

Participant Disposition

Table 1: All Cohorts, Participant Disposition

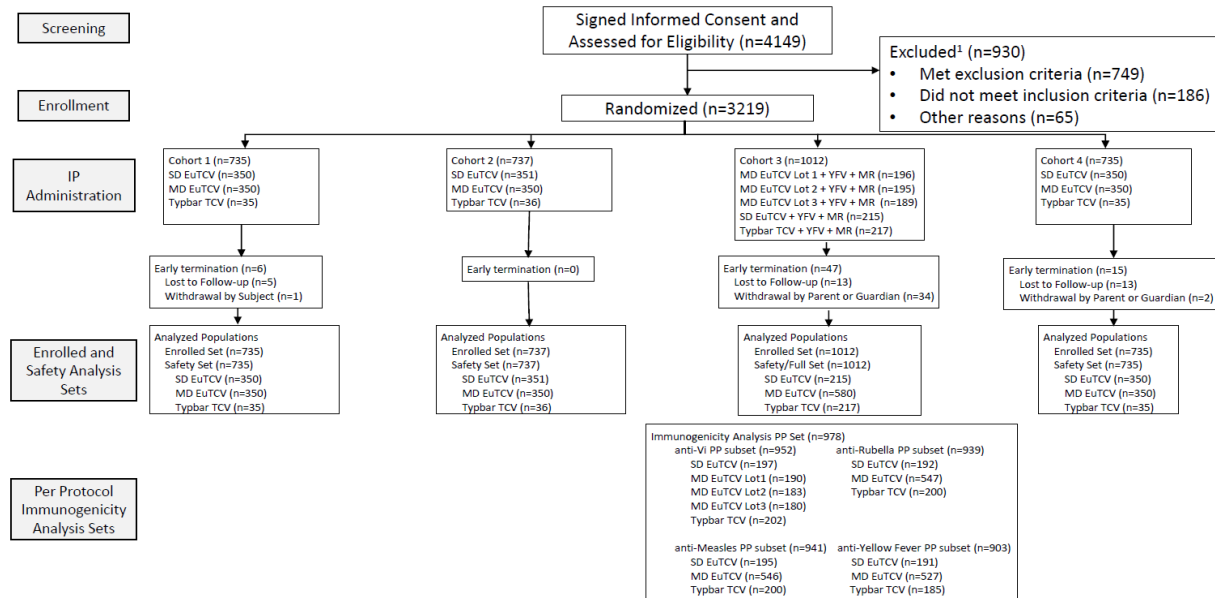
	Multi-dose Vial EuTCV	Single-dose Vial EuTCV	Typbar TCV®	Total
Informed Consent signed				4149
Eligible				3284
Randomized (N)	1630	1266	323	3219
Received study product at D1 (N)	1630	1266	323	3219
Participants who completed study (n, %)	1594 (97.8)	1248 (98.6)	309 (95.7)	3151 (97.9)
Received study product at D1 who discontinued early study (n, %)	36 (2.2)	18 (1.4)	14 (4.3)	68 (2.1)
Lost to follow-up	18 (1.1)	8 (0.6)	5 (1.5)	31 (1.0)
Withdrawal by parent or guardian	18 (1.1)	9 (0.7)	9 (2.8)	36 (1.1)
Withdrawal by participant	0 (0.0)	1 (0.1)	0 (0.0)	1 (0.0)
Expected Enrollment	1650	1275	330	3255
Enrolled population (n, %)	1630 (100)	1266 (100)	323 (100)	4149
Full analysis population (n, %)	1630 (100)	1266 (100)	323 (100)	3219 (100)
Received study product at D1 (Cohort 3)	580	215	217	1012
Per protocol population (n, %)	567 (97.8%)	202 (94.0%)	209 (96.3%)	978 (96.6%)
Anti-Vi subset	553 (95.3%)	197 (91.6%)	202 (93.1%)	952 (94.1%)
Anti-Measles subset	546 (94.1%)	195 (90.7%)	200 (92.2%)	941 (93.0%)
Anti-Rubella subset	547 (94.3%)	192 (89.3%)	200 (92.2%)	939 (92.8%)
Anti-Yellow fever subset	527 (90.9%)	191 (88.8%)	185 (85.3%)	903 (89.2%)

Note: Treatments administered included EuTCV: typhoid Vi-CRM197 conjugate vaccine; MR: measles-rubella vaccine; N: number of participants randomized to treatment; n: number of participants in treatment group; TCV: typhoid Vi- tetanus toxoid conjugate vaccine; YFV: yellow fever vaccine
Cohort 1: 18≤age≤45 yrs; Cohort 2: 2≤age<18 yrs; Cohort 3: 9≤age≤12 months; Cohort 4: 6≤age<9 months and 12<age<24 months.
Denominator of percentage is number of participants randomized and received the vaccine.

Denominator of percentage of Per Protocol population and its subsets is number of participants randomized and received the vaccine in Cohort 3.
Participant 20668 did not have a date of birth or age reported and was not assigned a cohort.

Consort Diagram

F10.1.1 - CONSORT Diagram for CVIA 092 EuTCV



¹ 865 participants did not satisfy at least one eligibility criterion, 70 of which met at least one exclusionary criteria and failed to meet at least one inclusion criteria. An additional 65 participants met all eligibility criteria but were not enrolled for other reasons.

Note: Treatments administered included EuTCV: typhoid Vi-CRM197 conjugate vaccine; MR: measles-rubella vaccine; N: number of participants randomized to treatment; n: number of participants in treatment group; TCV: typhoid Vi- tetanus toxoid conjugate vaccine; YFV: yellow fever vaccine. Cohort 1: $18 \leq \text{age} \leq 45$ yrs; Cohort 2: $2 \leq \text{age} < 18$ yrs; Cohort 3: $9 \leq \text{age} \leq 12$ months; Cohort 4: $6 \leq \text{age} < 9$ months and $12 < \text{age} < 24$ months.

Baseline Characteristics

Table 2: All Cohorts, Baseline Characteristics

	Multi-dose Vial EuTCV	Single-dose Vial EuTCV	Typhar TCV®	Total
Age (years), n	1630	1266	323	3219
Mean (SD)	8.6 (12.04)	11.1 (12.83)	4.8 (9.41)	9.2 (12.27)
Median	1.4	4.9	0.8	1.6
Q1, Q3	0.8, 13.8	1.0, 18.6	0.7, 1.6	0.8, 15.4
Min, Max	0.5, 45.9	0.5, 45.9	0.5, 45.4	0.5, 45.9
Sex, (n [%])				
Female	845 (51.8)	682 (53.9)	171 (52.9)	1698 (52.7)
Male	785 (48.2)	584 (46.1)	152 (47.1)	1521 (47.3)
Race (n [%])				
Black	1630 (100)	1266 (100)	323 (100)	3219 (100)
BMI (kg/m²), n				
Mean (SD)	17.8 (3.90)	18.0 (4.10)	17.5 (2.72)	17.9 (3.88)
Median	17.1	17.2	17.2	17.1
Q1, Q3	15.5, 19.0	15.4, 19.4	15.9, 18.2	15.6, 19.1
Min, Max	7.4, 71.4	9.2, 46.9	9.2, 31.9	7.4, 71.4

N: total number of participants in each group

n: total number of participants in each category

Cohort 1: 18≤age≤45 yrs; Cohort 2: 2≤age<18 yrs; Cohort 3: 9≤age≤12 months; Cohort 4: 6≤age<9 months and 12<age<24 months

Immunogenicity: Seroconversion rates (≥ 4 -fold rise from baseline) of anti-Vi IgG ELISA titers at 28 days after vaccination of EuTCV multi-dose vial, EuTCV single-dose vial, or Typbar TCV[®] (immunogenicity subset)

Table 3: Non-inferiority Tests by Seroconversion Rate at Visit 4 (Per Protocol Population)

		Difference in % Seroconversion										
EuTCV					Typbar TCV [®]				Unadjusted		Adjusted	
Antibody	Group	N	n	Seroconversion Rate (%)	N	n	Seroconversion Rate (%)	Difference Order	Value	95% CI	Value	95% CI
Anti-Vi	Single-Dose	197	197	100.00	202	198	98.02	Single-Dose - Typbar	1.98	0.04 - 4.99	1.98	0.06 - 3.90
	Multi-Dose	553	551	99.64	202	198	98.02	Multi-Dose - Typbar	1.62	0.17 - 4.64	1.62	-0.37 - 3.60

N: number of participants included in each treatment group (without missing values at Visit 4 (Day 29)), n: number of participants with seroconversion.

Anti-Vi seroconversion is defined as greater than 4-fold rise in antibody concentration at post dose over baseline; Anti-Measles, Anti-Rubella and Anti-Yellow Fever seroconversion are defined as sero-positive at post dose while sero-negative at prior dose

The adjusted and unadjusted differences in seroconversion rates and their 95% confidence intervals are calculated using Mantel-Haenszel (adjusted) and Miettinen-Nurminen (unadjusted) methods (site as covariate for adjusted differences).

GMTs of anti-Vi IgG 28 days after vaccination of EuTCV single-dose vial, EuTCV multi-dose vial, or Typbar TCV® (immunogenicity subset)

Table 4: Anti-Vi Geometric Mean Concentrations (GMCs) at Predose (Day 1) and Visit 4 (Day 29) (Anti-Vi Subset of Per Protocol Population)

Visit	Group	Lot	N	GMC	95% CI	Median
Predose (Day 1)						
	Single-dose EuTCV		197	1.14	1.02 - 1.28	1.01
	Multi-dose EuTCV	1	190	0.99	0.88 - 1.11	1.00
		2	183	0.94	0.83 - 1.06	1.01
		3	180	1.00	0.88 - 1.12	1.01
		Total	553	0.98	0.91 - 1.04	1.00
	Typbar TCV®		202	1.14	1.01 - 1.27	1.08
Visit 4 (Day 29)						
	Single-dose EuTCV		197	458.63	408.92 - 514.38	485.29
	Multi-dose EuTCV	1	190	416.77	370.82 - 468.42	475.55
		2	183	426.83	378.93 - 480.78	467.03
		3	180	381.62	338.45 - 430.28	401.55
		Total	553	408.66	382.27 - 436.88	448.56
	Typbar TCV®		202	406.92	363.34 - 455.74	446.70

N: number of participants included in each treatment group (without missing values), GMC: Geometric Mean Concentration, %: percentage, CI: Confidence Interval

GMCs and their 95% CIs are calculated from the censored regression model using the log transformed concentrations as responses (group as fixed effect and site as covariate).

Table 5: Non-inferiority Tests by GMT/C at Visit 4 (Day 29) (Per Protocol Population)

Antibody	Group	EuTCV		Typbar TCV®		Ratio Order	GMT/C Ratio		Value	95% CI
		N	GMT/C (95% CI)	N	GMT/C (95% CI)		Unadjusted	Adjusted		
							Value	95% CI	Value	95% CI
Anti-Vi	Single-Dose	197	457.05 (410.89-508.40)	202	405.75 (365.25-450.74)	Single-Dose/Typbar	1.13	0.97 - 1.31	1.13	0.97 - 1.31
	Multi-Dose	553	406.40 (381.37-433.08)	202	405.75 (365.25-450.74)	Multi-Dose/Typbar	1.00	0.89 - 1.13	1.00	0.89 - 1.13
Anti-Measles	Single-Dose	195	885.01 (800.59-978.33)	200	885.26 (801.83-977.36)	Single-Dose/Typbar	1.00	0.87 - 1.15	1.00	0.87 - 1.15
	Multi-Dose	546	874.76 (823.87-928.79)	200	885.26 (801.83-977.36)	Multi-Dose/Typbar	0.99	0.88 - 1.11	0.99	0.88 - 1.11
Anti-Rubella	Single-Dose	192	24.69 (22.04-27.66)	200	24.08 (21.54-26.91)	Single-Dose/Typbar	1.03	0.88 - 1.20	1.03	0.87 - 1.20
	Multi-Dose	547	23.99 (22.43-25.66)	200	24.08 (21.54-26.91)	Multi-Dose/Typbar	1.00	0.87 - 1.13	1.00	0.88 - 1.13
Anti-Yellow Fever	Single-Dose	191	526.14 (398.99-693.81)	185	624.21 (471.19-826.92)	Single-Dose/Typbar	0.83	0.55 - 1.23	0.84	0.57 - 1.25
	Multi-Dose	527	507.96 (429.99-600.08)	185	624.21 (471.19-826.92)	Multi-Dose/Typbar	0.81	0.58 - 1.12	0.81	0.59 - 1.13

N: number of participants included in each treatment group (without missing values at Visit 4 (Day 29)).

95% CI: 95% Confidence Interval, GMT/C: Geometric Mean Titer/Concentration.

The adjusted and unadjusted GMT/C ratios and their 95% confidence intervals are calculated from the censored regression model using the log transformed titer/concentration as responses (Treatment group as fixed effect and site as covariate).

GMTs and GMFR from baseline of Anti-Vi serum IgG at 180 days post-vaccination either multi-dose and single-dose formulations of EuTCV or Typbar TCV® (immunogenicity subset)

Table 6: Seroconversion Rate and GMFR of Anti-Vi Antibody Concentrations at Each Post- Vaccination Timepoint Compared to Predose (Anti-Vi Subset of Per Protocol Population)

Treatment Cohort	Lot	Visit	N	Ratio Order	GMFR	95% CI	n	Seroconversion	
								%	95% CI
Single-dose EuTCV		Visit 5	188	V5/V2	32.67	28.17 - 37.90	184	97.9	94.64 - 99.42
Multi-dose EuTCV	1	Visit 5	181	V5/V2	32.88	27.96 - 38.66	173	95.6	91.48 - 98.07
	2	Visit 5	173	V5/V2	38.13	32.51 - 44.73	170	98.3	95.02 - 99.64
	3	Visit 5	170	V5/V2	35.71	30.65 - 41.61	166	97.6	94.09 - 99.36
	Total	Visit 5	524	V5/V2	35.47	32.38 - 38.85	509	97.1	95.32 - 98.39
Typbar TCV®		Visit 5	192	V5/V2	44.03	36.56 - 53.02	185	96.4	92.63 - 98.52

N: number of participants included in each treatment group (without missing values).

n: number of positive seroconversion participants, %: Percentage, GMFR: Geometric Mean Fold Rise.

95% CI: 95% Confidence Interval,

Ratios and their 95% confidence interval are calculated through t-distribution.

Seroconversion rates (fold rise ≥ 4) and their 95% confidence interval are calculated through Clopper-Pearson method.

Table 7: Anti-Vi Geometric Mean Concentrations (GMCs) at Predose (Day 1) and Visit 5 (Day 181) (Anti-Vi Subset of Per Protocol Population)

Visit	Group	Lot	N	GMC	95% CI	Median
Predose (Day 1)	Single-dose EuTCV		197	1.14	1.02 - 1.28	1.01
	Multi-dose EuTCV	1	190	0.99	0.88 - 1.11	1.00
		2	183	0.94	0.83 - 1.06	1.01

Visit	Group	Lot	N	GMC	95% CI	Median
Visit 5 (Day 181)	Typbar TCV [®]	3	180	1.00	0.88 - 1.12	1.01
		Total	553	0.98	0.91 - 1.04	1.00
			202	1.14	1.01 - 1.27	1.08
	Single-dose EuTCV		188	36.39	32.36 - 40.93	34.51
	Multi-dose EuTCV	1	181	33.41	29.64 - 37.66	36.35
		2	173	36.38	32.18 - 41.11	36.41
		3	170	35.69	31.54 - 40.38	34.95
		Total	524	35.12	32.80 - 37.62	35.91
	Typbar TCV [®]		192	48.95	43.58 - 54.98	47.23

N: number of participants included in each treatment group (without missing values), GMC: Geometric Mean Concentration, %: percentage, CI: Confidence Interval

GMCs and their 95% CIs are calculated from the censored regression model using the log transformed concentrations as responses (group as fixed effect and site as covariate).

Table 8: Non-inferiority Tests by GMT/C at Visit 5 (Day 181) (Per Protocol Population)

Group	EuTCV		Typbar TCV [®]		Ratio Order	GMT/C Ratio	
	N	GMT/C (95% CI)	N	GMT/C (95% CI)		Value	95% CI
Single-Dose	188	36.39 (33.04-40.09)	192	48.99 (44.52-53.91)	Single-Dose/Typbar	0.74	0.65 – 0.85
Multi-Dose	524	35.05 (33.08-37.14)	192	48.99 (44.52-53.91)	Multi-Dose/Typbar	0.72	0.34 – 0.80

N: number of participants included in each treatment group (without missing values), GMC: Geometric Mean Concentration, %: percentage, CI: Confidence Interval

GMCs and their 95% CIs are calculated from the censored regression model using the log transformed concentrations as responses (group as fixed effect and site as covariate).

GMTs of anti-Vi ELISA 28 days following a single dose of multi-dose vial EuTCV for the assessment of consistency of response across three lots of vaccine (immunogenicity subset)

Table 9: Lot-to-Lot Comparison of Anti-Vi GMCs at Visit 4 for Multi-Dose EuTCV Vial Formulation (Anti-Vi subset of Per Protocol Population)

GMC Ratio										
Lot	N	GMC	Lot	N	GMC	Ratio Order	Unadjusted		Adjusted	
							Ratio	95% CI	Ratio	95% CI
Lot 1	190	415.56 (373.22-462.69)	Lot 2	183	425.70 (381.56 - 474.95)	Lot1/Lot2	0.98	0.84 - 1.14	0.98	0.84 - 1.14
Lot 2	183	425.70 (381.56-474.95)	Lot 3	180	380.15 (340.42 - 424.53)	Lot2/Lot3	1.12	0.96 - 1.31	1.12	0.96 - 1.31
Lot 3	180	380.15 (340.42-424.53)	Lot 1	190	415.56 (373.22 - 462.69)	Lot3/Lot1	0.91	0.78 - 1.07	0.91	0.78 - 1.07

CI: confidence interval; %: Percentage, EuTCV: typhoid Vi-CRM197 Conjugate Vaccine; GMC: geometric mean conversion; GMT: geometric mean titer; N: number of participants included in each lot of multi-dose EuTCV (without missing values) at Visit 4

GMC, its ratio and 95% confidence interval are calculated from the censored regression model using the log transformed antibody titers as response (lot as fixed effect and site as covariate)

Percentage of participants with measles IgG seroconversion by ELISA 28 days following vaccination with either single-dose vial and multi-dose vial formulations of EuTCV or Typbar TCV®.(Measles seroconversion in initially seronegative infants will be defined as concentrations ≥ 200 mlU/mL) (immunogenicity subset)

Table 10: Comparison of post dose seropositivity rates of Measles concomitant vaccine between Single dose, Multi-dose EuTCV and Typbar TCV at Visit 4 (Day 29) (Per protocol population)

								Difference in % Seropositivity			
EuTCV				Typbar TCV			Difference Order	Unadjusted		Adjusted	
Group	N	n	Seropositivity Rate (%)	N	n	Seropositivity Rate (%)		Value	95% CI	Value	95% CI
Single-dose	195	187	95.90	200	195	97.50	Single-dose – Typbar	-1.60	-5.70 - 2.16	-1.58	-5.09 - 1.94
Multi-dose	546	521	95.42	200	195	97.50	Multi-dose – Typbar	-2.08	-4.69 - 1.41	-2.10	-4.87 – 0.68

N = number of participants included in each treatment group (without missing values) at visit 4 (Day 29), n, number of seropositive participants.

Post dose seropositivity are entirely based on the antibody concentration/titer at post dose time point regardless of their prior dose seropositivity status at baseline.

The adjusted and unadjusted differences in seroconversion rates and their 95% confidence intervals are calculated using Mantel-Haenszel and Miettinen-Nurminen methods respectively (site as covariate for adjusted differences).

Measles IgG GMC 28 days following vaccination with either single-dose vial and multi-dose vial formulations of EuTCV or Typbar TCV®(immunogenicity subset)

Table 11: Non-inferiority Tests by GMT/C at Visit 4 (Day 29) (Per Protocol Population)

Antibody	Group	EuTCV		Typbar TCV®		Ratio Order	GMT/C Ratio		Value	95% CI
		N	GMT/C (95% CI)	N	GMT/C (95% CI)		Unadjusted	Adjusted		
Anti-Measles	Single-Dose	195	885.01 (800.59-978.33)	200	885.26 (801.83-977.36)	Single-Dose/Typbar	1.00	0.87 - 1.15	1.00	0.87 - 1.15
	Multi-Dose	546	874.76 (823.87-928.79)	200	885.26 (801.83-977.36)	Multi-Dose/Typbar	0.99	0.88 - 1.11	0.99	0.88 - 1.11

N: number of participants included in each treatment group (without missing values at Visit 4 (Day 29)).

95% CI: 95% Confidence Interval, GMT/C: Geometric Mean Titer/Concentration.

The adjusted and unadjusted GMT/C ratios and their 95% confidence intervals are calculated from the censored regression model using the log transformed titer/concentration as responses (Treatment group as fixed effect and site as covariate).

Percentage of participants with rubella IgG seroconversion by ELISA 28 days following vaccination with either single-dose vial and multi-dose vial formulations of EuTCV or Typbar TCV®. (Rubella seroconversion in initially seronegative infants will be defined as concentrations ≥ 10 IU/mL) (immunogenicity subset)

Table 12: Comparison of post dose seropositivity rates of rubella concomitant vaccine between Single dose, Multi-dose EuTCV and Typbar TCV at Visit 4 (Day 29) (Per protocol population)

							Difference in % Seropositivity				
EuTCV				Typbar TCV			Unadjusted		Adjusted		
Group	N	n	Seropositivity Rate (%)	N	n	Seropositivity Rate (%)	Difference Order	Value	95% CI	Value	95% CI
Single-dose	192	167	86.98	200	177	88.50	Single-dose – Typbar	-1.52	-8.20 – 5.06	-1.55	-8.04 - 4.94
Multi-dose	547	475	86.84	200	177	88.50	Multi-dose – Typbar	-1.66	-6.55 – 4.10	-1.65	-6.90 – 3.60

N = number of participants included in each treatment group (without missing values) at visit 4 (Day 29), n, number of seropositive participants.

Post dose seropositivity are entirely based on the antibody concentration/titer at post dose time point regardless of their prior dose seropositivity status at baseline.

The adjusted and unadjusted differences in seroconversion rates and their 95% confidence intervals are calculated using Mantel-Haenszel and Miettinen-Nurminen methods respectively (site as covariate for adjusted differences).

Rubella IgG GMCs 28 days following vaccination with either single-dose vial and multi-dose vial formulations of EuTCV or Typbar TCV® (immunogenicity subset)

Table 13: Non-inferiority Tests by GMT/C at Visit 4 (Day 29) (Per Protocol Population)

Antibody	Group	EuTCV		Typbar TCV®		Ratio Order	GMT/C Ratio		Value	95% CI
		N	GMT/C (95% CI)	N	GMT/C (95% CI)		Unadjusted	Adjusted		
Anti-Rubella	Single-Dose	192	24.69 (22.04-27.66)	200	24.08 (21.54-26.91)	Single-Dose/Typbar	1.03	0.88 - 1.20	1.03	0.87 - 1.20
	Multi-Dose	547	23.99 (22.43-25.66)	200	24.08 (21.54-26.91)	Multi-Dose/Typbar	1.00	0.87 - 1.13	1.00	0.88 - 1.13

N: number of participants included in each treatment group (without missing values at Visit 4 (Day 29)).

95% CI: 95% Confidence Interval, GMT/C: Geometric Mean Titer/Concentration.

The adjusted and unadjusted GMT/C ratios and their 95% confidence intervals are calculated from the censored regression model using the log transformed titer/concentration as responses (Treatment group as fixed effect and site as covariate).

Percentage of participants with yellow fever neutralizing antibody seroconversion 28 days following vaccination with either single-dose vial and multi-dose vial formulations of EuTCV or TypbarTCV® (YFV seroconversion is defined as a reciprocal 50% plaque reduction neutralization titer (PRNT50) of ≥ 10 among those participants negative (PRNT50 < 10) at baseline) (immunogenicity subset)

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Table 14: Comparison of post dose seropositivity rates of yellow fever concomitant vaccine between Single dose, Multi-dose EuTCV and Typbar TCV at Visit 4 (Day 29) (Per protocol population)

								Difference in % Seropositivity			
EuTCV				Typbar TCV				Unadjusted		Adjusted	
Group	N	n	Seropositivity Rate (%)	N	n	Seropositivity Rate (%)	Difference Order	Value	95% CI	Value	95% CI
Single-dose	191	182	95.29	185	181	97.84	Single-dose – Typbar	-2.55	-6.83 - 1.32	-2.52	-6.18 - 1.14
Multi-dose	527	511	96.96	185	181	97.84	Multi-dose – Typbar	-0.87	-3.20 - 2.56	-0.83	-3.38 – 1.72

N = number of participants included in each treatment group (without missing values) at visit 4 (Day 29), n, number of seropositive participants.

Post dose seropositivity are entirely based on the antibody concentration/titer at post dose time point regardless of their prior dose seropositivity status at baseline.

The adjusted and unadjusted differences in seroconversion rates and their 95% confidence intervals are calculated using Mantel-Haenszel and Miettinen-Nurminen methods respectively (site as covariate for adjusted differences).

Safety Results:**Table 15: Overall Safety Profile by Treatment – Full Analysis Population**

n (%) [CI]	Multi-dose Vial EuTCV (N=1630)	Single-dose Vial EuTCV (N=1266)	Typbar TCV® (N=323)	Total (N=3219)
Number of Local Solicited Adverse Events	481	464	102	1047
Number of Participants with any Local Solicited Adverse Events	442 (27.1%) [25.0-29.3]	422 (33.3%) [30.7-36.0]	92 (28.5%) [23.6-33.7]	956 (29.7%) [28.1-31.3]
Number of Systemic Solicited Adverse Events	1324	1062	245	2631
Number of Participants with any Systemic Solicited Adverse Events	617 (37.9%) [35.5-40.3]	500 (39.5%) [36.8-42.2]	127 (39.3%) [34.0-44.9]	1244 (38.6%) [37.0-40.4]
Number of Unsolicited Adverse Events	1356	904	239	2499
Number of Participants with any Unsolicited Adverse Events	744 (45.6%) [43.2-48.1]	529 (41.8%) [39.1-44.6]	138 (42.7%) [37.3-48.3]	1411 (43.8%) [42.1-45.6]
Number of Medically Attended Adverse Events	1133	728	213	2074
Number of Participants with any Medically Attended Adverse Events	633 (38.8%) [36.5-41.2]	420 (33.2%) [30.6-35.8]	128 (39.6%) [34.3-45.2]	1181 (36.7%) [35.0-38.4]
Number of Adverse Drug Reactions	2279	1965	445	4689
Number of Participants with any Adverse Drug Reactions (ADRs)	777 (47.7%) [45.2-50.1]	666 (52.6%) [49.8-55.4]	159 (49.2%) [43.6-54.8]	1602 (49.8%) [48.0-51.5]
Number of Serious Adverse Events	5	6	5	16
Number of Participants with any Serious Adverse Events	5 (0.3%) [0.1-0.7]	5 (0.4%) [0.1-0.9]	4 (1.2%) [0.3-3.1]	14 (0.4%) [0.2-0.7]
Number of Non-SAEs (Solicited or Unsolicited)	3597	2848	671	7116

n (%) [CI]	Multi-dose Vial EuTCV (N=1630)	Single-dose Vial EuTCV (N=1266)	Typbar TCV® (N=323)	Total (N=3219)
Number of Participants with any Non-SAEs (Solicited or Unsolicited)	1141 (70.0%) [67.7-72.2]	915 (72.3%) [69.7-74.7]	221 (68.4%) [63.0-73.5]	2277 (70.7%) [69.1-72.3]
Number of Unsolicited Adverse Events Related to Study Treatment	33	15	8	56
Number of Participants with any Unsolicited Adverse Events Related to Study Treatment	29 (1.8%) [1.2-2.5]	14 (1.1%) [0.6-1.8]	7 (2.2%) [0.9-4.4]	50 (1.6%) [1.2-2.0]

EuTCV: typhoid Vi-CRM197 conjugate vaccine; N: total number of participants in each cohort; n: number of participants in each category; Typbar TCV® : typhoid Vi- tetanus toxoid conjugate vaccine

Cohort 1: 18≤age≤45 yrs; Cohort 2: 2≤age<18 yrs; Cohort 3: 9≤age≤12 months; Cohort 4: 6≤age<9 months and 12<age<24 months. Denominator of percentage is number of participants randomized and received the vaccine.

Note: All single-dose or multi-dose groups from 4 cohorts are combined even though group 3 participants also receive Measles, Rubella or Yellow Fever vaccine at the same time.

All confidence intervals are two-sided 95% via Clopper-Pearson method.

Adverse Drug Reactions (ADRs) include solicited adverse events and unsolicited adverse events related to study treatment.

The ADR event of 'Pain or Tenderness' is counted as two separate events of 'Pain' and 'Tenderness' respectively.

The ADR event of 'Swelling/Induration' is each counted as two separate events of 'Swelling' and 'Induration' respectively.