Clinical trial results:
A Double-Blind, Randomized, Placebo-Controlled, Age Descending and Expansion Phase 2 Study to Investigate the Safety and Immunogenicity of a Tetravalent Chimeric Dengue Vaccine in Healthy Volunteers Between the Ages of 1.5 - 45 Years

Summary

EudraCT number	2022-003455-33
Trial protocol	Outside EU/EEA
Global end of trial date	15 April 2016

Results information

Result version number	v2 (current)
This version publication date	26 May 2023
First version publication date	26 January 2023
Version creation reason	
Summary attachment (see zip file)	Additional Endpoints (INV-DEN-203 EudraCT Summary attachment for Endpoints not included with Full Data Set.docx)

Trial information

Trial identification

Sponsor protocol code	INV-DEN-203

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01511250
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Takeda
Sponsor organisation address	95 Hayden Avenue, Lexington, United States, MA 02421
Public contact	Study Director, Takeda, TrialDisclosures@takeda.com
Scientific contact	Study Director, Takeda, TrialDisclosures@takeda.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	15 April 2016
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	15 April 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is to assess the immunogenicity, safety and tolerability of Takeda's tetravalent dengue vaccine (TDV) (previously wild-type dengue virus vaccine [DENVax]) administered subcutaneously in healthy adults and children. In addition, the antibody response to the four dengue virus serotypes will be evaluated.

Protection of trial subjects:

All study participants were required to read and sign an Informed Consent Form. Assent is also obtained from the study participant where required.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 November 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Colombia: 47
Country: Number of subjects enrolled	Puerto Rico: 136
Country: Number of subjects enrolled	Singapore: 53
Country: Number of subjects enrolled	Thailand: 124
Worldwide total number of subjects	360
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	4
Children (2-11 years)	282
Adolescents (12-17 years)	23
Adults (18-64 years)	51

From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants took part in the study at 8 investigative sites in Puerto Rico, Colombia, Singapore and Thailand from 16 November 2011 to 15 April 2016. Healthy participants were enrolled in this study in 2-parts.

Pre-assignment

Screening details:

Participants received 0.5 mL TDV or placebo in 1 of 4 groups for Part1:21-45,12-20,6-11,1.5-5 years, and in 1 group for Part II:1.5-11 years. Part1 was in participants whose safety data for at least 28 days after first dose in each preceding age cohort, 12 and 24 participants in 1.5 to 5 years of age were evaluated and were safe to continue Part2.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Part I: TDV 21 to 45 Years

Arm description:

TDV 0.5 mL, injection, SC, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 21 to 45 years. TDV comprised of 4 recombinant, live attenuated dengue virus strains: TDV-1, TDV-2, TDV-3 and TDV-4 containing 2*10^4 plaque forming units (PFU), 5*10^4 PFU, 1*10^5 PFU, and 3*10^5 PFU respectively, total virus per dose: 4.7*10^5 PFU.

Arm type	Experimental
Investigational medicinal product name	Dengue Tetravalent Vaccine (Live, Attenuated)
Investigational medicinal product code	TAK-003
Other name	TDV
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

TDV 0.5 mL, injection, subcutaneously, once on Day 0 (first dose) and Day 90 (second dose).

Arm title	Part I: Placebo 21 to 45 Years

Arm description:

TDV placebo-matching 0.5 mL injection, SC, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 21 to 45 years.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

TDV placebo-matching 0.5 mL injection, subcutaneously, once on Day 0 (first dose) and Day 90 (second dose).

Arm title	Part I: TDV 12 to 20 Years

Arm description:

TDV 0.5 mL, injection, SC, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 12

to 20 years. TDV comprised of 4 recombinant, live attenuated dengue virus strains: TDV-1, TDV-2, TDV-3 and TDV-4 containing 2*10^4 PFU, 5*10^4 PFU, 1*10^5 PFU, and 3*10^5 PFU respectively, total virus per dose: 4.7*10^5 PFU.

Arm type	Experimental
Investigational medicinal product name	Dengue Tetravalent Vaccine (Live, Attenuated)
Investigational medicinal product code	TAK-003
Other name	TDV
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

TDV 0.5 mL, injection, subcutaneously, once on Day 0 (first dose) and Day 90 (second dose).

Arm title	Part I: Placebo 12 to 20 Years

Arm description:

TDV placebo-matching 0.5 mL injection, SC, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 12 to 20 years.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

TDV placebo-matching 0.5 mL injection, subcutaneously, once on Day 0 (first dose) and Day 90 (second dose).

Arm title	Part I: TDV 6 to 11 Years

Arm description:

TDV 0.5 mL, injection, SC, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 6 to 11 years. TDV comprised of 4 recombinant, live attenuated dengue virus strains: TDV-1, TDV-2, TDV-3 and TDV-4 containing 2*10^4 PFU, 5*10^4 PFU, 1*10^5 PFU, and 3*10^5 PFU respectively, total virus per dose: 4.7*10^5 PFU.

Arm type	Experimental
Investigational medicinal product name	Dengue Tetravalent Vaccine (Live, Attenuated)
Investigational medicinal product code	TAK-003
Other name	TDV
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

TDV 0.5 mL, injection, subcutaneously, once on Day 0 (first dose) and Day 90 (second dose).

Arm title	Part I: Placebo 6 to 11 Years

Arm description:

TDV placebo-matching 0.5 mL injection, SC, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 6 to 11 years.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

TDV placebo-matching 0.5 mL injection, subcutaneously, once on Day 0 (first dose) and Day 90 (second dose).

Arm title	Part I: TDV 1.5 to 5 Years

Arm description:

TDV 0.5 mL, injection, SC, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 1.5 to 5 years. TDV comprised of 4 recombinant, live attenuated dengue virus strains: TDV-1, TDV-2, TDV-3 and TDV-4 containing 2*10^4 PFU, 5*10^4 PFU, 1*10^5 PFU, and 3*10^5 PFU respectively, total virus per dose: 4.7*10^5 PFU.

Arm type	Experimental
Investigational medicinal product name	Dengue Tetravalent Vaccine (Live, Attenuated)
Investigational medicinal product code	TAK-003
Other name	TDV
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

TDV 0.5 mL, injection, subcutaneously, once on Day 0 (first dose) and Day 90 (second dose).

Arm title	Part I: Placebo 1.5 to 5 Years

Arm description:

TDV placebo-matching 0.5 mL injection, SC, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 1.5 to 5 years.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

TDV placebo-matching 0.5 mL injection, subcutaneously, once on Day 0 (first dose) and Day 90 (second dose).

Arm title	Part II: TDV 1.5 to 11 Years

Arm description:

TDV 0.5 mL, injection, SC, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 1.5 to 11 years. TDV comprised of 4 recombinant, live attenuated dengue virus strains: TDV-1, TDV-2, TDV-3 and TDV-4 containing 2*10^4 PFU, 5*10^4 PFU, 1*10^5 PFU, and 3*10^5 PFU respectively, total virus per dose: 4.7*10^5 PFU.

Arm type	Experimental
Investigational medicinal product name	Dengue Tetravalent Vaccine (Live, Attenuated)
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Other name	TDV
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

TDV 0.5 mL, injection, subcutaneously, once on Day 0 (first dose) and Day 90 (second dose).

Arm title	Part II: Placebo 1.5 to 11 Years

Arm description:

TDV placebo-matching 0.5 mL injection, SC, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 1.5 to 5 years.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

TDV placebo-matching 0.5 mL injection, subcutaneously, once on Day 0 (first dose) and Day 90 (second dose).

Number of subjects in period 1	Part I: TDV 21 to 45 Years	Part I: Placebo 21 to 45 Years	Part I: TDV 12 to 20 Years
Started	24	14	22
Completed	15	9	18
Not completed	9	5	4
Withdrawal of Consent	1	-	-
Lost to follow-up	7	3	3
Sponsor/Investigator Decision	1	-	-
Protocol deviation	-	2	1

Number of subjects in period 1	Part I: Placebo 12 to 20 Years	Part I: TDV 6 to 11 Years	Part I: Placebo 6 to 11 Years
Started	14	21	17
Completed	11	21	17
Not completed	3	0	0
Withdrawal of Consent	-	-	-
Lost to follow-up	3	-	-
Sponsor/Investigator Decision	-	-	-
Protocol deviation	-	-	-

Number of subjects in period 1	Part I: TDV 1.5 to 5 Years	Part I: Placebo 1.5 to 5 Years	Part II: TDV 1.5 to 11 Years
Started	23	13	159
Completed	21	9	145
Not completed	2	4	14
Withdrawal of Consent	-	1	1
Lost to follow-up	2	3	13
Sponsor/Investigator Decision	-	-	-
Protocol deviation	-	-	-

Number of subjects in period 1	Part II: Placebo 1.5 to 11 Years
Started	53
Completed	48
Not completed	5
Withdrawal of Consent	-
Lost to follow-up	5
Sponsor/Investigator Decision	-
Protocol deviation	-

Baseline characteristics

Reporting groups

Reporting group title	Part I: TDV 21 to 45 Years
Reporting group description:	
TDV 0.5 mL, injection, SC, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 21 to 45 years. TDV comprised of 4 recombinant, live attenuated dengue virus strains: TDV-1, TDV-2, TDV-3 and TDV-4 containing 2*10^4 plaque forming units (PFU), 5*10^4 PFU, 1*10^5 PFU, and 3*10^5 PFU respectively, total virus per dose: 4.7*10^5 PFU.	
Reporting group title	Part I: Placebo 21 to 45 Years
Reporting group description:	
TDV placebo-matching 0.5 mL injection, SC, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 21 to 45 years.	
Reporting group title	Part I: TDV 12 to 20 Years
Reporting group description:	
TDV 0.5 mL, injection, SC, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 12 to 20 years. TDV comprised of 4 recombinant, live attenuated dengue virus strains: TDV-1, TDV-2, TDV-3 and TDV-4 containing 2*10^4 PFU, 5*10^4 PFU, 1*10^5 PFU, and 3*10^5 PFU respectively, total virus per dose: 4.7*10^5 PFU.	
Reporting group title	Part I: Placebo 12 to 20 Years
Reporting group description:	
TDV placebo-matching 0.5 mL injection, SC, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 12 to 20 years.	
Reporting group title	Part I: TDV 6 to 11 Years
Reporting group description:	
TDV 0.5 mL, injection, SC, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 6 to 11 years. TDV comprised of 4 recombinant, live attenuated dengue virus strains: TDV-1, TDV-2, TDV-3 and TDV-4 containing 2*10^4 PFU, 5*10^4 PFU, 1*10^5 PFU, and 3*10^5 PFU respectively, total virus per dose: 4.7*10^5 PFU.	
Reporting group title	Part I: Placebo 6 to 11 Years
Reporting group description:	
TDV placebo-matching 0.5 mL injection, SC, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 6 to 11 years.	
Reporting group title	Part I: TDV 1.5 to 5 Years
Reporting group description:	
TDV 0.5 mL, injection, SC, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 1.5 to 5 years. TDV comprised of 4 recombinant, live attenuated dengue virus strains: TDV-1, TDV-2, TDV-3 and TDV-4 containing 2*10^4 PFU, 5*10^4 PFU, 1*10^5 PFU, and 3*10^5 PFU respectively, total virus per dose: 4.7*10^5 PFU.	
Reporting group title	Part I: Placebo 1.5 to 5 Years
Reporting group description:	
TDV placebo-matching 0.5 mL injection, SC, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 1.5 to 5 years.	
Reporting group title	Part II: TDV 1.5 to 11 Years
Reporting group description:	
TDV 0.5 mL, injection, SC, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 1.5 to 11 years. TDV comprised of 4 recombinant, live attenuated dengue virus strains: TDV-1, TDV-2, TDV-3 and TDV-4 containing 2*10^4 PFU, 5*10^4 PFU, 1*10^5 PFU, and 3*10^5 PFU respectively, total virus per dose: 4.7*10^5 PFU.	
Reporting group title	Part II: Placebo 1.5 to 11 Years
Reporting group description:	
TDV placebo-matching 0.5 mL injection, SC, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 1.5 to 5 years.	

Reporting group values	Part I: TDV 21 to 45 Years	Part I: Placebo 21 to 45 Years	Part I: TDV 12 to 20 Years
Number of subjects	24	14	22
Age Categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	29.2	30.1	15.5
full range (min-max)	21.0 to 45.0	21.0 to 40.0	12.0 to 19.0
Gender categorical			
Units: Subjects			
Male	14	6	10
Female	10	8	12
Race			
Units: Subjects			
Asian	3	3	16
Hispanic or Latino	20	10	6
White	1	1	0
Black or African American	0	0	0
Seropositive to any Serotype at Day 0			
Seropositivity is defined as a reciprocal neutralising titer measured by a microneutralising test 50% (MNT50) greater or equal to (≥)10.			
Units: Subjects			
Seropositive to any Serotype=No	5	2	7
Seropositive to any Serotype=Yes	19	12	15
Height			
Units: meters (m)			
arithmetic mean	1.68	1.65	1.58
full range (min-max)	1.57 to 1.82	1.53 to 1.87	1.38 to 1.72
Weight			
Units: kilograms (kg)			
arithmetic mean	81.6	80.2	57.0
full range (min-max)	41.4 to 115.1	56.3 to 120.4	28.6 to 93.4
Body Mass Index (BMI)			
Units: kg/m^2			
arithmetic mean	28.81	29.05	22.60
full range (min-max)	14.70 to 41.30	21.30 to 38.70	15.00 to 33.60

Reporting group values	Part I: Placebo 12 to 20 Years	Part I: TDV 6 to 11 Years	Part I: Placebo 6 to 11 Years
Number of subjects	14	21	17
Age Categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	16.8	8.4	7.8
full range (min-max)	12.0 to 20.0	6.0 to 11.0	6.0 to 11.0
Gender categorical			
Units: Subjects			
Male	7	15	9

Female	7	6	8

Race Units: Subjects			
Asian	8	16	12
Hispanic or Latino	6	4	5
White	0	1	0
Black or African American	0	0	0
Seropositive to any Serotype at Day 0			
Seropositivity is defined as a reciprocal neutralising titer measured by a microneutralising test 50% (MNT50) greater or equal to (≥)10.			
Units: Subjects			
Seropositive to any Serotype=No	1	12	14
Seropositive to any Serotype=Yes	13	9	3
Height Units: meters (m)			
arithmetic mean	1.60	1.29	1.27
full range (min-max)	1.41 to 1.73	1.08 to 1.52	1.13 to 1.42
Weight Units: kilograms (kg)			
arithmetic mean	59.5	31.2	27.0
full range (min-max)	48.6 to 89.9	18.5 to 51.2	20.3 to 37.5
Body Mass Index (BMI) Units: kg/m^2			
arithmetic mean	23.09	18.38	16.56
full range (min-max)	18.60 to 31.50	12.90 to 28.80	14.20 to 20.60

Reporting group values	Part I: TDV 1.5 to 5 Years	Part I: Placebo 1.5 to 5 Years	Part II: TDV 1.5 to 11 Years
Number of subjects	23	13	159
Age Categorical Units: Subjects			

Age continuous Units: years			
arithmetic mean	3.3	3.5	6.6
full range (min-max)	1.5 to 5.0	2.3 to 5.0	1.6 to 11.0
Gender categorical Units: Subjects			
Male	16	6	71
Female	7	7	88
Race Units: Subjects			
Asian	12	6	77
Hispanic or Latino	11	7	79
White	0	0	0
Black or African American	0	0	3
Seropositive to any Serotype at Day 0			
Seropositivity is defined as a reciprocal neutralising titer measured by a microneutralising test 50% (MNT50) greater or equal to (≥)10.			
Units: Subjects			

Seropositive to any Serotype=No	16	12	93
Seropositive to any Serotype=Yes	7	1	66

Height			
Units: meters (m)			
arithmetic mean	0.98	0.99	1.20
full range (min-max)	0.83 to 1.13	0.90 to 1.06	0.77 to 1.62
Weight			
Units: kilograms (kg)			
arithmetic mean	15.1	16.5	25.7
full range (min-max)	10.3 to 22.2	13.3 to 20.8	10.4 to 61.0
Body Mass Index (BMI)			
Units: kg/m^2			
arithmetic mean	15.63	16.95	17.02
full range (min-max)	12.50 to 19.00	13.20 to 20.40	12.10 to 30.10

Reporting group values	Part II: Placebo 1.5 to 11 Years	Total	
Number of subjects	53	360	
Age Categorical			
Units: Subjects			

Age continuous			
Units: years			
arithmetic mean	6.8		
full range (min-max)	2.1 to 11.0	-	
Gender categorical			
Units: Subjects			
Male	34	188	
Female	19	172	
Race			
Units: Subjects			
Asian	24	177	
Hispanic or Latino	27	175	
White	0	3	
Black or African American	2	5	
Seropositive to any Serotype at Day 0			
Seropositivity is defined as a reciprocal neutralising titer measured by a microneutralising test 50% (MNT50) greater or equal to (≥)10.			
Units: Subjects			
Seropositive to any Serotype=No	24	186	
Seropositive to any Serotype=Yes	29	174	
Height			
Units: meters (m)			
arithmetic mean	1.22		
full range (min-max)	0.83 to 1.63	-	
Weight			
Units: kilograms (kg)			
arithmetic mean	26.7		
full range (min-max)	10.6 to 53.2	-	
Body Mass Index (BMI)			
Units: kg/m^2			

arithmetic mean	17.08		
full range (min-max)	13.20 to 24.30	-	

End points

End points reporting groups

Reporting group title	Part I: TDV 21 to 45 Years
Reporting group description:	
TDV 0.5 mL, injection, SC, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 21 to 45 years. TDV comprised of 4 recombinant, live attenuated dengue virus strains: TDV-1, TDV-2, TDV-3 and TDV-4 containing 2*10^4 plaque forming units (PFU), 5*10^4 PFU, 1*10^5 PFU, and 3*10^5 PFU respectively, total virus per dose: 4.7*10^5 PFU.	
Reporting group title	Part I: Placebo 21 to 45 Years
Reporting group description:	
TDV placebo-matching 0.5 mL injection, SC, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 21 to 45 years.	
Reporting group title	Part I: TDV 12 to 20 Years
Reporting group description:	
TDV 0.5 mL, injection, SC, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 12 to 20 years. TDV comprised of 4 recombinant, live attenuated dengue virus strains: TDV-1, TDV-2, TDV-3 and TDV-4 containing 2*10^4 PFU, 5*10^4 PFU, 1*10^5 PFU, and 3*10^5 PFU respectively, total virus per dose: 4.7*10^5 PFU.	
Reporting group title	Part I: Placebo 12 to 20 Years
Reporting group description:	
TDV placebo-matching 0.5 mL injection, SC, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 12 to 20 years.	
Reporting group title	Part I: TDV 6 to 11 Years
Reporting group description:	
TDV 0.5 mL, injection, SC, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 6 to 11 years. TDV comprised of 4 recombinant, live attenuated dengue virus strains: TDV-1, TDV-2, TDV-3 and TDV-4 containing 2*10^4 PFU, 5*10^4 PFU, 1*10^5 PFU, and 3*10^5 PFU respectively, total virus per dose: 4.7*10^5 PFU.	
Reporting group title	Part I: Placebo 6 to 11 Years
Reporting group description:	
TDV placebo-matching 0.5 mL injection, SC, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 6 to 11 years.	
Reporting group title	Part I: TDV 1.5 to 5 Years
Reporting group description:	
TDV 0.5 mL, injection, SC, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 1.5 to 5 years. TDV comprised of 4 recombinant, live attenuated dengue virus strains: TDV-1, TDV-2, TDV-3 and TDV-4 containing 2*10^4 PFU, 5*10^4 PFU, 1*10^5 PFU, and 3*10^5 PFU respectively, total virus per dose: 4.7*10^5 PFU.	
Reporting group title	Part I: Placebo 1.5 to 5 Years
Reporting group description:	
TDV placebo-matching 0.5 mL injection, SC, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 1.5 to 5 years.	
Reporting group title	Part II: TDV 1.5 to 11 Years
Reporting group description:	
TDV 0.5 mL, injection, SC, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 1.5 to 11 years. TDV comprised of 4 recombinant, live attenuated dengue virus strains: TDV-1, TDV-2, TDV-3 and TDV-4 containing 2*10^4 PFU, 5*10^4 PFU, 1*10^5 PFU, and 3*10^5 PFU respectively, total virus per dose: 4.7*10^5 PFU.	
Reporting group title	Part II: Placebo 1.5 to 11 Years
Reporting group description:	
TDV placebo-matching 0.5 mL injection, SC, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 1.5 to 5 years.	
Subject analysis set title	c vbxcv
Subject analysis set type	Full analysis

Subject analysis set description:

xcvbxc

Primary: Number of Participants With Solicited Local (Injection Site) Adverse Events (AEs) (Diary-Recorded) Following Either Vaccination Dose by Severity

End point title	Number of Participants With Solicited Local (Injection Site) Adverse Events (AEs) (Diary-Recorded) Following Either Vaccination Dose by Severity[1]

End point description:

Solicited local injection site reactions were collected by subject diary and graded based on the Common Terminology Criteria for Adverse Events (CTCAE), Version 4.03 for pain [Grade 0 (no pain), 1 (mild), 2 (moderate) and 3 (severe)] and itching (pruritus) [Grade 0 (no itching), 1 (mild), 2 (moderate) and 3 (Severe]. Severity grade for redness (erythema) and swelling (edema/induration) were derived from recorded length of the longest diameter measurement using the FDA Guidance for Industry: Toxicity Grading Scale of Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trial were Grade 0 (<2.5 cm), 1 (mild: 2.5-5 cm), 2 (moderate: 5.1-10 cm) and 3 (severe: >10 cm) and Grade 4 (Potentially Life-threatening: necrosis or exfoliative dermatitis). The safety set included all randomised participants who received at least one dose of study vaccine (or placebo). Only severity categories for which there was at least 1 participant are reported.

End point type	Primary

End point timeframe:

Within 14 days after either of the vaccination given on Day 0 or 90 (Day 14 for first vaccination, Day 104 for second vaccination)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Number of participants is the analysis defined in the description.

End point values	Part I: TDV 21 to 45 Years	Part I: Placebo 21 to 45 Years	Part I: TDV 12 to 20 Years	Part I: Placebo 12 to 20 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	14	22	14
Units: participants				
Pain, Any Severity	7	0	14	3
Pain, Grade 1	7	0	11	2
Pain, Grade 2	0	0	3	1
Pain, Grade 3	0	0	0	0
Itching, Any Severity	3	1	7	1
Itching, Grade 1	3	1	7	1
Itching, Grade 2	0	0	0	0
Itching, Grade 3	0	0	0	0
Erythema, Any Severity	6	0	4	0
Erythema, Grade 1	5	0	4	0
Erythema, Grade 2	1	0	0	0
Erythema, Grade 3	0	0	0	0
Edema, Any Severity	0	0	1	0
Edema, Grade 1	0	0	1	0
Edema, Grade 2	0	0	0	0
Edema, Grade 3	0	0	0	0

End point values	Part I: TDV 6 to 11 Years	Part I: Placebo 6 to 11 Years	Part I: TDV 1.5 to 5 Years	Part I: Placebo 1.5 to 5 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	17	23	13

Units: participants				
Pain, Any Severity	9	0	7	2
Pain, Grade 1	4	0	7	2
Pain, Grade 2	4	0	0	0
Pain, Grade 3	1	0	0	0
Itching, Any Severity	2	1	2	0
Itching, Grade 1	1	1	2	0
Itching, Grade 2	1	0	0	0
Itching, Grade 3	0	0	0	0
Erythema, Any Severity	2	0	3	0
Erythema, Grade 1	1	0	3	0
Erythema, Grade 2	0	0	0	0
Erythema, Grade 3	1	0	0	0
Edema, Any Severity	3	0	1	0
Edema, Grade 1	3	0	1	0
Edema, Grade 2	0	0	0	0
Edema, Grade 3	0	0	0	0

End point values	Part II: TDV 1.5 to 11 Years	Part II: Placebo 1.5 to 11 Years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	159	53		
Units: participants				
Pain, Any Severity	56	6		
Pain, Grade 1	41	3		
Pain, Grade 2	11	3		
Pain, Grade 3	4	0		
Itching, Any Severity	26	4		
Itching, Grade 1	19	3		
Itching, Grade 2	6	1		
Itching, Grade 3	1	0		
Erythema, Any Severity	24	1		
Erythema, Grade 1	21	0		
Erythema, Grade 2	2	0		
Erythema, Grade 3	1	1		
Edema, Any Severity	13	0		
Edema, Grade 1	9	0		
Edema, Grade 2	3	0		
Edema, Grade 3	1	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Solicited Local (Injection Site) Adverse Events (AEs) (In Clinic Assessment) Following Either Vaccination Dose by Severity

End point title	Number of Participants With Solicited Local (Injection Site)

	Adverse Events (AEs) (In Clinic Assessment) Following Either Vaccination Dose by Severity[2]

End point description:

Solicited local injection site reactions were collected by subject diary and graded based on the Common Terminology Criteria for Adverse Events (CTCAE), Version 4.03 for pain [Grade 0 (no pain), 1 (mild), 2 (moderate) and 3 (severe)] and itching (pruritus) [Grade 0 (no itching), 1 (mild), 2 (moderate) and 3 (Severe]. Severity grade for redness (erythema) and swelling (edema/induration) were derived from recorded length of the longest diameter measurement using the FDA Guidance for Industry: Toxicity Grading Scale of Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trial were Grade 0 (<2.5 cm), 1 (mild: 2.5-5 cm), 2 (moderate: 5.1-10 cm) and 3 (severe: >10 cm) and Grade 4 (Potentially Life-threatening: necrosis or exfoliative dermatitis). The safety set included all randomised participants who received at least one dose of study vaccine (or placebo). Only severity categories for which there was at least 1 participant are reported.

End point type	Primary

End point timeframe:

Within 28 days after either of the vaccination given on Day 0 or 90 (Day 28 for first vaccination, Day 118 for second vaccination)

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Number of participants is the analysis defined in the description.

End point values	Part I: TDV 21 to 45 Years	Part I: Placebo 21 to 45 Years	Part I: TDV 12 to 20 Years	Part I: Placebo 12 to 20 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	14	22	14
Units: participants				
Pain, Any Severity	2	0	4	2
Pain, Grade 1	2	0	3	2
Pain, Grade 2	0	0	1	0
Itching, Any Severity	2	2	2	1
Itching, Grade 1	2	2	2	1
Erythema, Any Severity	0	0	0	0
Edema, Any Severity	0	0	0	0

End point values	Part I: TDV 6 to 11 Years	Part I: Placebo 6 to 11 Years	Part I: TDV 1.5 to 5 Years	Part I: Placebo 1.5 to 5 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	17	23	13
Units: participants				
Pain, Any Severity	9	5	5	1
Pain, Grade 1	9	5	5	1
Pain, Grade 2	0	0	0	0
Itching, Any Severity	1	1	1	0
Itching, Grade 1	1	1	1	0
Erythema, Any Severity	0	0	0	0
Edema, Any Severity	0	0	0	0

End point values	Part II: TDV 1.5 to 11 Years	Part II: Placebo 1.5 to 11 Years		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	159	53		
Units: participants				
Pain, Any Severity	33	14		
Pain, Grade 1	28	13		
Pain, Grade 2	3	1		
Itching, Any Severity	4	5		
Itching, Grade 1	4	5		
Erythema, Any Severity	0	0		
Edema, Any Severity	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Solicited Systemic Adverse Events (AEs) (Diary-Recorded) Following Either Vaccination Dose by Severity

End point title	Number of Participants With Solicited Systemic Adverse Events (AEs) (Diary-Recorded) Following Either Vaccination Dose by Severity[3]

End point description:

Solicited systemic AEs (headache, muscle pain [myalgia], joint pain [arthralgia], eye pain, sensitivity to light [photophobia], tiredness [fatigue], body rash, nausea:recorded in participant's-diary with vomiting [number of times]), body temperature). Diary-recorded severity grades:based on Common Terminology Criteria for Adverse Events (CTCAE). Severity grades:Mild(Grade 1):transient symptoms, discomfort noticed but was easily tolerated by participant with no interference to normal daily activities. Moderate(Grade 2):marked symptoms, moderate interference with participant's daily activities. Severe(Grade 3):Considerable interference with participant's daily activities.CTCAE severity grades for fever and vomiting:derived from diary-recorded measurements of temperature level, number of episodes, respectively.Safety set:all randomised participants who received at least one dose of study vaccine(or placebo).Only severity categories for which there was at least 1 participant are reported.

End point type	Primary

End point timeframe:

Within 14 days after either of the vaccination given on Day 0 or 90 (Day 14 for first vaccination, Day 104 for second vaccination)

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Number of participants is the analysis defined in the description.

End point values	Part I: TDV 21 to 45 Years	Part I: Placebo 21 to 45 Years	Part I: TDV 12 to 20 Years	Part I: Placebo 12 to 20 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	14	22	14
Units: participants				
Fever, Any Severity	1	3	4	1
Fever, Grade 1	0	1	4	1
Fever, Grade 2	1	2	0	0
Fever, Grade 3	0	0	0	0
Headache, Any Grade	6	4	9	8
Headache, Grade 1	3	1	4	5
Headache, Grade 2	2	2	5	3
Headache, Grade 3	1	1	0	0

Myalgia, Any Severity	4	3	4	5
Myalgia, Grade 1	3	1	2	2
Myalgia, Grade 2	0	1	2	2
Myalgia, Grade 3	1	1	0	1
Arthralgia, Any Severity	1	3	2	2
Arthralgia, Grade 1	1	1	1	0
Arthralgia, Grade 2	0	1	1	2
Arthralgia, Grade 3	0	1	0	0
Eye Pain, Any Severity	3	3	1	3
Eye Pain, Grade 1	1	2	0	2
Eye Pain, Grade 2	1	0	1	1
Eye Pain, Grade 3	1	1	0	0
Photophobia, Any Severity	3	1	0	4
Photophobia, Grade 1	1	1	0	4
Photophobia, Grade 2	1	0	0	0
Photophobia, Grade 3	1	0	0	0
Fatigue, Any Severity	4	4	9	6
Fatigue, Grade 1	2	2	7	2
Fatigue, Grade 2	0	0	2	4
Fatigue, Grade 3	2	2	0	0
Body rash, Any Severity	1	0	2	2
Body rash, Grade 1	1	0	1	1
Body rash, Grade 2	0	0	1	0
Body rash, Grade 3	0	0	0	1
Nausea, Any Severity	4	1	3	4
Nausea, Grade 1	2	1	3	2
Nausea, Grade 2	1	0	0	2
Nausea, Grade 3	1	0	0	0
Vomiting, Any Severity	2	1	0	2
Vomiting, Grade 1	0	1	0	2
Vomiting, Grade 2	1	0	0	0
Vomiting, Grade 3	1	0	0	0

End point values	Part I: TDV 6 to 11 Years	Part I: Placebo 6 to 11 Years	Part I: TDV 1.5 to 5 Years	Part I: Placebo 1.5 to 5 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	17	23	13
Units: participants				
Fever, Any Severity	1	1	4	4
Fever, Grade 1	1	1	4	2
Fever, Grade 2	0	0	0	1
Fever, Grade 3	0	0	0	1
Headache, Any Grade	4	5	3	4
Headache, Grade 1	3	3	3	3
Headache, Grade 2	1	2	0	1
Headache, Grade 3	0	0	0	0
Myalgia, Any Severity	1	3	5	2
Myalgia, Grade 1	1	3	3	0
Myalgia, Grade 2	0	0	2	1

Myalgia, Grade 3	0	0	0	1
Arthralgia, Any Severity	0	0	1	1
Arthralgia, Grade 1	0	0	1	0
Arthralgia, Grade 2	0	0	0	0
Arthralgia, Grade 3	0	0	0	1
Eye Pain, Any Severity	0	0	2	1
Eye Pain, Grade 1	0	0	2	1
Eye Pain, Grade 2	0	0	0	0
Eye Pain, Grade 3	0	0	0	0
Photophobia, Any Severity	1	0	0	0
Photophobia, Grade 1	0	0	0	0
Photophobia, Grade 2	1	0	0	0
Photophobia, Grade 3	0	0	0	0
Fatigue, Any Severity	2	5	3	3
Fatigue, Grade 1	1	2	1	2
Fatigue, Grade 2	0	3	2	0
Fatigue, Grade 3	1	0	0	1
Body rash, Any Severity	2	1	2	2
Body rash, Grade 1	2	1	2	2
Body rash, Grade 2	0	0	0	0
Body rash, Grade 3	0	0	0	0
Nausea, Any Severity	1	0	3	3
Nausea, Grade 1	0	0	2	3
Nausea, Grade 2	1	0	1	0
Nausea, Grade 3	0	0	0	0
Vomiting, Any Severity	1	1	4	5
Vomiting, Grade 1	0	1	1	2
Vomiting, Grade 2	1	0	3	3
Vomiting, Grade 3	0	0	0	0

End point values	Part II: TDV 1.5 to 11 Years	Part II: Placebo 1.5 to 11 Years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	159	53		
Units: participants				
Fever, Any Severity	33	9		
Fever, Grade 1	27	6		
Fever, Grade 2	5	2		
Fever, Grade 3	1	1		
Headache, Any Grade	46	12		
Headache, Grade 1	30	6		
Headache, Grade 2	12	4		
Headache, Grade 3	4	2		
Myalgia, Any Severity	30	6		
Myalgia, Grade 1	21	4		
Myalgia, Grade 2	6	1		
Myalgia, Grade 3	3	1		
Arthralgia, Any Severity	10	2		
Arthralgia, Grade 1	7	1		

Arthralgia, Grade 2	3	1		
Arthralgia, Grade 3	0	0		
Eye Pain, Any Severity	14	3		
Eye Pain, Grade 1	11	3		
Eye Pain, Grade 2	3	0		
Eye Pain, Grade 3	0	0		
Photophobia, Any Severity	11	3		
Photophobia, Grade 1	9	3		
Photophobia, Grade 2	2	0		
Photophobia, Grade 3	0	0		
Fatigue, Any Severity	29	10		
Fatigue, Grade 1	19	6		
Fatigue, Grade 2	7	3		
Fatigue, Grade 3	3	1		
Body rash, Any Severity	14	2		
Body rash, Grade 1	12	2		
Body rash, Grade 2	1	0		
Body rash, Grade 3	1	0		
Nausea, Any Severity	22	4		
Nausea, Grade 1	14	4		
Nausea, Grade 2	4	0		
Nausea, Grade 3	4	0		
Vomiting, Any Severity	18	3		
Vomiting, Grade 1	5	2		
Vomiting, Grade 2	11	1		
Vomiting, Grade 3	2	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Any Solicited AE Following Either Vaccination Dose

End point title	Number of Participants With Any Solicited AE Following Either Vaccination Dose[4]

End point description:

An AE is defined as any untoward medical occurrence in a clinical investigation participant administered a drug; it does not necessarily have to have a causal relationship with this treatment. Solicited local injection site reactions included pain, itching, erythema, edema and solicited systemic AEs include myalgia, arthralgia, eye pain, photophobia, fatigue, body rash, nausea, vomiting, and fever. The safety set included all randomised participants who received at least one dose of study vaccine (or placebo).

End point type	Primary

End point timeframe:

Within 14 days after either of the vaccination given on Day 0 or 90 (Day 14 for first vaccination, Day 104 for second vaccination)

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Number of participants is the analysis defined in the description.

End point values	Part I: TDV 21 to 45 Years	Part I: Placebo 21 to 45 Years	Part I: TDV 12 to 20 Years	Part I: Placebo 12 to 20 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	14	22	14
Units: participants	13	9	17	12

End point values	Part I: TDV 6 to 11 Years	Part I: Placebo 6 to 11 Years	Part I: TDV 1.5 to 5 Years	Part I: Placebo 1.5 to 5 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	17	23	13
Units: participants	12	8	17	10

End point values	Part II: TDV 1.5 to 11 Years	Part II: Placebo 1.5 to 11 Years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	159	53		
Units: participants	110	28		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With at Least One Unsolicited AE Following Either Vaccination Dose by Severity

End point title	Number of Participants With at Least One Unsolicited AE Following Either Vaccination Dose by Severity[5]

End point description:

An Adverse Event (AE) is defined as any untoward medical occurrence in a clinical investigation participant administered a drug; it does not necessarily have to have a causal relationship with this treatment. The severity of all unsolicited AEs was evaluated by the Investigator (using the Common Terminology Criteria for Adverse Events [CTCAE] v4.03) as follows. Mild (Grade 1): Transient symptoms, discomfort noticed but was easily tolerated by the participant with no interference to normal daily activities. Moderate (Grade 2): Marked symptoms, moderate interference with participant's daily activities. Severe (Grade 3): Considerable interference with participant's daily activities. The safety set included all randomised participants who received at least one dose of study vaccine (or placebo).

End point type	Primary

End point timeframe:

Unsolicited AEs were collected within 28 days of all vaccinations. Serious AEs were collected throughout the study up to Day 1080

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Number of participants is the analysis defined in the description.

End point values	Part I: TDV 21 to 45 Years	Part I: Placebo 21 to 45 Years	Part I: TDV 12 to 20 Years	Part I: Placebo 12 to 20 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	14	22	14
Units: participants				
At least one unsolicited AE	13	7	14	8
Unsolicited AEs by severity: Mild	6	2	7	2
Unsolicited AEs by severity: Moderate	5	5	6	5
Unsolicited AEs by severity: Severe	2	0	1	1

End point values	Part I: TDV 6 to 11 Years	Part I: Placebo 6 to 11 Years	Part I: TDV 1.5 to 5 Years	Part I: Placebo 1.5 to 5 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	17	23	13
Units: participants				
At least one unsolicited AE	12	11	17	12
Unsolicited AEs by severity: Mild	10	8	13	10
Unsolicited AEs by severity: Moderate	1	3	4	2
Unsolicited AEs by severity: Severe	1	0	0	0

End point values	Part II: TDV 1.5 to 11 Years	Part II: Placebo 1.5 to 11 Years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	159	53		
Units: participants				
At least one unsolicited AE	101	37		
Unsolicited AEs by severity: Mild	72	31		
Unsolicited AEs by severity: Moderate	25	6		
Unsolicited AEs by severity: Severe	4	0		

Statistical analyses

No statistical analyses for this end point

Primary: Seropositivity Rate to Each of the Four Dengue Serotypes at Day 120

End point title	Seropositivity Rate to Each of the Four Dengue Serotypes at Day 120[6]

End point description:

Seropositivity rate, defined as the percentage of participants seropositive, was derived from titers of dengue-neutralising antibodies. Participants were classified by titer after Day 0 as seropositive or seronegative. Seropositive was defined as a MNT50 titre value of ≥10 for any serotype and seronegative was defined as titre value of less than (<) 10 for all 4 serotypes. Seropositivity was assessed for the four dengue serotypes: TDV-1, TDV-2, TDV-3, TDV-4. FAS included all randomised participants who received at least one dose of study vaccine or placebo and for whom valid pre-dosing and at least one valid post-dosing blood sample has been received.

End point type	Primary

End point timeframe:

30 days after second vaccination (Day 120)

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Percentage of participants is defined in the description of this endpoint.

End point values	Part I: TDV 21 to 45 Years	Part I: Placebo 21 to 45 Years	Part I: TDV 12 to 20 Years	Part I: Placebo 12 to 20 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22	13	22	14
Units: percentage of participants				
number (confidence interval 95%)				
TDV-1	100.0 (84.6 to 100.0)	92.3 (64 to 99.8)	100.0 (84.6 to 100.0)	85.7 (57.2 to 98.2)
TDV-2	100.0 (84.6 to 100.0)	84.6 (54.6 to 98.1)	95.5 (77.2 to 99.9)	85.7 (57.2 to 98.2)
TDV-3	100.0 (84.6 to 100.0)	100.0 (75.3 to 100.0)	100.0 (84.6 to 100.0)	85.7 (57.2 to 98.2)
TDV-4	90.9 (70.8 to 98.9)	61.5 (31.6 to 86.1)	72.7 (49.8 to 89.3)	71.4 (41.9 to 91.6)

End point values	Part I: TDV 6 to 11 Years	Part I: Placebo 6 to 11 Years	Part I: TDV 1.5 to 5 Years	Part I: Placebo 1.5 to 5 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	17	22	11
Units: percentage of participants				
number (confidence interval 95%)				
TDV-1	100.0 (83.9 to 100.0)	23.5 (6.8 to 49.9)	100.0 (84.6 to 100.0)	0.0 (0.0 to 28.5)
TDV-2	100.0 (83.9 to 100.0)	23.5 (6.8 to 49.9)	100.0 (84.6 to 100.0)	0.0 (0.0 to 28.5)
TDV-3	100.0 (83.9 to 100.0)	29.4 (10.3 to 56.0)	100.0 (84.6 to 100.0)	0.0 (0.0 to 28.5)
TDV-4	85.7 (63.7 to 97.0)	29.4 (10.3 to 56.0)	100.0 (84.6 to 100.0)	0.0 (0.0 to 28.5)

End point values	Part II: TDV 1.5 to 11 Years	Part II: Placebo 1.5 to 11 Years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	156	53		
Units: percentage of participants				
number (confidence interval 95%)				
TDV-1	100.0 (97.7 to 100.0)	43.4 (29.8 to 57.7)		
TDV-2	100.0 (97.7 to 100.0)	35.8 (23.1 to 50.2)		
TDV-3	99.4 (96.5 to 100.0)	35.8 (23.1 to 50.2)		
TDV-4	94.9 (90.1 to 97.8)	35.8 (23.1 to 50.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part I: Number of Participants Positive for Vaccine Viremia for Each of Four Vaccine Strain Serotypes After the Each Vaccination

End point title	Part I: Number of Participants Positive for Vaccine Viremia for Each of Four Vaccine Strain Serotypes After the Each Vaccination

End point description:

Vaccine viremia was assessed for each of the four vaccine strain serotypes: TDV-1, TDV-2, TDV-3 and TDV-4 for Part-1. Vaccine viral ribonucleic acid (RNA) was detected by a quantitative reverse transcription-polymerase chain reaction (qRT-PCR) assay. The FAS included all randomised participants who received at least one dose of study vaccine and for whom valid pre-dosing and at least one valid post-dosing blood sample have been received.

End point type	Secondary

End point timeframe:

Days 0, 7, 14, 90, 97, and 104

End point values	Part I: TDV 21 to 45 Years	Part I: Placebo 21 to 45 Years	Part I: TDV 12 to 20 Years	Part I: Placebo 12 to 20 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	14	22	14
Units: participants				
Day 0, TDV-1	0	0	0	0
Day 0, TDV-2	0	0	0	0
Day 0, TDV-3	0	0	0	0
Day 0, TDV-4	0	0	0	0
Day 7, TDV-1	0	0	0	0
Day 7, TDV-2	2	0	4	0
Day 7, TDV-3	0	0	0	0
Day 7, TDV-4	0	0	0	0
Day 14, TDV-1	0	0	0	0
Day 14, TDV-2	0	0	3	0
Day 14, TDV-3	0	0	0	0
Day 14, TDV-4	0	0	0	0
Day 90, TDV-1	0	0	0	0
Day 90, TDV-2	0	0	0	0
Day 90, TDV-3	0	0	0	0
Day 90, TDV-4	0	0	0	0
Day 97, TDV-1	0	0	0	0
Day 97, TDV-2	0	0	0	0
Day 97, TDV-3	0	0	0	0
Day 97, TDV-4	0	0	0	0

Day 104, TDV-1	0	0	0	0
Day 104, TDV-2	1	0	0	0
Day 104, TDV-3	0	0	0	0
Day 104, TDV-4	0	0	0	0

End point values	Part I: TDV 6 to 11 Years	Part I: Placebo 6 to 11 Years	Part I: TDV 1.5 to 5 Years	Part I: Placebo 1.5 to 5 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	17	23	13
Units: participants				
Day 0, TDV-1	0	0	0	0
Day 0, TDV-2	0	0	0	0
Day 0, TDV-3	0	0	0	0
Day 0, TDV-4	0	0	0	0
Day 7, TDV-1	0	0	0	0
Day 7, TDV-2	4	0	9	0
Day 7, TDV-3	0	0	0	0
Day 7, TDV-4	0	0	0	0
Day 14, TDV-1	0	0	0	0
Day 14, TDV-2	6	0	4	0
Day 14, TDV-3	0	0	0	0
Day 14, TDV-4	0	0	0	0
Day 90, TDV-1	0	0	0	0
Day 90, TDV-2	0	0	0	0
Day 90, TDV-3	0	0	0	0
Day 90, TDV-4	0	0	0	0
Day 97, TDV-1	0	0	0	0
Day 97, TDV-2	1	0	0	0
Day 97, TDV-3	0	0	0	0
Day 97, TDV-4	0	0	0	0
Day 104, TDV-1	0	0	0	0
Day 104, TDV-2	0	0	1	0
Day 104, TDV-3	0	0	0	0
Day 104, TDV-4	0	0	0	0

End point values	Part II: TDV 1.5 to 11 Years	Part II: Placebo 1.5 to 11 Years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	5		
Units: participants				
Day 0, TDV-1	0	0		
Day 0, TDV-2	0	0		
Day 0, TDV-3	0	0		
Day 0, TDV-4	0	0		
Day 7, TDV-1	0	0		
Day 7, TDV-2	0	0		
Day 7, TDV-3	0	0		

Day 7, TDV-4	0	0		
Day 14, TDV-1	0	0		
Day 14, TDV-2	0	0		
Day 14, TDV-3	0	0		
Day 14, TDV-4	0	0		
Day 90, TDV-1	0	0		
Day 90, TDV-2	0	0		
Day 90, TDV-3	0	0		
Day 90, TDV-4	0	0		
Day 97, TDV-1	0	0		
Day 97, TDV-2	0	0		
Day 97, TDV-3	0	0		
Day 97, TDV-4	0	0		
Day 104, TDV-1	0	0		
Day 104, TDV-2	0	0		
Day 104, TDV-3	0	0		
Day 104, TDV-4	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Seropositivity Rate to Each of the Four Dengue Serotypes

End point title	Seropositivity Rate to Each of the Four Dengue Serotypes

End point description:

Seropositivity rate, defined as the percentage of participants seropositive, was derived from titers of dengue-neutralising antibodies. Participants were classified by titer after Day 0 as seropositive or seronegative. Seropositive was defined as a MNT50 titre value of ≥10 and seronegative was defined as titre value of less than (<) 10. Seropositivity was assessed for the four dengue serotypes: TDV-1, TDV-2, TDV-3, TDV-4. FAS included all randomised participants who received at least one dose of study vaccine or placebo and for whom valid pre-dosing and at least one valid post-dosing blood sample have been received. n=number of subjects available for analysis at a specific timepoint. 9999=Data were not collected at this timepoint.

End point type	Secondary

End point timeframe:

Day 28 and Day 90 (Parts 1 and 2) and Days 180, 360, 720 and 1080 in Part 1

End point values	Part I: TDV 21 to 45 Years	Part I: Placebo 21 to 45 Years	Part I: TDV 12 to 20 Years	Part I: Placebo 12 to 20 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	14	22	14
Units: percentage of participants				
number (confidence interval 95%)				
Day28, TDV-1(n=24,13,22,14,21,17,23,13,158,53)	100.0 (85.8 to 100.0)	92.3 (64.0 to 99.8)	86.4 (65.1 to 97.1)	85.7 (57.2 to 98.2)
Day 28, TDV-2(n=24,13,22,14,21,17,23,13,158,53)	100.0 (85.8 to 100.0)	92.3 (64.0 to 99.8)	86.4 (65.1 to 97.1)	85.7 (57.2 to 98.2)
Day 28, TDV-3(n=24,13,22,14,21,17,23,13,158,53)	95.8 (78.9 to 99.9)	84.6 (54.6 to 98.1)	90.9 (70.8 to 98.9)	92.9 (66.1 to 99.8)

Day 28, TDV-4(n=24,13,22,14,21,17,23,13,158,53)	79.2 (57.8 to 92.9)	76.9 (46.2 to 95.0)	59.1 (36.4 to 79.2)	78.6 (49.2 to 95.3)
Day 90, TDV-1(n=23,13,22,14,21,17,22,11,159,53)	100.0 (85.2 to 100.0)	92.3 (64.0 to 99.8)	90.9 (70.8 to 98.9)	85.7 (57.2 to 98.2)
Day 90, TDV-2(n=23,13,22,14,21,17,22,11,159,53)	100.0 (85.2 to 100.0)	84.6 (54.6 to 98.1)	90.9 (70.8 to 98.9)	85.7 (57.2 to 98.2)
Day 90, TDV-3(n=23,13,22,14,21,17,22,11,159,53)	95.7 (78.1 to 99.9)	100.0 (75.3 to 100.0)	90.9 (70.8 to 98.9)	85.7 (57.2 to 98.2)
Day 90, TDV-4(n=23,13,22,14,21,17,22,11,159,53)	82.6 (61.2 to 95.0)	69.2 (38.6 to 90.9)	77.3 (54.6 to 92.2)	78.6 (49.2 to 95.3)
Day 180, TDV-1(n=20,12,21,14,21,17,22,11,0,0)	100.0 (83.2 to 100.0)	91.7 (61.5 to 99.8)	95.2 (76.2 to 99.9)	85.7 (57.2 to 98.2)
Day 180, TDV-2(n=20,12,21,14,21,17,22,11,0,0)	100.0 (83.2 to 100.0)	83.3 (51.6 to 97.9)	95.2 (76.2 to 99.9)	85.7 (57.2 to 98.2)
Day 180, TDV-3(n=20,12,21,14,21,17,22,11,0,0)	100.0 (83.2 to 100.0)	91.7 (61.5 to 99.8)	95.2 (76.2 to 99.9)	85.7 (57.2 to 98.2)
Day 180, TDV-4(n=20,12,21,14,21,17,22,11,0,0)	90.0 (68.3 to 98.8)	66.7 (34.9 to 90.1)	76.2 (52.8 to 91.8)	78.6 (49.2 to 95.3)
Day 360, TDV-1(n=19,12,21,13,21,17,22,11,0,0)	100.0 (82.4 to 100.0)	91.7 (61.5 to 99.8)	90.5 (69.6 to 98.8)	84.6 (54.6 to 98.1)
Day 360, TDV-2(n=19,12,21,13,21,17,22,11,0,0)	100.0 (82.4 to 100.0)	83.3 (51.6 to 97.9)	95.2 (76.2 to 99.9)	84.6 (54.6 to 98.1)
Day 360, TDV-3(n=19,12,21,13,21,17,22,11,0,0)	89.5 (66.9 to 98.7)	83.3 (51.6 to 97.9)	81.0 (58.1 to 94.6)	84.6 (54.6 to 98.1)
Day 360, TDV-4(n=19,12,21,13,21,17,22,11,0,0)	84.2 (60.4 to 96.6)	75.0 (42.8 to 94.5)	66.7 (43.0 to 85.4)	84.6 (54.6 to 98.1)
Day 720, TDV-1(n=16,9,19,13,21,17,22,10,0,0)	100.0 (79.4 to 100.0)	100.0 (66.4 to 100.0)	89.5 (66.9 to 98.7)	84.6 (54.6 to 98.1)
Day 720, TDV-2(n=16,9,19,13,21,17,22,10,0,0)	100.0 (79.4 to 100.0)	88.9 (51.8 to 99.7)	94.7 (74.0 to 99.9)	84.6 (54.6 to 98.1)
Day 720, TDV-3(n=16,9,19,13,21,17,22,10,0,0)	87.5 (61.7 to 98.4)	88.9 (51.8 to 99.7)	68.4 (43.4 to 87.4)	84.6 (54.6 to 98.1)
Day 720, TDV-4(n=16,9,19,13,21,17,22,10,0,0)	81.3 (54.4 to 96.0)	77.8 (40.0 to 97.2)	63.2 (38.4 to 83.7)	84.6 (54.6 to 98.1)
Day 1080, TDV-1(n=15,8,18,11,21,17,21,9,0,0)	100.0 (78.2 to 100.0)	100.0 (63.1 to 100.0)	94.4 (72.7 to 99.9)	81.8 (48.2 to 97.7)
Day 1080, TDV-2(n=15,8,18,11,21,17,21,9,0,0)	100.0 (78.2 to 100.0)	87.5 (47.3 to 99.7)	100.0 (81.5 to 100.0)	81.8 (48.2 to 97.7)
Day 1080, TDV-3(n=15,8,18,11,21,17,21,9,0,0)	93.3 (68.1 to 99.8)	87.5 (47.3 to 99.7)	77.8 (52.4 to 93.6)	81.8 (48.2 to 97.7)
Day 1080, TDV-4(n=15,8,18,11,21,17,21,9,0,0)	80.0 (51.9 to 95.7)	87.5 (47.3 to 99.7)	61.1 (35.7 to 82.7)	72.7 (39.0 to 94.0)

End point values	Part I: TDV 6 to 11 Years	Part I: Placebo 6 to 11 Years	Part I: TDV 1.5 to 5 Years	Part I: Placebo 1.5 to 5 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	17	23	13
Units: percentage of participants				
number (confidence interval 95%)				
Day28, TDV-1(n=24,13,22,14,21,17,23,13,158,53)	100.0 (83.9 to 100.0)	23.5 (6.8 to 49.9)	100.0 (85.2 to 100.0)	7.7 (0.2 to 36.0)
Day 28, TDV-2(n=24,13,22,14,21,17,23,13,158,53)	100.0 (83.9 to 100.0)	23.5 (6.8 to 49.9)	95.7 (78.1 to 99.9)	0.0 (0.0 to 24.7)
Day 28, TDV-3(n=24,13,22,14,21,17,23,13,158,53)	100.0 (83.9 to 100.0)	17.6 (3.8 to 43.4)	91.3 (72.0 to 98.9)	0.0 (0.0 to 24.7)
Day 28, TDV-4(n=24,13,22,14,21,17,23,13,158,53)	85.7 (63.7 to 97.0)	11.8 (1.5 to 36.4)	69.6 (47.1 to 86.8)	0.0 (0.0 to 24.7)

Day 90, TDV-1(n=23,13,22,14,21,17,22,11,159,53)	95.2 (76.2 to 99.9)	17.6 (3.8 to 43.4)	95.5 (77.2 to 99.9)	0.0 (0.0 to 28.5)
Day 90, TDV-2(n=23,13,22,14,21,17,22,11,159,53)	100.0 (83.9 to 100.0)	17.6 (3.8 to 43.4)	100.0 (84.6 to 100.0)	0.0 (0.0 to 28.5)
Day 90, TDV-3(n=23,13,22,14,21,17,22,11,159,53)	100.0 (83.9 to 100.0)	17.6 (3.8 to 43.4)	81.8 (59.7 to 94.8)	9.1 (0.2 to 41.3)
Day 90, TDV-4(n=23,13,22,14,21,17,22,11,159,53)	66.7 (43.0 to 85.4)	11.8 (1.5 to 36.4)	63.6 (40.7 to 82.8)	9.1 (0.2 to 41.3)
Day 180, TDV-1(n=20,12,21,14,21,17,22,11,0,0)	100.0 (83.9 to 100.0)	23.5 (6.8 to 49.9)	100.0 (84.6 to 100.0)	0.0 (0.0 to 28.5)
Day 180, TDV-2(n=20,12,21,14,21,17,22,11,0,0)	100.0 (83.9 to 100.0)	23.5 (6.8 to 49.9)	100.0 (84.6 to 100.0)	0.0 (0.0 to 28.5)
Day 180, TDV-3(n=20,12,21,14,21,17,22,11,0,0)	100.0 (83.9 to 100.0)	35.3 (14.2 to 61.7)	95.5 (77.2 to 99.9)	9.1 (0.2 to 41.3)
Day 180, TDV-4(n=20,12,21,14,21,17,22,11,0,0)	81.0 (58.1 to 94.6)	17.6 (3.8 to 43.4)	77.3 (54.6 to 92.2)	0.0 (0.0 to 28.5)
Day 360, TDV-1(n=19,12,21,13,21,17,22,11,0,0)	95.2 (76.2 to 99.9)	29.4 (10.3 to 56.0)	100.0 (84.6 to 100.0)	9.1 (0.2 to 41.3)
Day 360, TDV-2(n=19,12,21,13,21,17,22,11,0,0)	95.2 (76.2 to 99.9)	29.4 (10.3 to 56.0)	100.0 (84.6 to 100.0)	0.0 (0.0 to 28.5)
Day 360, TDV-3(n=19,12,21,13,21,17,22,11,0,0)	95.2 (76.2 to 99.9)	29.4 (10.3 to 56.0)	95.5 (77.2 to 99.9)	0.0 (0.0 to 28.5)
Day 360, TDV-4(n=19,12,21,13,21,17,22,11,0,0)	61.9 (38.4 to 81.9)	17.6 (3.8 to 43.4)	63.6 (40.7 to 82.8)	0.0 (0.0 to 28.5)
Day 720, TDV-1(n=16,9,19,13,21,17,22,10,0,0)	100.0 (83.9 to 100.0)	23.5 (6.8 to 49.9)	100.0 (84.6 to 100.0)	10.0 (0.3 to 44.5)
Day 720, TDV-2(n=16,9,19,13,21,17,22,10,0,0)	100.0 (83.9 to 100.0)	23.5 (6.8 to 49.9)	100.0 (84.6 to 100.0)	10.0 (0.3 to 44.5)
Day 720, TDV-3(n=16,9,19,13,21,17,22,10,0,0)	71.4 (47.8 to 88.7)	17.6 (3.8 to 43.4)	90.9 (70.8 to 98.9)	10.0 (0.3 to 44.5)
Day 720, TDV-4(n=16,9,19,13,21,17,22,10,0,0)	57.1 (34.0 to 78.2)	23.5 (6.8 to 49.9)	72.7 (49.8 to 89.3)	10.0 (0.3 to 44.5)
Day 1080, TDV-1(n=15,8,18,11,21,17,21,9,0,0)	95.2 (76.2 to 99.9)	23.5 (6.8 to 49.9)	100.0 (83.9 to 100.0)	11.1 (0.3 to 48.2)
Day 1080, TDV-2(n=15,8,18,11,21,17,21,9,0,0)	100.0 (83.9 to 100.0)	23.5 (6.8 to 49.9)	95.2 (76.2 to 99.9)	0.0 (0.0 to 33.6)
Day 1080, TDV-3(n=15,8,18,11,21,17,21,9,0,0)	85.7 (63.7 to 97.0)	23.5 (6.8 to 49.9)	95.2 (76.2 to 99.9)	11.1 (0.3 to 48.2)
Day 1080, TDV-4(n=15,8,18,11,21,17,21,9,0,0)	42.9 (21.8 to 66.0)	17.6 (3.8 to 43.4)	47.6 (25.7 to 70.2)	11.1 (0.3 to 48.2)

End point values	Part II: TDV 1.5 to 11 Years	Part II: Placebo 1.5 to 11 Years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	159	53		
Units: percentage of participants				
number (confidence interval 95%)				
Day28, TDV-1(n=24,13,22,14,21,17,23,13,158,53)	100.0 (97.7 to 100.0)	41.5 (28.1 to 55.9)		
Day 28, TDV-2(n=24,13,22,14,21,17,23,13,158,53)	96.8 (92.8 to 99.0)	34.0 (21.5 to 48.3)		
Day 28, TDV-3(n=24,13,22,14,21,17,23,13,158,53)	95.6 (91.1 to 98.2)	39.6 (26.5 to 54.0)		
Day 28, TDV-4(n=24,13,22,14,21,17,23,13,158,53)	74.1 (66.5 to 80.7)	35.8 (23.1 to 50.2)		
Day 90, TDV-1(n=23,13,22,14,21,17,22,11,159,53)	99.4 (96.5 to 100.0)	41.5 (28.1 to 55.9)		

Day 90, TDV-2(n=23,13,22,14,21,17,22,11,159,53)	98.7 (95.5 to 99.8)	34.0 (21.5 to 48.3)		
Day 90, TDV-3(n=23,13,22,14,21,17,22,11,159,53)	89.9 (84.2 to 94.1)	34.0 (21.5 to 48.3)		
Day 90, TDV-4(n=23,13,22,14,21,17,22,11,159,53)	69.8 (62.0 to 76.8)	35.8 (23.1 to 50.2)		
Day 180, TDV-1(n=20,12,21,14,21,17,22,11,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 180, TDV-2(n=20,12,21,14,21,17,22,11,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 180, TDV-3(n=20,12,21,14,21,17,22,11,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 180, TDV-4(n=20,12,21,14,21,17,22,11,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 360, TDV-1(n=19,12,21,13,21,17,22,11,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 360, TDV-2(n=19,12,21,13,21,17,22,11,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 360, TDV-3(n=19,12,21,13,21,17,22,11,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 360, TDV-4(n=19,12,21,13,21,17,22,11,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 720, TDV-1(n=16,9,19,13,21,17,22,10,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 720, TDV-2(n=16,9,19,13,21,17,22,10,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 720, TDV-3(n=16,9,19,13,21,17,22,10,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 720, TDV-4(n=16,9,19,13,21,17,22,10,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 1080, TDV-1(n=15,8,18,11,21,17,21,9,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 1080, TDV-2(n=15,8,18,11,21,17,21,9,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 1080, TDV-3(n=15,8,18,11,21,17,21,9,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 1080, TDV-4(n=15,8,18,11,21,17,21,9,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Seroconversion Rate to Each of the Four Dengue Serotypes

End point title	Seroconversion Rate to Each of the Four Dengue Serotypes

End point description:

Seroconversion rate was defined as the percentage of participants with microneutralisation test 50% (MNT50) titer ≥10 or, if the titer on Day 0 was ≥10, a 4-fold rise in antibody titer. FAS included all randomised participants who received at least one dose of study vaccine or placebo and for whom valid pre-dosing and at least one valid post-dosing blood sample have been received. n=number of subjects available for analysis at a specific timepoint. 9999=Data were not collected at this timepoint.

End point type	Secondary

End point timeframe:

Day 28, 90 and 120 (Parts 1 and 2) and Days 180, 360, 720 and 1080 in Part 1

End point values	Part I: TDV 21 to 45 Years	Part I: Placebo 21 to 45 Years	Part I: TDV 12 to 20 Years	Part I: Placebo 12 to 20 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	14	22	14
Units: percentage of participants				
number (confidence interval 95%)				
Day28, TDV-1(n=24,13,22,14,21,17,23,13,158,53)	45.8 (25.6 to 67.2)	7.7 (0.2 to 36.0)	63.6 (40.7 to 82.8)	0.0 (0.0 to 23.2)
Day28, TDV-2(n=24,13,22,14,21,17,23,13,158,53)	33.3 (15.6 to 55.3)	15.4 (1.9 to 45.4)	59.1 (36.4 to 79.3)	0.0 (0.0 to 23.2)
Day28, TDV-3(n=24,13,22,14,21,17,23,13,158,53)	33.3 (15.6 to 55.3)	0.0 (0.0 to 24.7)	63.6 (40.7 to 82.8)	7.1 (0.2 to 33.9)
Day28, TDV-4(n=24,13,22,14,21,17,23,13,158,53)	20.8 (7.1 to 42.2)	15.4 (1.9 to 45.4)	31.8 (13.9 to 54.9)	0.0 (0.0 to 23.2)
Day 90, TDV-1(n=23,13,22,14,21,17,22,11,159,53)	39.1 (19.7 to 61.5)	15.4 (1.9 to 45.4)	54.5 (32.2 to 75.6)	7.1 (0.2 to 33.9)
Day 90, TDV-2(n=23,13,22,14,21,17,22,11,159,53)	30.4 (13.2 to 52.9)	15.4 (1.9 to 45.4)	59.1 (36.4 to 79.3)	7.1 (0.2 to 33.9)
Day 90, TDV-3(n=23,13,22,14,21,17,22,11,159,53)	30.4 (13.2 to 52.9)	23.1 (5.0 to 53.8)	59.1 (36.4 to 79.3)	14.3 (1.8 to 42.8)
Day 90, TDV-4(n=23,13,22,14,21,17,22,11,159,53)	21.7 (7.5 to 43.7)	0.0 (0.0 to 24.7)	50.0 (28.2 to 71.8)	21.4 (4.7 to 50.8)
Day 120, TDV-1(n=22,13,22,14,21,17,22,11,156,53)	45.5 (24.4 to 67.8)	0.0 (0.0 to 24.7)	68.2 (45.1 to 86.1)	14.3 (1.8 to 42.8)
Day 120, TDV-2(n=22,13,22,14,21,17,22,11,156,53)	45.5 (24.4 to 67.8)	0.0 (0.0 to 24.7)	63.6 (40.7 to 82.8)	0.0 (0.0 to 23.2)
Day 120, TDV-3(n=22,13,22,14,21,17,22,11,156,53)	45.5 (24.4 to 67.8)	30.8 (9.1 to 61.4)	68.2 (45.1 to 86.1)	14.3 (1.8 to 42.8)
Day 120, TDV-4(n=22,13,22,14,21,17,22,11,156,53)	40.9 (20.7 to 63.6)	7.7 (0.2 to 36.0)	45.5 (24.4 to 67.8)	14.3 (1.8 to 42.8)
Day 180, TDV-1(n=20,12,21,14,21,17,22,11,0,0)	50.0 (27.2 to 72.8)	8.3 (0.2 to 38.5)	61.9 (38.4 to 81.9)	0.0 (0.0 to 23.2)
Day 180, TDV-2(n=20,12,21,14,21,17,22,11,0,0)	60.0 (36.1 to 80.9)	8.3 (0.2 to 38.5)	61.9 (38.4 to 81.9)	7.1 (0.2 to 33.9)
Day 180, TDV-3(n=20,12,21,14,21,17,22,11,0,0)	40.0 (19.1 to 63.9)	8.3 (0.2 to 38.5)	61.9 (38.4 to 81.9)	7.1 (0.2 to 33.9)
Day 180, TDV-4(n=20,12,21,14,21,17,22,11,0,0)	45.0 (23.1 to 68.5)	8.3 (0.2 to 38.5)	47.6 (25.7 to 70.2)	7.1 (0.2 to 33.9)
Day 360, TDV-1(n=19,12,21,13,21,17,22,11,0,0)	52.6 (28.9 to 75.6)	0.0 (0.0 to 26.5)	57.1 (34.0 to 78.2)	15.4 (1.9 to 45.4)
Day 360, TDV-2(n=19,12,21,13,21,17,22,11,0,0)	47.4 (24.4 to 71.1)	0.0 (0.0 to 26.5)	61.9 (38.4 to 81.9)	15.4 (1.9 to 45.4)
Day 360, TDV-3(n=19,12,21,13,21,17,22,11,0,0)	36.8 (16.3 to 61.6)	0.0 (0.0 to 26.5)	57.1 (34.0 to 78.2)	15.4 (1.9 to 45.4)
Day 360, TDV-4(n=19,12,21,13,21,17,22,11,0,0)	42.1 (20.3 to 66.5)	0.0 (0.0 to 26.5)	38.1 (18.1 to 61.6)	7.7 (0.2 to 36.0)
Day 720, TDV-1(n=16,9,19,13,21,17,22,10,0,0)	50.0 (24.7 to 75.3)	0.0 (0.0 to 33.6)	47.4 (24.4 to 71.1)	15.4 (1.9 to 45.4)
Day 720, TDV-2(n=16,9,19,13,21,17,22,10,0,0)	50.0 (24.7 to 75.3)	0.0 (0.0 to 33.6)	57.9 (33.5 to 79.7)	7.7 (0.2 to 36.0)
Day 720, TDV-3(n=16,9,19,13,21,17,22,10,0,0)	43.8 (19.8 to 70.1)	0.0 (0.0 to 33.6)	31.6 (12.6 to 56.6)	15.4 (1.9 to 45.4)
Day 720, TDV-4(n=16,9,19,13,21,17,22,10,0,0)	18.8 (4.0 to 45.6)	0.0 (0.0 to 36.9)	36.8 (16.3 to 61.6)	15.4 (1.9 to 45.4)
Day 1080, TDV-1(n=15,8,18,11,21,17,21,9,0,0)	46.7 (21.3 to 73.4)	0.0 (0.0 to 36.9)	55.6 (30.8 to 78.5)	18.2 (2.3 to 51.8)

Day 1080, TDV-2(n=15,8,18,11,21,17,21,9,0,0)	46.7 (21.3 to 73.4)	0.0 (0.0 to 36.9)	61.1 (35.7 to 82.7)	9.1 (0.2 to 41.3)
Day 1080, TDV-3(n=15,8,18,11,21,17,21,9,0,0)	33.3 (11.8 to 61.6)	0.0 (0.0 to 36.9)	44.4 (21.5 to 69.2)	18.2 (2.3 to 51.8)
Day 1080, TDV-4(n=15,8,18,11,21,17,21,9,0,0)	13.3 (1.7 to 40.5)	12.5 (0.3 to 52.7)	27.8 (9.7 to 53.5)	18.2 (2.3 to 51.8)

End point values	Part I: TDV 6 to 11 Years	Part I: Placebo 6 to 11 Years	Part I: TDV 1.5 to 5 Years	Part I: Placebo 1.5 to 5 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	17	23	13
Units: percentage of participants				
number (confidence interval 95%)				
Day28, TDV-1(n=24,13,22,14,21,17,23,13,158,53)	90.5 (69.6 to 98.8)	5.9 (0.1 to 28.7)	87.0 (66.4 to 97.2)	7.7 (0.2 to 36.0)
Day28, TDV-2(n=24,13,22,14,21,17,23,13,158,53)	85.7 (63.7 to 97.0)	11.8 (1.5 to 36.4)	87.0 (66.4 to 97.2)	0.0 (0.0 to 24.7)
Day28, TDV-3(n=24,13,22,14,21,17,23,13,158,53)	90.5 (69.6 to 98.8)	0.0 (0.0 to 19.5)	78.3 (56.3 to 92.5)	0.0 (0.0 to 24.7)
Day28, TDV-4(n=24,13,22,14,21,17,23,13,158,53)	71.4 (47.8 to 88.7)	5.9 (0.1 to 28.7)	60.9 (38.5 to 80.3)	0.0 (0.0 to 24.7)
Day 90, TDV-1(n=23,13,22,14,21,17,22,11,159,53)	81.0 (58.1 to 94.6)	0.0 (0.0 to 19.5)	81.8 (59.7 to 94.8)	0.0 (0.0 to 28.5)
Day 90, TDV-2(n=23,13,22,14,21,17,22,11,159,53)	85.7 (63.7 to 97.0)	0.0 (0.0 to 19.5)	90.9 (70.8 to 98.9)	0.0 (0.0 to 28.5)
Day 90, TDV-3(n=23,13,22,14,21,17,22,11,159,53)	81.0 (58.1 to 94.6)	0.0 (0.0 to 19.5)	63.6 (40.7 to 82.8)	9.1 (0.2 to 41.3)
Day 90, TDV-4(n=23,13,22,14,21,17,22,11,159,53)	61.9 (38.4 to 81.9)	5.9 (0.1 to 28.7)	54.5 (32.2 to 75.6)	9.1 (0.2 to 41.3)
Day 120, TDV-1(n=22,13,22,14,21,17,22,11,156,53)	90.5 (69.6 to 98.8)	5.9 (0.1 to 28.7)	95.5 (77.2 to 99.9)	0.0 (0.0 to 28.5)
Day 120, TDV-2(n=22,13,22,14,21,17,22,11,156,53)	95.2 (76.2 to 99.9)	5.9 (0.1 to 28.7)	95.5 (77.2 to 99.9)	0.0 (0.0 to 28.5)
Day 120, TDV-3(n=22,13,22,14,21,17,22,11,156,53)	90.5 (69.6 to 98.8)	17.6 (3.8 to 43.4)	95.5 (77.2 to 99.9)	0.0 (0.0 to 28.5)
Day 120, TDV-4(n=22,13,22,14,21,17,22,11,156,53)	85.7 (63.7 to 97.0)	23.5 (6.8 to 49.9)	95.5 (77.2 to 99.9)	0.0 (0.0 to 28.5)
Day 180, TDV-1(n=20,12,21,14,21,17,22,11,0,0)	95.2 (76.2 to 99.9)	5.9 (0.1 to 28.7)	90.9 (70.8 to 99.9)	0.0 (0.0 to 28.5)
Day 180, TDV-2(n=20,12,21,14,21,17,22,11,0,0)	95.2 (76.2 to 99.9)	5.9 (0.1 to 28.7)	95.5 (77.2 to 99.9)	0.0 (0.0 to 28.5)
Day 180, TDV-3(n=20,12,21,14,21,17,22,11,0,0)	90.5 (69.5 to 98.8)	17.6 (3.8 to 43.4)	86.4 (65.1 to 97.1)	9.1 (0.2 to 41.3)
Day 180, TDV-4(n=20,12,21,14,21,17,22,11,0,0)	81.0 (58.1 to 94.6)	11.8 (1.5 to 36.4)	72.7 (49.8 to 98.3)	0.0 (0.0 to 28.5)
Day 360, TDV-1(n=19,12,21,13,21,17,22,11,0,0)	85.7 (63.7 to 97.0)	11.8 (1.5 to 36.4)	90.9 (70.8 to 98.9)	9.1 (0.2 to 41.3)
Day 360, TDV-2(n=19,12,21,13,21,17,22,11,0,0)	76.2 (52.8 to 91.8)	17.6 (3.8 to 43.4)	95.5 (77.2 to 99.9)	0.0 (0.0 to 28.5)
Day 360, TDV-3(n=19,12,21,13,21,17,22,11,0,0)	76.2 (52.8 to 91.8)	11.8 (1.5 to 36.4)	81.8 (59.7 to 94.8)	0.0 (0.0 to 28.5)
Day 360, TDV-4(n=19,12,21,13,21,17,22,11,0,0)	57.1 (34.0 to 78.2)	11.8 (1.5 to 36.4)	59.1 (36.4 to 79.3)	0.0 (0.0 to 28.5)
Day 720, TDV-1(n=16,9,19,13,21,17,22,10,0,0)	95.2 (76.2 to 99.9)	5.9 (0.1 to 28.7)	86.4 (65.1 to 97.1)	10.0 (0.3 to 44.5)
Day 720, TDV-2(n=16,9,19,13,21,17,22,10,0,0)	85.7 (63.7 to 97.0)	5.9 (0.1 to 28.7)	95.5 (77.2 to 99.9)	10.0 (0.3 to 44.5)

Day 720, TDV-3(n=16,9,19,13,21,17,22,10,0,0)	66.7 (43.0 to 85.4)	5.9 (0.1 to 28.7)	86.4 (65.1 to 97.1)	10.0 (0.3 to 44.5)
Day 720, TDV-4(n=16,9,19,13,21,17,22,10,0,0)	47.6 (25.7 to 70.2)	17.6 (3.8 to 43.4)	63.6 (40.7 to 82.8)	10.0 (0.3 to 44.5)
Day 1080, TDV-1(n=15,8,18,11,21,17,21,9,0,0)	90.5 (69.6 to 98.8)	5.9 (0.1 to 28.7)	85.7 (63.7 to 97.0)	11.1 (0.3 to 48.2)
Day 1080, TDV-2(n=15,8,18,11,21,17,21,9,0,0)	81.0 (58.1 to 94.6)	5.9 (0.1 to 28.7)	85.7 (63.7 to 97.0)	0.0 (0.0 to 33.6)
Day 1080, TDV-3(n=15,8,18,11,21,17,21,9,0,0)	81.0 (58.1 to 94.6)	5.9 (0.1 to 28.7)	90.5 (69.6 to 98.8)	11.1 (0.3 to 48.2)
Day 1080, TDV-4(n=15,8,18,11,21,17,21,9,0,0)	33.3 (14.6 to 57.0)	11.8 (1.5 to 36.4)	38.1 (18.1 to 61.6)	11.1 (0.3 to 48.2)

End point values	Part II: TDV 1.5 to 11 Years	Part II: Placebo 1.5 to 11 Years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	159	53		
Units: percentage of participants				
number (confidence interval 95%)				
Day28, TDV-1(n=24,13,22,14,21,17,23,13,158,53)	86.1 (79.7 to 91.1)	1.9 (0.0 to 10.1)		
Day28, TDV-2(n=24,13,22,14,21,17,23,13,158,53)	86.7 (80.4 to 91.6)	0.0 (0.0 to 6.7)		
Day28, TDV-3(n=24,13,22,14,21,17,23,13,158,53)	82.3 (75.4 to 87.9)	1.9 (0.0 to 10.1)		
Day28, TDV-4(n=24,13,22,14,21,17,23,13,158,53)	62.7 (54.6 to 70.2)	5.7 (1.2 to 15.7)		
Day 90, TDV-1(n=23,13,22,14,21,17,22,11,159,53)	82.4 (75.6 to 88.0)	3.8 (0.5 to 13.0)		
Day 90, TDV-2(n=23,13,22,14,21,17,22,11,159,53)	86.2 (79.8 to 91.1)	1.9 (0.0 to 10.1)		
Day 90, TDV-3(n=23,13,22,14,21,17,22,11,159,53)	76.1 (68.7 to 82.5)	0.0 (0.0 to 6.7)		
Day 90, TDV-4(n=23,13,22,14,21,17,22,11,159,53)	57.9 (49.8 to 65.6)	5.7 (1.2 to 15.7)		
Day 120, TDV-1(n=22,13,22,14,21,17,22,11,156,53)	88.5 (82.4 to 93.0)	3.8 (0.5 to 13.0)		
Day 120, TDV-2(n=22,13,22,14,21,17,22,11,156,53)	90.4 (84.6 to 94.5)	3.8 (0.5 to 13.0)		
Day 120, TDV-3(n=22,13,22,14,21,17,22,11,156,53)	86.5 (80.2 to 91.5)	1.9 (0.0 to 10.1)		
Day 120, TDV-4(n=22,13,22,14,21,17,22,11,156,53)	84.0 (77.3 to 89.4)	3.8 (0.5 to 13.0)		
Day 180, TDV-1(n=20,12,21,14,21,17,22,11,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 180, TDV-2(n=20,12,21,14,21,17,22,11,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 180, TDV-3(n=20,12,21,14,21,17,22,11,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 180, TDV-4(n=20,12,21,14,21,17,22,11,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 360, TDV-1(n=19,12,21,13,21,17,22,11,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 360, TDV-2(n=19,12,21,13,21,17,22,11,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 360, TDV-3(n=19,12,21,13,21,17,22,11,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		

Day 360, TDV-4(n=19,12,21,13,21,17,22,11,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 720, TDV-1(n=16,9,19,13,21,17,22,10,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 720, TDV-2(n=16,9,19,13,21,17,22,10,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 720, TDV-3(n=16,9,19,13,21,17,22,10,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 720, TDV-4(n=16,9,19,13,21,17,22,10,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 1080, TDV-1(n=15,8,18,11,21,17,21,9,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 1080, TDV-2(n=15,8,18,11,21,17,21,9,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 1080, TDV-3(n=15,8,18,11,21,17,21,9,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 1080, TDV-4(n=15,8,18,11,21,17,21,9,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Neutralising Antibody Titers (GMTs) of All Four Dengue Serotypes

End point title	Geometric Mean Neutralising Antibody Titers (GMTs) of All Four Dengue Serotypes

End point description:

GMTs were assessed for the four dengue serotypes: TDV-1, TDV-2, TDV-3, and TDV-4. The FAS included all randomised participants who received at least one dose of study vaccine and for whom valid pre-dosing and at least one valid post-dosing blood sample have been received. Here "n" is the number of participants with microneutralising (MN) assay samples. 9999=Data were not collected at this timepoint. 0.99999 and 99999=Lower and upper limits of CI could not be evaluated as titers were below the lower limit of detection (LLOD).

End point type	Secondary

End point timeframe:

Day 28, 90 and 120 (Parts 1 and 2) and Days 180, 360, 720 and 1080 in Part 1

End point values	Part I: TDV 21 to 45 Years	Part I: Placebo 21 to 45 Years	Part I: TDV 12 to 20 Years	Part I: Placebo 12 to 20 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	14	22	14
Units: titer				
geometric mean (confidence interval 95%)				
Day 28, TDV-1(n=24,13,22,14,21,17,23,13,158,53)	1156.9 (582.0 to 2299.9)	396.1 (120.6 to 1301.2)	919.5 (273.1 to 3096.1)	204.9 (59.8 to 702.6)
Day 28, TDV-2(n=24,13,22,14,21,17,23,13,158,53)	2313.9 (1328.1 to 4031.2)	178.0 (44.4 to 712.9)	1726.6 (539.2 to 5528.8)	420.2 (116.5 to 1515.6)
Day 28, TDV-3(n=24,13,22,14,21,17,23,13,158,53)	538.2 (218.3 to 1326.5)	226.3 (70.1 to 730.7)	330.2 (94.4 to 1155.9)	304.5 (83.9 to 1105.6)

Day 28, TDV-4(n=24,13,22,14,21,17,23,13,158,53)	130.7 (54.3 to 314.5)	55.1 (15.6 to 194.9)	56.6 (19.1 to 167.3)	46.4 (17.6 to 122.4)
Day 90, TDV-1(n=23,13,22,14,21,17,22,11,159,53)	961.3 (413.5 to 2235.2)	751.0 (227.1 to 2483.1)	555.4 (156.9 to 1966.2)	215.3 (55.4 to 836.4)
Day 90, TDV-2(n=23,13,22,14,21,17,22,11,159,53)	2073.1 (1267.0 to 3392.1)	320.0 (74.2 to 1379.3)	1146.4 (416.7 to 3153.6)	463.9 (120.1 to 1792.0)
Day 90, TDV-3(n=23,13,22,14,21,17,22,11,159,53)	510.5 (218.3 to 1194.1)	272.7 (86.4 to 860.4)	193.3 (54.9 to 680.7)	336.2 (95.3 to 1185.8)
Day 90, TDV-4(n=23,13,22,14,21,17,22,11,159,53)	125.7 (57.7 to 274.1)	36.0 (13.3 to 97.2)	76.3 (29.3 to 198.9)	69.0 (23.7 to 200.4)
Day 120, TDV-1(n=22,13,22,14,21,17,22,11,156,53)	1240.3 (585.2 to 2628.8)	356.0 (117.8 to 1076.1)	1300.3 (528.5 to 3199.4)	164.0 (52.8 to 509.4)
Day 120, TDV-2(n=22,13,22,14,21,17,22,11,156,53)	2403.7 (1443.5 to 4002.6)	272.7 (60.9 to 1221.6)	1754.0 (744.2 to 4134.4)	399.9 (109.7 to 1457.7)
Day 120, TDV-3(n=22,13,22,14,21,17,22,11,156,53)	650.2 (288.1 to 1467.0)	287.6 (116.7 to 709.1)	340.8 (121.3 to 957.6)	289.8 (82.7 to 1016.1)
Day 120, TDV-4(n=22,13,22,14,21,17,22,11,156,53)	193.3 (84.7 to 441.1)	36.0 (10.5 to 123.2)	82.6 (31.8 to 214.1)	69.0 (23.5 to 202.7)
Day 180, TDV-1(n=20,12,21,14,21,17,22,11,0,0)	831.7 (332.7 to 2078.8)	320.0 (86.0 to 1191.4)	954.7 (280.8 to 3245.7)	141.6 (38.8 to 516.4)
Day 180, TDV-2(n=20,12,21,14,21,17,22,11,0,0)	2521.2 (1444.5 to 4400.4)	226.3 (48.9 to 1046.4)	1515.6 (593.7 to 3869.0)	412.3 (104.9 to 1620.6)
Day 180, TDV-3(n=20,12,21,14,21,17,22,11,0,0)	422.2 (179.1 to 995.5)	285.1 (74.7 to 1087.6)	321.2 (101.3 to 1018.4)	206.1 (65.9 to 645.0)
Day 180, TDV-4(n=20,12,21,14,21,17,22,11,0,0)	146.7 (62.8 to 342.7)	44.9 (13.0 to 155.7)	71.5 (27.6 to 185.0)	51.2 (19.8 to 132.4)
Day 360, TDV-1(n=19,12,21,13,21,17,22,11,0,0)	1417.4 (474.5 to 4233.5)	320.0 (78.5 to 1304.5)	642.5 (179.5 to 2299.8)	221.0 (48.9 to 999.6)
Day 360, TDV-2(n=19,12,21,13,21,17,22,11,0,0)	2410.7 (1120.9 to 5185.0)	271.8 (60.9 to 1212.7)	852.2 (369.9 to 1963.3)	523.6 (113.4 to 2416.7)
Day 360, TDV-3(n=19,12,21,13,21,17,22,11,0,0)	537.9 (158.5 to 1825.3)	256.2 (70.2 to 935.3)	171.3 (51.1 to 574.0)	209.5 (55.4 to 792.9)
Day 360, TDV-4(n=19,12,21,13,21,17,22,11,0,0)	163.6 (56.2 to 476.4)	44.9 (13.5 to 149.1)	73.8 (26.9 to 202.8)	59.9 (19.4 to 184.4)
Day 720, TDV-1(n=16,9,19,13,21,17,22,10,0,0)	924.9 (289.1 to 2959.4)	691.2 (175.7 to 2720.1)	452.5 (124.5 to 1644.5)	258.5 (67.0 to 997.9)
Day 720, TDV-2(n=16,9,19,13,21,17,22,10,0,0)	1399.4 (704.8 to 2778.8)	244.9 (50.1 to 1197.1)	714.0 (247.9 to 2056.8)	396.1 (98.3 to 1595.4)
Day 720, TDV-3(n=16,9,19,13,21,17,22,10,0,0)	515.4 (140.6 to 1888.5)	403.2 (96.0 to 1692.5)	154.3 (36.7 to 649.1)	303.4 (70.9 to 1297.4)
Day 720, TDV-4(n=16,9,19,13,21,17,22,10,0,0)	106.0 (40.5 to 277.3)	48.5 (13.1 to 180.2)	66.7 (22.5 to 197.2)	93.9 (29.0 to 303.8)
Day 1080, TDV-1(n=15,8,18,11,21,17,21,9,0,0)	718.4 (239.3 to 2156.7)	905.1 (243.2 to 3368.4)	508.0 (137.6 to 1874.9)	219.3 (41.2 to 1165.6)
Day 1080, TDV-2(n=15,8,18,11,21,17,21,9,0,0)	702.0 (403.1 to 1222.4)	146.7 (27.3 to 787.7)	615.8 (277.5 to 1366.8)	256.7 (61.0 to 1079.3)
Day 1080, TDV-3(n=15,8,18,11,21,17,21,9,0,0)	291.8 (82.5 to 1032.3)	472.6 (84.6 to 2641.0)	201.6 (54.6 to 744.0)	264.9 (53.4 to 1313.1)
Day 1080, TDV-4(n=15,8,18,11,21,17,21,9,0,0)	81.9 (30.9 to 216.9)	80.0 (17.5 to 364.8)	61.1 (21.7 to 172.3)	80.0 (18.9 to 338.6)

End point values	Part I: TDV 6 to 11 Years	Part I: Placebo 6 to 11 Years	Part I: TDV 1.5 to 5 Years	Part I: Placebo 1.5 to 5 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	17	23	13

Units: titer				
geometric mean (confidence interval 95%)				
Day 28, TDV-1(n=24,13,22,14,21,17,23,13,158,53)	383.7 (178.1 to 826.5)	11.3 (4.4 to 29.3)	395.2 (190.0 to 822.0)	5.3 (4.7 to 5.9)
Day 28, TDV-2(n=24,13,22,14,21,17,23,13,158,53)	2357.2 (1218.6 to 4559.7)	13.9 (5.0 to 38.6)	1134.6 (479.9 to 2682.6)	5.0 (0.99999 to 99999)
Day 28, TDV-3(n=24,13,22,14,21,17,23,13,158,53)	314.8 (135.3 to 732.3)	8.5 (4.1 to 17.4)	129.6 (52.9 to 317.6)	5.0 (0.99999 to 99999)
Day 28, TDV-4(n=24,13,22,14,21,17,23,13,158,53)	61.4 (27.1 to 139.4)	7.2 (3.9 to 13.4)	27.0 (12.5 to 58.5)	5.0 (0.99999 to 99999)
Day 90, TDV-1(n=23,13,22,14,21,17,22,11,159,53)	245.7 (82.2 to 734.7)	10.8 (4.2 to 28.3)	165.1 (69.4 to 392.8)	5.0 (0.99999 to 99999)
Day 90, TDV-2(n=23,13,22,14,21,17,22,11,159,53)	966.9 (451.8 to 2069.2)	10.0 (4.3 to 23.1)	467.0 (205.7 to 1060.3)	5.0 (0.99999 to 99999)
Day 90, TDV-3(n=23,13,22,14,21,17,22,11,159,53)	195.0 (73.3 to 518.8)	8.5 (4.4 to 16.5)	66.2 (28.3 to 154.8)	5.3 (4.6 to 6.1)
Day 90, TDV-4(n=23,13,22,14,21,17,22,11,159,53)	31.2 (12.3 to 79.3)	7.5 (4.0 to 14.3)	16.8 (9.3 to 30.5)	5.3 (4.6 to 6.1)
Day 120, TDV-1(n=22,13,22,14,21,17,22,11,156,53)	551.7 (231.6 to 1313.8)	13.9 (4.9 to 39.2)	582.3 (275.9 to 1229.1)	5.0 (0.99999 to 99999)
Day 120, TDV-2(n=22,13,22,14,21,17,22,11,156,53)	983.0 (423.5 to 2281.6)	17.3 (4.6 to 65.9)	459.7 (232.6 to 908.7)	5.0 (0.99999 to 99999)
Day 120, TDV-3(n=22,13,22,14,21,17,22,11,156,53)	377.4 (170.3 to 836.6)	14.4 (5.0 to 41.8)	196.4 (115.2 to 334.8)	5.0 (0.99999 to 99999)
Day 120, TDV-4(n=22,13,22,14,21,17,22,11,156,53)	64.6 (27.6 to 151.1)	13.9 (5.4 to 35.3)	41.3 (24.9 to 68.3)	5.0 (0.99999 to 99999)
Day 180, TDV-1(n=20,12,21,14,21,17,22,11,0,0)	230.5 (107.2 to 495.4)	12.8 (4.7 to 34.4)	249.2 (113.5 to 546.8)	5.0 (0.99999 to 99999)
Day 180, TDV-2(n=20,12,21,14,21,17,22,11,0,0)	642.5 (325.9 to 1266.8)	14.4 (4.9 to 42.4)	399.3 (194.7 to 819.1)	5.0 (0.99999 to 99999)
Day 180, TDV-3(n=20,12,21,14,21,17,22,11,0,0)	189.1 (84.2 to 424.6)	12.5 (5.5 to 28.4)	93.6 (41.4 to 211.7)	6.0 (4.0 to 9.2)
Day 180, TDV-4(n=20,12,21,14,21,17,22,11,0,0)	47.2 (20.4 to 109.3)	9.2 (4.4 to 19.4)	28.3 (14.3 to 56.0)	5.0 (0.99999 to 99999)
Day 360, TDV-1(n=19,12,21,13,21,17,22,11,0,0)	132.0 (51.6 to 338.0)	15.7 (5.5 to 45.2)	220.9 (90.3 to 540.2)	5.3 (4.6 to 6.1)
Day 360, TDV-2(n=19,12,21,13,21,17,22,11,0,0)	329.5 (161.7 to 671.1)	17.1 (6.0 to 48.7)	298.8 (141.1 to 632.8)	5.0 (0.99999 to 99999)
Day 360, TDV-3(n=19,12,21,13,21,17,22,11,0,0)	103.1 (40.0 to 265.6)	11.8 (5.3 to 26.0)	89.9 (43.9 to 184.1)	5.0 (0.99999 to 99999)
Day 360, TDV-4(n=19,12,21,13,21,17,22,11,0,0)	27.0 (11.9 to 61.0)	7.5 (4.0 to 14.0)	20.0 (10.8 to 37.0)	5.0 (0.99999 to 99999)
Day 720, TDV-1(n=16,9,19,13,21,17,22,10,0,0)	115.0 (45.4 to 291.1)	12.8 (4.8 to 34.2)	248.7 (103.4 to 597.9)	5.7 (4.2 to 7.9)
Day 720, TDV-2(n=16,9,19,13,21,17,22,10,0,0)	280.4 (135.1 to 582.2)	13.0 (5.0 to 33.9)	219.3 (106.7 to 450.7)	5.4 (4.6 to 6.3)
Day 720, TDV-3(n=16,9,19,13,21,17,22,10,0,0)	65.6 (21.2 to 203.0)	8.8 (4.5 to 17.5)	104.6 (37.7 to 289.8)	8.1 (2.7 to 24.3)
Day 720, TDV-4(n=16,9,19,13,21,17,22,10,0,0)	24.4 (10.8 to 55.2)	8.5 (4.7 to 15.2)	26.6 (12.3 to 57.3)	5.7 (4.2 to 7.9)
Day 1080, TDV-1(n=15,8,18,11,21,17,21,9,0,0)	92.8 (36.5 to 236.2)	12.8 (4.8 to 34.2)	149.8 (63.9 to 351.1)	6.3 (3.7 to 10.7)
Day 1080, TDV-2(n=15,8,18,11,21,17,21,9,0,0)	160.0 (76.5 to 334.8)	12.8 (5.2 to 31.7)	118.9 (57.0 to 248.0)	5.0 (0.99999 to 99999)
Day 1080, TDV-3(n=15,8,18,11,21,17,21,9,0,0)	70.1 (27.6 to 178.4)	9.6 (4.6 to 20.1)	80.0 (31.9 to 200.7)	9.3 (2.2 to 38.3)
Day 1080, TDV-4(n=15,8,18,11,21,17,21,9,0,0)	17.5 (8.4 to 36.6)	7.2 (4.2 to 12.3)	17.0 (8.6 to 33.3)	5.4 (4.5 to 6.4)

End point values	Part II: TDV 1.5 to 11 Years	Part II: Placebo 1.5 to 11 Years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	159	53		
Units: titer				
geometric mean (confidence interval 95%)				
Day 28, TDV-1(n=24,13,22,14,21,17,23,13,158,53)	522.2 (396.5 to 687.7)	28.7 (14.8 to 55.5)		
Day 28, TDV-2(n=24,13,22,14,21,17,23,13,158,53)	1496.5 (1129.1 to 1983.4)	16.4 (9.7 to 27.9)		
Day 28, TDV-3(n=24,13,22,14,21,17,23,13,158,53)	206.9 (149.9 to 285.7)	19.4 (11.5 to 32.6)		
Day 28, TDV-4(n=24,13,22,14,21,17,23,13,158,53)	45.4 (33.2 to 62.0)	11.0 (7.8 to 15.6)		
Day 90, TDV-1(n=23,13,22,14,21,17,22,11,159,53)	324.2 (239.1 to 439.6)	27.9 (14.6 to 53.4)		
Day 90, TDV-2(n=23,13,22,14,21,17,22,11,159,53)	463.5 (364.0 to 590.2)	15.2 (8.9 to 25.9)		
Day 90, TDV-3(n=23,13,22,14,21,17,22,11,159,53)	139.5 (99.7 to 195.1)	17.1 (10.2 to 28.5)		
Day 90, TDV-4(n=23,13,22,14,21,17,22,11,159,53)	33.7 (25.4 to 44.7)	11.8 (8.2 to 16.9)		
Day 120, TDV-1(n=22,13,22,14,21,17,22,11,156,53)	710.4 (547.5 to 921.9)	29.6 (15.6 to 56.1)		
Day 120, TDV-2(n=22,13,22,14,21,17,22,11,156,53)	605.4 (490.6 to 747.1)	16.2 (9.5 to 27.8)		
Day 120, TDV-3(n=22,13,22,14,21,17,22,11,156,53)	332.3 (263.1 to 419.7)	19.0 (11.3 to 32.0)		
Day 120, TDV-4(n=22,13,22,14,21,17,22,11,156,53)	76.5 (60.5 to 96.8)	11.2 (8.0 to 15.9)		
Day 180, TDV-1(n=20,12,21,14,21,17,22,11,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 180, TDV-2(n=20,12,21,14,21,17,22,11,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 180, TDV-3(n=20,12,21,14,21,17,22,11,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 180, TDV-4(n=20,12,21,14,21,17,22,11,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 360, TDV-1(n=19,12,21,13,21,17,22,11,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 360, TDV-2(n=19,12,21,13,21,17,22,11,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 360, TDV-3(n=19,12,21,13,21,17,22,11,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 360, TDV-4(n=19,12,21,13,21,17,22,11,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 720, TDV-1(n=16,9,19,13,21,17,22,10,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 720, TDV-2(n=16,9,19,13,21,17,22,10,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 720, TDV-3(n=16,9,19,13,21,17,22,10,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 720, TDV-4(n=16,9,19,13,21,17,22,10,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		

Day 1080, TDV-1(n=15,8,18,11,21,17,21,9,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 1080, TDV-2(n=15,8,18,11,21,17,21,9,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 1080, TDV-3(n=15,8,18,11,21,17,21,9,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 1080, TDV-4(n=15,8,18,11,21,17,21,9,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Fold Rise (GMFR) of Dengue Neutralising Antibody Titers for Each of the 4 Dengue Serotypes

End point title	Geometric Mean Fold Rise (GMFR) of Dengue Neutralising Antibody Titers for Each of the 4 Dengue Serotypes

End point description:

FAS included all randomised participants who received at least one dose of study vaccine or placebo and for whom valid pre-dosing and at least one valid post-dosing blood sample have been received. n=number of subjects available for analysis at a specific timepoint. 9999=Data were not evaluated at this timepoint. 0.99999 and 99999=Lower and upper limits of CI could not be evaluated as titers were below the LLOD.

End point type	Secondary

End point timeframe:

Day 28 and Day 90 (Parts 1 and 2) and Days 120, 180, 360, 720 and 1080 in Part 1

End point values	Part I: TDV 21 to 45 Years	Part I: Placebo 21 to 45 Years	Part I: TDV 12 to 20 Years	Part I: Placebo 12 to 20 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	14	22	14
Units: fold rise				
geometric mean (confidence interval 95%)				
Day 28, TDV-1(n=24,13,22,14,21,17,23,13,158,53)	3.41 (1.61 to 7.24)	0.90 (0.57 to 1.41)	8.93 (3.61 to 22.09)	1.03 (0.67 to 1.56)
Day 28, TDV-2(n=24,13,22,14,21,17,23,13,158,53)	7.89 (2.01 to 31.00)	0.71 (0.45 to 1.11)	20.26 (5.34 to 76.93)	1.05 (0.69 to 1.59)
Day 28, TDV-3(n=24,13,22,14,21,17,23,13,158,53)	2.34 (1.22 to 4.52)	0.97 (0.74 to 1.28)	4.40 (1.85 to 10.48)	1.08 (0.71 to 1.63)
Day 28, TDV-4(n=24,13,22,14,21,17,23,13,158,53)	1.71 (0.88 to 3.31)	1.11 (0.65 to 1.90)	2.74 (1.11 to 6.80)	0.82 (0.53 to 1.26)
Day 90, TDV-1(n=23,13,22,14,21,17,22,11,159,53)	3.10 (1.26 to 7.59)	1.70 (0.75 to 3.90)	5.40 (2.50 to 11.63)	1.08 (0.71 to 1.63)
Day 90, TDV-2(n=23,13,22,14,21,17,22,11,159,53)	7.09 (2.20 to 22.83)	1.27 (0.78 to 2.08)	13.45 (4.52 to 40.08)	1.16 (0.74 to 1.83)
Day 90, TDV-3(n=23,13,22,14,21,17,22,11,159,53)	2.29 (1.29 to 4.05)	1.17 (0.74 to 1.85)	2.57 (1.14 to 5.80)	1.19 (0.67 to 2.13)
Day 90, TDV-4(n=23,13,22,14,21,17,22,11,159,53)	1.64 (1.02 to 2.66)	0.73 (0.52 to 1.01)	3.70 (1.78 to 7.66)	1.22 (0.72 to 2.07)
Day 120, TDV-1(n=22,13,22,14,21,17,22,11,156,53)	3.64 (1.09 to 12.10)	0.81 (0.56 to 1.16)	12.63 (5.56 to 28.70)	0.82 (0.34 to 2.01)

Day 120, TDV-2(n=22,13,22,14,21,17,22,11,156,53)	8.79 (2.81 to 27.47)	1.08 (0.79 to 1.49)	20.59 (6.45 to 65.66)	1.00 (0.67 to 1.50)
Day 120, TDV-3(n=22,13,22,14,21,17,22,11,156,53)	2.78 (1.44 to 5.37)	1.24 (0.70 to 2.20)	4.54 (2.02 to 10.17)	1.03 (0.60 to 1.75)
Day 120, TDV-4(n=22,13,22,14,21,17,22,11,156,53)	2.45 (1.44 to 4.19)	0.73 (0.43 to 1.23)	4.00 (2.00 to 8.00)	1.22 (0.72 to 2.07)
Day 180, TDV-1(n=20,12,21,14,21,17,22,11,0,0)	3.94 (1.35 to 11.54)	0.89 (0.59 to 1.35)	9.16 (2.89 to 29.05)	0.71 (0.45 to 1.10)
Day 180, TDV-2(n=20,12,21,14,21,17,22,11,0,0)	11.53 (3.61 to 36.83)	0.94 (0.55 to 1.63)	17.16 (5.15 to 57.17)	1.03 (0.58 to 1.84)
Day 180, TDV-3(n=20,12,21,14,21,17,22,11,0,0)	2.42 (1.23 to 4.76)	1.26 (0.95 to 1.68)	4.58 (1.72 to 12.21)	0.73 (0.44 to 1.20)
Day 180, TDV-4(n=20,12,21,14,21,17,22,11,0,0)	2.38 (1.43 to 3.95)	1.00 (0.63 to 1.58)	3.35 (1.60 to 7.01)	0.91 (0.60 to 1.37)
Day 360, TDV-1(n=19,12,21,13,21,17,22,11,0,0)	5.51 (2.13 to 14.26)	0.67 (0.47 to 0.95)	6.17 (2.36 to 16.14)	1.09 (0.50 to 2.37)
Day 360, TDV-2(n=19,12,21,13,21,17,22,11,0,0)	9.04 (2.76 to 29.60)	0.93 (0.64 to 1.34)	9.65 (3.34 to 27.83)	1.16 (0.54 to 2.46)
Day 360, TDV-3(n=19,12,21,13,21,17,22,11,0,0)	2.56 (1.21 to 5.39)	0.95 (0.71 to 1.27)	2.44 (1.00 to 5.96)	0.83 (0.44 to 1.57)
Day 360, TDV-4(n=19,12,21,13,21,17,22,11,0,0)	2.32 (1.15 to 4.70)	0.75 (0.53 to 1.06)	3.45 (1.66 to 7.17)	1.03 (0.45 to 2.38)
Day 720, TDV-1(n=16,9,19,13,21,17,22,10,0,0)	4.65 (1.45 to 14.97)	0.63 (0.43 to 0.92)	3.65 (1.68 to 7.96)	1.27 (0.64 to 2.54)
Day 720, TDV-2(n=16,9,19,13,21,17,22,10,0,0)	9.13 (2.52 to 33.07)	0.80 (0.51 to 1.24)	8.61 (3.28 to 22.56)	0.88 (0.52 to 1.48)
Day 720, TDV-3(n=16,9,19,13,21,17,22,10,0,0)	3.15 (1.38 to 7.21)	0.93 (0.67 to 1.28)	2.00 (0.76 to 5.28)	1.21 (0.72 to 2.02)
Day 720, TDV-4(n=16,9,19,13,21,17,22,10,0,0)	1.54 (0.77 to 3.10)	0.56 (0.39 to 0.82)	2.88 (1.41 to 5.90)	1.62 (0.76 to 3.43)
Day 1080, TDV-1(n=15,8,18,11,21,17,21,9,0,0)	3.91 (1.40 to 10.94)	0.77 (0.45 to 1.31)	3.43 (1.66 to 7.08)	1.33 (0.73 to 2.41)
Day 1080, TDV-2(n=15,8,18,11,21,17,21,9,0,0)	4.59 (1.45 to 14.59)	0.68 (0.51 to 0.90)	6.35 (2.54 to 15.87)	0.83 (0.51 to 1.34)
Day 1080, TDV-3(n=15,8,18,11,21,17,21,9,0,0)	1.87 (0.98 to 3.54)	1.04 (0.75 to 1.45)	2.33 (0.97 to 5.59)	1.17 (0.65 to 2.10)
Day 1080, TDV-4(n=15,8,18,11,21,17,21,9,0,0)	1.15 (0.71 to 1.87)	1.00 (0.58 to 1.71)	2.42 (1.18 to 4.98)	1.46 (0.66 to 3.21)

End point values	Part I: TDV 6 to 11 Years	Part I: Placebo 6 to 11 Years	Part I: TDV 1.5 to 5 Years	Part I: Placebo 1.5 to 5 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	17	23	13
Units: fold rise				
geometric mean (confidence interval 95%)				
Day 28, TDV-1(n=24,13,22,14,21,17,23,13,158,53)	29.47 (11.70 to 74.22)	1.00 (0.88 to 1.13)	27.94 (13.64 to 57.23)	1.05 (0.94 to 1.18)
Day 28, TDV-2(n=24,13,22,14,21,17,23,13,158,53)	181.02 (47.86 to 684.60)	1.39 (0.81 to 2.37)	128.00 (44.62 to 367.22)	1.00 (0.99999 to 99999)
Day 28, TDV-3(n=24,13,22,14,21,17,23,13,158,53)	24.17 (10.16 to 57.49)	1.02 (0.98 to 1.07)	13.76 (6.01 to 31.50)	1.00 (0.99999 to 99999)
Day 28, TDV-4(n=24,13,22,14,21,17,23,13,158,53)	7.49 (3.60 to 15.58)	1.13 (0.94 to 1.36)	4.00 (1.85 to 8.66)	0.95 (0.84 to 1.06)
Day 90, TDV-1(n=23,13,22,14,21,17,22,11,159,53)	18.87 (7.61 to 46.81)	0.96 (0.88 to 1.05)	11.14 (5.37 to 23.09)	1.00 (0.99999 to 99999)
Day 90, TDV-2(n=23,13,22,14,21,17,22,11,159,53)	74.25 (30.35 to 181.64)	1.00 (0.88 to 1.13)	51.33 (20.33 to 129.62)	1.00 (0.99999 to 99999)

Day 90, TDV-3(n=23,13,22,14,21,17,22,11,159,53)	14.98 (6.11 to 36.75)	1.02 (0.92 to 1.13)	6.83 (3.13 to 14.93)	1.07 (0.93 to 1.23)
Day 90, TDV-4(n=23,13,22,14,21,17,22,11,159,53)	3.81 (1.73 to 8.36)	1.18 (0.90 to 1.54)	2.45 (1.39 to 4.32)	1.00 (0.81 to 1.23)
Day 120, TDV-1(n=22,13,22,14,21,17,22,11,156,53)	42.36 (19.57 to 91.70)	1.23 (0.72 to 2.09)	39.27 (24.12 to 63.94)	1.00 (0.99999 to 99999)
Day 120, TDV-2(n=22,13,22,14,21,17,22,11,156,53)	75.48 (29.82 to 191.08)	1.73 (0.56 to 5.38)	50.53 (24.11 to 105.89)	1.00 (0.99999 to 99999)
Day 120, TDV-3(n=22,13,22,14,21,17,22,11,156,53)	28.98 (14.52 to 57.87)	1.73 (0.73 to 4.14)	20.26 (12.02 to 34.17)	1.00 (0.99999 to 99999)
Day 120, TDV-4(n=22,13,22,14,21,17,22,11,156,53)	7.87 (4.25 to 14.57)	2.17 (0.99 to 4.76)	6.02 (3.81 to 9.53)	0.94 (0.82 to 1.08)
Day 180, TDV-1(n=20,12,21,14,21,17,22,11,0,0)	17.70 (10.04 to 31.22)	1.13 (0.77 to 1.66)	16.81 (9.56 to 29.53)	1.00 (0.99999 to 99999)
Day 180, TDV-2(n=20,12,21,14,21,17,22,11,0,0)	49.34 (22.02 to 110.57)	1.44 (0.66 to 3.17)	43.89 (21.22 to 90.80)	1.00 (0.99999 to 99999)
Day 180, TDV-3(n=20,12,21,14,21,17,22,11,0,0)	14.52 (7.70 to 27.38)	1.50 (0.86 to 2.64)	9.66 (4.84 to 19.30)	1.21 (0.79 to 1.84)
Day 180, TDV-4(n=20,12,21,14,21,17,22,11,0,0)	5.76 (3.14 to 10.55)	1.44 (0.88 to 2.36)	4.13 (2.29 to 7.43)	0.94 (0.82 to 1.08)
Day 360, TDV-1(n=19,12,21,13,21,17,22,11,0,0)	10.14 (4.81 to 21.39)	1.39 (0.91 to 2.12)	14.90 (7.48 to 29.66)	1.07 (0.93 to 1.23)
Day 360, TDV-2(n=19,12,21,13,21,17,22,11,0,0)	25.30 (10.10 to 63.38)	1.71 (0.81 to 3.59)	32.84 (15.76 to 68.42)	1.00 (0.99999 to 99999)
Day 360, TDV-3(n=19,12,21,13,21,17,22,11,0,0)	7.92 (3.28 to 19.10)	1.41 (0.88 to 2.29)	9.28 (4.55 to 18.92)	1.00 (0.99999 to 99999)
Day 360, TDV-4(n=19,12,21,13,21,17,22,11,0,0)	3.29 (1.83 to 5.89)	1.18 (0.96 to 1.44)	2.92 (1.71 to 4.98)	0.94 (0.82 to 1.08)
Day 720, TDV-1(n=16,9,19,13,21,17,22,10,0,0)	8.83 (4.69 to 16.64)	1.13 (0.87 to 1.46)	16.77 (7.12 to 39.51)	1.15 (0.84 to 1.57)
Day 720, TDV-2(n=16,9,19,13,21,17,22,10,0,0)	21.53 (9.91 to 46.81)	1.30 (0.73 to 2.32)	24.10 (11.73 to 49.52)	1.07 (0.92 to 1.25)
Day 720, TDV-3(n=16,9,19,13,21,17,22,10,0,0)	5.04 (2.21 to 11.50)	1.06 (0.80 to 1.41)	10.79 (4.16 to 28.00)	1.62 (0.54 to 4.87)
Day 720, TDV-4(n=16,9,19,13,21,17,22,10,0,0)	2.97 (1.56 to 5.66)	1.33 (0.95 to 1.86)	3.88 (1.89 to 7.96)	1.07 (0.74 to 1.55)
Day 1080, TDV-1(n=15,8,18,11,21,17,21,9,0,0)	7.13 (3.86 to 13.17)	1.13 (0.79 to 1.62)	9.59 (4.72 to 19.48)	1.26 (0.74 to 2.15)
Day 1080, TDV-2(n=15,8,18,11,21,17,21,9,0,0)	12.29 (5.76 to 26.22)	1.28 (0.73 to 2.24)	12.70 (5.92 to 27.25)	1.00 (0.99999 to 99999)
Day 1080, TDV-3(n=15,8,18,11,21,17,21,9,0,0)	5.38 (2.71 to 10.71)	1.15 (0.89 to 1.50)	8.55 (3.97 to 18.38)	1.85 (0.45 to 7.67)
Day 1080, TDV-4(n=15,8,18,11,21,17,21,9,0,0)	2.14 (1.23 to 3.72)	1.13 (0.94 to 1.36)	2.44 (1.40 to 4.25)	1.00 (0.77 to 1.31)

End point values	Part II: TDV 1.5 to 11 Years	Part II: Placebo 1.5 to 11 Years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	159	53		
Units: fold rise				
geometric mean (confidence interval 95%)				
Day 28, TDV-1(n=24,13,22,14,21,17,23,13,158,53)	27.58 (20.91 to 36.38)	0.97 (0.82 to 1.16)		
Day 28, TDV-2(n=24,13,22,14,21,17,23,13,158,53)	113.02 (0.1 to 8192.0)	0.94 (0.0 to 2.0)		
Day 28, TDV-3(n=24,13,22,14,21,17,23,13,158,53)	12.47 (9.18 to 16.92)	0.82 (0.71 to 0.94)		

Day 28, TDV-4(n=24,13,22,14,21,17,23,13,158,53)	74.1 (66.5 to 80.7)	35.8 (23.1 to 50.2)		
Day 90, TDV-1(n=23,13,22,14,21,17,22,11,159,53)	324.2 (239.1 to 439.6)	27.9 (14.6 to 53.4)		
Day 90, TDV-2(n=23,13,22,14,21,17,22,11,159,53)	463.5 (364.0 to 590.2)	15.2 (8.9 to 25.9)		
Day 90, TDV-3(n=23,13,22,14,21,17,22,11,159,53)	139.5 (99.7 to 195.1)	17.1 (10.2 to 28.5)		
Day 90, TDV-4(n=23,13,22,14,21,17,22,11,159,53)	33.7 (25.4 to 44.7)	11.8 (8.2 to 16.9)		
Day 120, TDV-1(n=22,13,22,14,21,17,22,11,156,53)	35.44 (26.46 to 47.48)	1.01 (0.79 to 1.28)		
Day 120, TDV-2(n=22,13,22,14,21,17,22,11,156,53)	44.16 (33.51 to 58.20)	0.92 (0.67 to 1.28)		
Day 120, TDV-3(n=22,13,22,14,21,17,22,11,156,53)	19.20 (14.75 to 24.98)	0.80 (0.64 to 1.01)		
Day 120, TDV-4(n=22,13,22,14,21,17,22,11,156,53)	7.43 (5.96 to 9.27)	1.03 (0.91 to 1.16)		
Day 180, TDV-1(n=20,12,21,14,21,17,22,11,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 180, TDV-2(n=20,12,21,14,21,17,22,11,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 180, TDV-3(n=20,12,21,14,21,17,22,11,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 180, TDV-4(n=20,12,21,14,21,17,22,11,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 360, TDV-1(n=19,12,21,13,21,17,22,11,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 360, TDV-2(n=19,12,21,13,21,17,22,11,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 360, TDV-3(n=19,12,21,13,21,17,22,11,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 360, TDV-4(n=19,12,21,13,21,17,22,11,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 720, TDV-1(n=16,9,19,13,21,17,22,10,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 720, TDV-2(n=16,9,19,13,21,17,22,10,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 720, TDV-3(n=16,9,19,13,21,17,22,10,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 720, TDV-4(n=16,9,19,13,21,17,22,10,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 1080, TDV-1(n=15,8,18,11,21,17,21,9,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 1080, TDV-2(n=15,8,18,11,21,17,21,9,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 1080, TDV-3(n=15,8,18,11,21,17,21,9,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		
Day 1080, TDV-4(n=15,8,18,11,21,17,21,9,0,0)	9999 (9999 to 9999)	9999 (9999 to 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Confirmed Dengue Fever

End point title	Number of Participants With Confirmed Dengue Fever

End point description:

Dengue fever was assessed in participants who had 3 consecutive days of fever >38°C and tested positive for dengue virus by polymerase chain reaction (PCR) analysis. The safety set included all randomised participants who received at least one dose of study vaccine (or placebo).

End point type	Secondary

End point timeframe:

Day 1 to Day 1080

End point values	Part I: TDV 21 to 45 Years	Part I: Placebo 21 to 45 Years	Part I: TDV 12 to 20 Years	Part I: Placebo 12 to 20 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	14	22	14
Units: participants	0	0	1	0

End point values	Part I: TDV 6 to 11 Years	Part I: Placebo 6 to 11 Years	Part I: TDV 1.5 to 5 Years	Part I: Placebo 1.5 to 5 Years
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	17	23	13
Units: participants	1	0	0	1

End point values	Part II: TDV 1.5 to 11 Years	Part II: Placebo 1.5 to 11 Years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	159	53		
Units: participants	2	1		

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Serious AEs were collected throughout the study Day 0 up to Day 1080. Other (non-serious) AEs were collected within 28 days of all vaccinations (up to Day 28 and Day 118).

Adverse event reporting additional description:

At each visit the investigator had to document any occurrence of adverse events and abnormal laboratory findings. Any event spontaneously reported by the participant or observed by the investigator was recorded, irrespective of the relation to study treatment.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	14.0

Reporting groups

Reporting group title	Part I: TDV 21 to 45 Years

Reporting group description:

TDV 0.5 mL, injection, SC, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 21 to 45 years. TDV comprised of 4 recombinant, live attenuated dengue virus strains: TDV-1, TDV-2, TDV-3 and TDV-4 containing 2*10^4 plaque forming units (PFU), 5*10^4 PFU, 1*10^5 PFU, and 3*10^5 PFU respectively, total virus per dose: 4.7*10^5 PFU.

Reporting group title	Part I: Placebo 21 to 45 Years

Reporting group description:

TDV placebo-matching 0.5 mL injection, SC, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 21 to 45 years.

Reporting group title	Part I: TDV 12 to 20 Years

Reporting group description:

TDV 0.5 mL, injection, SC, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 12 to 20 years. TDV comprised of 4 recombinant, live attenuated dengue virus strains: TDV-1, TDV-2, TDV-3 and TDV-4 containing 2*10^4 PFU, 5*10^4 PFU, 1*10^5 PFU, and 3*10^5 PFU respectively, total virus per dose: 4.7*10^5 PFU.

Reporting group title	Part I: Placebo 12 to 20 Years

Reporting group description:

TDV placebo-matching 0.5 mL injection, SC, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 12 to 20 years.

Reporting group title	Part I: TDV 6 to 11 Years

Reporting group description:

TDV 0.5 mL, injection, SC, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 6 to 11 years. TDV comprised of 4 recombinant, live attenuated dengue virus strains: TDV-1, TDV-2, TDV-3 and TDV-4 containing 2*10^4 PFU, 5*10^4 PFU, 1*10^5 PFU, and 3*10^5 PFU respectively, total virus per dose: 4.7*10^5 PFU.

Reporting group title	Part I: Placebo 6 to 11 Years

Reporting group description:

TDV placebo-matching 0.5 mL injection, SC, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 6 to 11 years.

Reporting group title	Part I: TDV 1.5 to 5 Years

Reporting group description:

TDV 0.5 mL, injection, SC, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 1.5 to 5 years. TDV comprised of 4 recombinant, live attenuated dengue virus strains: TDV-1, TDV-2, TDV-3 and TDV-4 containing 2*10^4 PFU, 5*10^4 PFU, 1*10^5 PFU, and 3*10^5 PFU respectively, total virus per dose: 4.7*10^5 PFU.

Reporting group title	Part I: Placebo 1.5 to 5 Years

Reporting group description:

TDV placebo-matching 0.5 mL injection, subcutaneously, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 1.5 to 5 years.

Reporting group title	Part II: TDV 1.5 to 11 Years

Reporting group description:

TDV 0.5 mL, injection, SC, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 1.5 to 11 years. TDV comprised of 4 recombinant, live attenuated dengue virus strains: TDV-1, TDV-2, TDV-3 and TDV-4 containing 2*10^4 PFU, 5*10^4 PFU, 1*10^5 PFU, and 3*10^5 PFU respectively, total virus per dose: 4.7*10^5 PFU.

Reporting group title	Part II: Placebo 1.5 to 11 Years

Reporting group description:

TDV placebo-matching 0.5 mL injection, SC, once on Day 0 (first dose) and Day 90 (second dose) in participants aged 1.5 to 5 years.

Serious adverse events	Part I: TDV 21 to 45 Years	Part I: Placebo 21 to 45 Years	Part I: TDV 12 to 20 Years
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 24 (16.67%)	0 / 14 (0.00%)	1 / 22 (4.55%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Incision site haemorrhage			
subjects affected / exposed	1 / 24 (4.17%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incision site haematoma			
subjects affected / exposed	1 / 24 (4.17%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Child maltreatment syndrome			
subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Forearm fracture			
subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull fractured base			
subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain contusion			

subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	1 / 24 (4.17%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	1 / 24 (4.17%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	1 / 24 (4.17%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Tonsillar hypertrophy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			

subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dengue fever			
subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis viral			
subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			

subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part I: Placebo 12 to 20 Years	Part I: TDV 6 to 11 Years	Part I: Placebo 6 to 11 Years
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 14 (0.00%)	4 / 21 (19.05%)	1 / 17 (5.88%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Incision site haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incision site haematoma			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Child maltreatment syndrome			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Forearm fracture			

subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull fractured base			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain contusion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Tonsillar hypertrophy			
subjects affected / exposed	0 / 14 (0.00%)	1 / 21 (4.76%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abscess limb			

subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dengue fever			
subjects affected / exposed	0 / 14 (0.00%)	1 / 21 (4.76%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis viral			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand-foot-and-mouth disease			

subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 14 (0.00%)	1 / 21 (4.76%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 14 (0.00%)	1 / 21 (4.76%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part I: TDV 1.5 to 5 Years	Part I: Placebo 1.5 to 5 Years	Part II: TDV 1.5 to 11 Years
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 23 (4.35%)	2 / 13 (15.38%)	14 / 159 (8.81%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Incision site haemorrhage			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incision site haematoma			

subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Child maltreatment syndrome			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Forearm fracture			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull fractured base			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain contusion			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory, thoracic and mediastinal disorders			
Tonsillar hypertrophy			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	3 / 159 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dengue fever			
subjects affected / exposed	0 / 23 (0.00%)	1 / 13 (7.69%)	2 / 159 (1.26%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis viral			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	5 / 159 (3.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastroenteritis rotavirus			
subjects affected / exposed	1 / 23 (4.35%)	0 / 13 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 23 (0.00%)	1 / 13 (7.69%)	2 / 159 (1.26%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part II: Placebo 1.5 to 11 Years		
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 53 (3.77%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
Incision site haemorrhage			

subjects affected / exposed	0 / 53 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Incision site haematoma			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Child maltreatment syndrome			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Forearm fracture			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skull fractured base			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Brain contusion			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Cholecystitis acute				
subjects affected / exposed	0 / 53 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Tonsillar hypertrophy				
subjects affected / exposed	0 / 53 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Abscess limb				
subjects affected / exposed	0 / 53 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cellulitis				
subjects affected / exposed	0 / 53 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Appendicitis				
subjects affected / exposed	0 / 53 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchitis				
subjects affected / exposed	0 / 53 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dengue fever				
subjects affected / exposed	1 / 53 (1.89%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastritis viral				
subjects affected / exposed	0 / 53 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Gastroenteritis			
subjects affected / exposed	1 / 53 (1.89%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Influenza			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Viral infection			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 53 (1.89%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Part I: TDV 21 to 45 Years	Part I: Placebo 21 to 45 Years	Part I: TDV 12 to 20 Years
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 24 (45.83%)	7 / 14 (50.00%)	13 / 22 (59.09%)
General disorders and administration site conditions			
Injection site pain			
subjects affected / exposed	2 / 24 (8.33%)	0 / 14 (0.00%)	2 / 22 (9.09%)
occurrences (all)	2	0	3
Influenza like illness			
subjects affected / exposed	0 / 24 (0.00%)	1 / 14 (7.14%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Fatigue			
subjects affected / exposed	0 / 24 (0.00%)	2 / 14 (14.29%)	2 / 22 (9.09%)
occurrences (all)	0	3	2
Injection site erythema			
subjects affected / exposed	1 / 24 (4.17%)	0 / 14 (0.00%)	2 / 22 (9.09%)
occurrences (all)	1	0	3
Pyrexia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 14 (7.14%)	2 / 22 (9.09%)
occurrences (all)	0	2	3
Reproductive system and breast disorders			
Endometriosis			
subjects affected / exposed	0 / 24 (0.00%)	1 / 14 (7.14%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Dysmenorrhoea			
subjects affected / exposed	0 / 24 (0.00%)	1 / 14 (7.14%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Nasal congestion			
subjects affected / exposed	1 / 24 (4.17%)	1 / 14 (7.14%)	0 / 22 (0.00%)
occurrences (all)	1	1	0
Cough			
subjects affected / exposed	1 / 24 (4.17%)	1 / 14 (7.14%)	0 / 22 (0.00%)
occurrences (all)	1	1	0
Rhinitis allergic			

subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Oropharyngeal pain			
subjects affected / exposed	0 / 24 (0.00%)	1 / 14 (7.14%)	1 / 22 (4.55%)
occurrences (all)	0	2	2
Asthma			
subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 24 (0.00%)	1 / 14 (7.14%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 24 (0.00%)	1 / 14 (7.14%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Anxiety			
subjects affected / exposed	0 / 24 (0.00%)	1 / 14 (7.14%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Investigations			
Blood pressure increased			
subjects affected / exposed	0 / 24 (0.00%)	1 / 14 (7.14%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Procedural pain			
subjects affected / exposed	0 / 24 (0.00%)	1 / 14 (7.14%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Laceration			
subjects affected / exposed	0 / 24 (0.00%)	1 / 14 (7.14%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Joint sprain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	4 / 24 (16.67%)	3 / 14 (21.43%)	7 / 22 (31.82%)
occurrences (all)	6	4	9

Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 14 (7.14%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Lymphadenitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 24 (0.00%)	1 / 14 (7.14%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 24 (4.17%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	0 / 24 (0.00%)	1 / 14 (7.14%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Food poisoning			
subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Nausea			

subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Aphthous stomatitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Urticaria papular			
subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 24 (0.00%)	1 / 14 (7.14%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Joint stiffness			
subjects affected / exposed	1 / 24 (4.17%)	1 / 14 (7.14%)	1 / 22 (4.55%)
occurrences (all)	1	1	1
Back pain			
subjects affected / exposed	2 / 24 (8.33%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Arthralgia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
Myalgia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 14 (7.14%)	2 / 22 (9.09%)
occurrences (all)	0	1	3
Infections and infestations			

Laryngitis			
subjects affected / exposed	2 / 24 (8.33%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Hordeolum			
subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	3 / 22 (13.64%)
occurrences (all)	0	0	3
Bronchitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 24 (0.00%)	1 / 14 (7.14%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	2 / 24 (8.33%)	1 / 14 (7.14%)	1 / 22 (4.55%)
occurrences (all)	2	1	1
Viral rash			
subjects affected / exposed	0 / 24 (0.00%)	0 / 14 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Dyslipidaemia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 14 (7.14%)	0 / 22 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Part I: Placebo 12 to 20 Years	Part I: TDV 6 to 11 Years	Part I: Placebo 6 to 11 Years
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 14 (57.14%)	9 / 21 (42.86%)	11 / 17 (64.71%)
General disorders and administration site conditions			

Injection site pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	2 / 14 (14.29%)	0 / 21 (0.00%)	1 / 17 (5.88%)
occurrences (all)	4	0	4
Injection site erythema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 14 (7.14%)	1 / 21 (4.76%)	0 / 17 (0.00%)
occurrences (all)	1	1	0
Reproductive system and breast disorders			
Endometriosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Dysmenorrhoea			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Nasal congestion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	2
Cough			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 14 (7.14%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Asthma			

subjects affected / exposed	0 / 14 (0.00%)	1 / 21 (4.76%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Rhinorrhoea			
subjects affected / exposed	2 / 14 (14.29%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences (all)	2	0	0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Investigations			
Blood pressure increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Procedural pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Laceration			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Joint sprain			
subjects affected / exposed	1 / 14 (7.14%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 14 (7.14%)	4 / 21 (19.05%)	3 / 17 (17.65%)
occurrences (all)	2	4	6
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Lymphadenitis			

subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Eye pain			
subjects affected / exposed	1 / 14 (7.14%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 14 (7.14%)	1 / 21 (4.76%)	0 / 17 (0.00%)
occurrences (all)	1	1	0
Vomiting			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Food poisoning			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Mouth ulceration			
subjects affected / exposed	1 / 14 (7.14%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	1 / 14 (7.14%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Aphthous stomatitis			

subjects affected / exposed	1 / 14 (7.14%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Urticaria papular			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Dermatitis contact			
subjects affected / exposed	1 / 14 (7.14%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Skin ulcer			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Pruritus			
subjects affected / exposed	0 / 14 (0.00%)	1 / 21 (4.76%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Musculoskeletal and connective tissue disorders			
Joint stiffness			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	1 / 14 (7.14%)	1 / 21 (4.76%)	0 / 17 (0.00%)
occurrences (all)	2	1	0
Myalgia			
subjects affected / exposed	4 / 14 (28.57%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences (all)	4	0	0
Infections and infestations			
Laryngitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hordeolum			

subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 21 (4.76%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Bronchitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	1 / 14 (7.14%)	3 / 21 (14.29%)	2 / 17 (11.76%)
occurrences (all)	1	3	3
Gastroenteritis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 21 (0.00%)	1 / 17 (5.88%)
occurrences (all)	1	0	1
Pharyngitis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Viral rash			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Dyslipidaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 21 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part I: TDV 1.5 to 5 Years	Part I: Placebo 1.5 to 5 Years	Part II: TDV 1.5 to 11 Years
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 23 (60.87%)	12 / 13 (92.31%)	87 / 159 (54.72%)
General disorders and administration site conditions			
Injection site pain			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	2 / 159 (1.26%)
occurrences (all)	0	0	2
Influenza like illness			

subjects affected / exposed	0 / 23 (0.00%)	1 / 13 (7.69%)	0 / 159 (0.00%)
occurrences (all)	0	1	0
Fatigue			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	6 / 159 (3.77%)
occurrences (all)	0	0	7
Injection site erythema			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	2 / 23 (8.70%)	1 / 13 (7.69%)	11 / 159 (6.92%)
occurrences (all)	2	1	12
Reproductive system and breast disorders			
Endometriosis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Dysmenorrhoea			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Nasal congestion			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	2 / 159 (1.26%)
occurrences (all)	0	0	2
Cough			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	2 / 159 (1.26%)
occurrences (all)	0	0	2
Rhinitis allergic			
subjects affected / exposed	0 / 23 (0.00%)	1 / 13 (7.69%)	5 / 159 (3.14%)
occurrences (all)	0	1	5
Oropharyngeal pain			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	1 / 159 (0.63%)
occurrences (all)	0	0	1
Asthma			
subjects affected / exposed	1 / 23 (4.35%)	1 / 13 (7.69%)	4 / 159 (2.52%)
occurrences (all)	1	1	4
Rhinorrhoea			

subjects affected / exposed	2 / 23 (8.70%)	1 / 13 (7.69%)	1 / 159 (0.63%)
occurrences (all)	2	1	1
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Investigations			
Blood pressure increased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Procedural pain			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Laceration			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Joint sprain			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 23 (4.35%)	0 / 13 (0.00%)	13 / 159 (8.18%)
occurrences (all)	1	0	16
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Lymphadenitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Eye disorders			

Conjunctival haemorrhage			
subjects affected / exposed	0 / 23 (0.00%)	1 / 13 (7.69%)	0 / 159 (0.00%)
occurrences (all)	0	1	0
Photophobia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	1 / 159 (0.63%)
occurrences (all)	0	0	1
Eye pain			
subjects affected / exposed	1 / 23 (4.35%)	0 / 13 (0.00%)	1 / 159 (0.63%)
occurrences (all)	1	0	1
Conjunctivitis allergic			
subjects affected / exposed	0 / 23 (0.00%)	1 / 13 (7.69%)	0 / 159 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis			
subjects affected / exposed	0 / 23 (0.00%)	1 / 13 (7.69%)	1 / 159 (0.63%)
occurrences (all)	0	1	1
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	3 / 23 (13.04%)	1 / 13 (7.69%)	1 / 159 (0.63%)
occurrences (all)	3	1	1
Vomiting			
subjects affected / exposed	0 / 23 (0.00%)	3 / 13 (23.08%)	4 / 159 (2.52%)
occurrences (all)	0	3	4
Food poisoning			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	1 / 159 (0.63%)
occurrences (all)	0	0	1
Aphthous stomatitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	2 / 159 (1.26%)
occurrences (all)	0	0	2
Skin and subcutaneous tissue disorders			

Rash			
subjects affected / exposed	1 / 23 (4.35%)	1 / 13 (7.69%)	2 / 159 (1.26%)
occurrences (all)	1	1	2
Urticaria papular			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	1 / 159 (0.63%)
occurrences (all)	0	0	1
Skin ulcer			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	2 / 159 (1.26%)
occurrences (all)	0	0	2
Musculoskeletal and connective tissue disorders			
Joint stiffness			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	1 / 23 (4.35%)	0 / 13 (0.00%)	0 / 159 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	1 / 23 (4.35%)	0 / 13 (0.00%)	2 / 159 (1.26%)
occurrences (all)	1	0	2
Infections and infestations			
Laryngitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 23 (0.00%)	1 / 13 (7.69%)	0 / 159 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			

subjects affected / exposed	2 / 23 (8.70%)	1 / 13 (7.69%)	16 / 159 (10.06%)
occurrences (all)	2	1	19
Bronchitis			
subjects affected / exposed	0 / 23 (0.00%)	1 / 13 (7.69%)	8 / 159 (5.03%)
occurrences (all)	0	1	8
Viral infection			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	1 / 159 (0.63%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	8 / 23 (34.78%)	7 / 13 (53.85%)	32 / 159 (20.13%)
occurrences (all)	11	10	34
Gastroenteritis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	6 / 159 (3.77%)
occurrences (all)	0	0	6
Pharyngitis			
subjects affected / exposed	1 / 23 (4.35%)	0 / 13 (0.00%)	3 / 159 (1.89%)
occurrences (all)	1	0	3
Viral rash			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Dyslipidaemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 13 (0.00%)	0 / 159 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part II: Placebo 1.5 to 11 Years		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	30 / 53 (56.60%)		
General disorders and administration site conditions			
Injection site pain			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences (all)	0		
Influenza like illness			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences (all)	0		
Fatigue			

subjects affected / exposed	1 / 53 (1.89%)		
occurrences (all)	1		
Injection site erythema			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	6 / 53 (11.32%)		
occurrences (all)	6		
Reproductive system and breast disorders			
Endometriosis			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences (all)	0		
Dysmenorrhoea			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Nasal congestion			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences (all)	0		
Cough			
subjects affected / exposed	3 / 53 (5.66%)		
occurrences (all)	3		
Rhinitis allergic			
subjects affected / exposed	1 / 53 (1.89%)		
occurrences (all)	2		
Oropharyngeal pain			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences (all)	0		
Asthma			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences (all)	0		
Rhinorrhoea			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			

Depression			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences (all)	0		
Anxiety			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences (all)	0		
Investigations			
Blood pressure increased			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Procedural pain			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences (all)	0		
Laceration			
subjects affected / exposed	1 / 53 (1.89%)		
occurrences (all)	1		
Joint sprain			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Headache			
subjects affected / exposed	3 / 53 (5.66%)		
occurrences (all)	3		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences (all)	0		
Lymphadenitis			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences (all)	0		
Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences (all)	0		
Photophobia			

subjects affected / exposed	1 / 53 (1.89%)		
occurrences (all)	1		
Eye pain			
subjects affected / exposed	1 / 53 (1.89%)		
occurrences (all)	1		
Conjunctivitis allergic			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences (all)	0		
Conjunctivitis			
subjects affected / exposed	1 / 53 (1.89%)		
occurrences (all)	1		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences (all)	0		
Vomiting			
subjects affected / exposed	1 / 53 (1.89%)		
occurrences (all)	1		
Food poisoning			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences (all)	0		
Mouth ulceration			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences (all)	0		
Nausea			
subjects affected / exposed	1 / 53 (1.89%)		
occurrences (all)	1		
Aphthous stomatitis			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	2 / 53 (3.77%)		
occurrences (all)	2		
Urticaria papular			

subjects affected / exposed	0 / 53 (0.00%)		
occurrences (all)	0		
Dermatitis contact			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences (all)	0		
Skin ulcer			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences (all)	0		
Pruritus			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Joint stiffness			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences (all)	0		
Back pain			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences (all)	0		
Arthralgia			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences (all)	0		
Myalgia			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Laryngitis			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences (all)	0		
Hordeolum			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences (all)	0		
Nasopharyngitis			
subjects affected / exposed	3 / 53 (5.66%)		
occurrences (all)	3		
Bronchitis			

subjects affected / exposed occurrences (all)	0 / 53 (0.00%) 0		
Viral infection subjects affected / exposed occurrences (all)	1 / 53 (1.89%) 2		
Upper respiratory tract infection subjects affected / exposed occurrences (all)	14 / 53 (26.42%) 18		
Gastroenteritis subjects affected / exposed occurrences (all)	2 / 53 (3.77%) 2		
Pharyngitis subjects affected / exposed occurrences (all)	2 / 53 (3.77%) 2		
Viral rash subjects affected / exposed occurrences (all)	0 / 53 (0.00%) 0		
Metabolism and nutrition disorders Dyslipidaemia subjects affected / exposed occurrences (all)	0 / 53 (0.00%) 0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 October 2011	The following changes were implemented with Protocol Amendment 1: -Most references regarding the Day 14 safety review were changed to Day 28 throughout the protocol. Additional clarification was added with regard to the review of group data in Part 1 as the basis for when Part 2 would be initiated. In addition, vaccine viremia testing was to be performed up to Day 120 if subjects developed systemic AEs consistent with dengue fever including fever (>38.0°C for 3 consecutive days) and generalized rash. Other changes included: -Updated inclusion criteria number 4 that defined the upper limit of normal for BMI. -Updated exclusion criteria number 2 that provided the lower age limit for exclusion from having an ECG performed. -Updated exclusion criteria number 4 that clarified measurement of body temperature. -The differentiation between solicited and unsolicited treatment emergent adverse events (TEAE) was removed from the protocol. -The word 'approximately' was added to each enrollment number.
11 May 2012	The following changes were implemented with Protocol Amendment 2: -Added clarification on how the study was to transition from Part 1 to Part 2 in terms of age cohort succession in conjunction with safety data review by the DSMB and in conjunction with the Sponsor during Part 1 and subsequent initiation of Part 2. Other changes included: -Changes to the required storage conditions for TDV (below 60°C at all times). -Updated inclusion criteria 4, 6, and 12. -Changes regarding how clinical laboratory data were to be reviewed and updated regarding total blood volumes to be drawn from study subjects. -Because it was known that a number of subjects living in a region endemic for dengue virus would be seropositive prior to study participation, instead of measuring seroconversion to one or more of the 4 dengue strains, an overall measure of seropositivity was to be performed instead.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported