a ≥ 2 -fold rise and a ≥ 4 -fold rise in MenA-specific IgG concentration (i.e., seroconversion) with respect to pre-campaign (persistence) MenA-specific IgG concentration, as measure by ELISA.

Table 4.1.8 The percentage and 95% CI of subjects with MenA-specific Serum IgG GMC by ELISA Seroresponse Rates in Relation to Pre-Campaign (Visit 1) at Visit 2 and Visit 3; ATP Set

	Group 1A % (95% CI)	Group 1B % (95% CI)	Group 2A % (95% CI)	Group 2B % (95% CI)	Control Group % (95% CI)
2-fold					
Visit 2	100.0 (93.0–100.0)	100.0 (93.4–100.0)	100.0 (93.4–100.0)	100.0 (93.4–100.0)	100.0 (93.4–100.0)
Visit 3	96.1 (86.5–99.5)	100.0 (93.3–100.0)	98.1 (89.7–100.0)	100.0 (93.6–100.0)	94.3 (84.3–98.8)
4-fold					
Visit 2	98.0 (89.6–100.0)	100.0 (93.4–100.0)	100.0 (93.4–100.0)	100.0 (93.6–100.0)	98.1 (90.1–100.0)
Visit 3	82.4 (69.1–91.6)	94.3 (84.3–98.8)	92.3 (81.5–97.9)	96.4 (87.7–99.6)	90.6 (79.3–96.9)

5. ADVERSE EVENTS

Adverse events were documented in a site study file and reported as per regulatory/ethical requirements, but not entered into the study database.