Clinical trial results:
An Open Label, Phase 2 Study to Investigate Cell-mediated Immunity and Safety of a Tetravalent Dengue Vaccine Candidate (TDV) Administered Subcutaneously in Healthy Children Aged 4 to 16 Years

Summary

EudraCT number	2022-003456-13
Trial protocol	Outside EU/EEA
Global end of trial date	14 December 2020

Results information

Result version number	v2 (current)
This version publication date	09 March 2024
First version publication date	26 January 2023
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	DEN-313

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02948829
WHO universal trial number (UTN)	U1111-1184-1893

Notes:

Sponsors

Sponsor organisation name	Takeda Vaccines, Inc
Sponsor organisation address	40 Landsdowne Street, Cambridge, United States, MA 02139
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	14 December 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	14 December 2020
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 cellular immune responses following 2 doses given 3 months apart of tetravalent dengue vaccine candidate (TDV) in 4 to 16 years' healthy participants.

Protection of trial subjects:

Study participants signed an Informed Consent Form. Assent is also obtained from the study participant where required.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 April 2017
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	Panama: 100
Country: Number of subjects enrolled	Philippines: 100
Worldwide total number of subjects	200
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)	0
Children (2-11 years)	190
Adolescents (12-17 years)	10
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants took part in the study at 2 investigative sites in Panama and Philippines from 03 April 2017 to 14 December 2020.

Pre-assignment

Screening details:

Healthy participants were enroled in a single arm in this study to receive 2 doses of Tetravalent Dengue Vaccine (TDV) injection subcutaneously (SC).

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Tetravalent Dengue Vaccine (TDV) 0.5 mL

Arm description:

TDV 0.5 mL, subcutaneous (SC) injection, on Day 1 (Month 0) and Day 90 (Month 3).

Arm type	Experimental
Investigational medicinal product name	Tetravalent Dengue Vaccine (TDV) 0.5 mL
Investigational medicinal product code	TAK-003
Other name	
Pharmaceutical forms	Powder and solution for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

TDV SC injection.

Number of subjects in period 1	Tetravalent Dengue Vaccine (TDV) 0.5 mL
Started	200
Completed	184
Not completed	16
Other	8
Pregnancy	1
Withdrawal by Subject	5
Lost to follow-up	2

Baseline characteristics

Reporting groups	
Reporting group title	Tetravalent Dengue Vaccine (TDV) 0.5 mL
Reporting group description:	
TDV 0.5 mL, subcutaneous (SC) injection, on Day 1 (Month 0) and Day 90 (Month 3).	

Reporting group values	Tetravalent Dengue Vaccine (TDV) 0.5 mL	Total	
Number of subjects	200	200	
Age Categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	6.7		
standard deviation	± 2.28	-	
Gender categorical Units: Subjects			
Male	99	99	
Female	101	101	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	99	99	
Not Hispanic or Latino	101	101	
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	76	76	
Asian	100	100	
Black or African American	8	8	
White	9	9	
More than one race	7	7	
Baseline Seropositivity Status			
Seropositive at Baseline was defined as a reciprocal neutralizing titer >=10 for one or more dengue serotypes. Seronegative at Baseline was defined as having a reciprocal neutralizing titer <10 for all dengue serotypes. The 4 dengue virus serotypes were dengue virus (DENV)-1, DENV-2, DENV-3 and DENV-4.			
Units: Subjects			
Seropositive	113	113	
Seronegative	87	87	
Height Units: Cm			
arithmetic mean	118.38		
standard deviation	± 14.564	-	
Weight Units: Kg			
arithmetic mean	23.54		
standard deviation	± 10.258	-	
Body Mass Index (BMI)			

BMI = weight (kg)/[height (m)^2]			
Units: Kg/m^2			
arithmetic mean	16.15		
standard deviation	± 3.104	-	

Subject analysis sets

Subject analysis set title	Tetravalent Dengue Vaccine (TDV) 0.5 mL: Panama
Subject analysis set type	Sub-group analysis
Subject analysis set description: TDV 0.5 mL, SC injection, on Day 1 (Month 0) and Day 90 (Month 3): Participants from Panama.	
Subject analysis set title	Tetravalent Dengue Vaccine (TDV) 0.5 mL: Philippines
Subject analysis set type	Sub-group analysis
Subject analysis set description: TDV 0.5 mL, SC injection, on Day 1 (Month 0) and Day 90 (Month 3): Participants from Philippines.	
Subject analysis set title	Tetravalent Dengue Vaccine (TDV) 0.5 mL: Seropositive
Subject analysis set type	Sub-group analysis
Subject analysis set description: TDV 0.5 mL, SC injection, on Day 1 (Month 0) and Day 90 (Month 3): Participants seropositive at Baseline.	
Subject analysis set title	Tetravalent Dengue Vaccine (TDV) 0.5 mL: Seronegative
Subject analysis set type	Sub-group analysis
Subject analysis set description: TDV 0.5 mL, SC injection, on Day 1 (Month 0) and Day 90 (Month 3): Participants seronegative status at Baseline.	
Subject analysis set title	Tetravalent Dengue Vaccine (TDV) 0.5 mL: CD4+ T Cells
Subject analysis set type	Sub-group analysis
Subject analysis set description: TDV 0.5 mL, SC injection, on Day 1 (Month 0) and Day 90 (Month 3): CD4+ T cells.	
Subject analysis set title	Tetravalent Dengue Vaccine (TDV) 0.5 mL: CD8+ T Cells
Subject analysis set type	Sub-group analysis
Subject analysis set description: TDV 0.5 mL, SC injection, on Day 1 (Month 0) and Day 90 (Month 3): CD8+ T cells.	
Subject analysis set title	TDV 0.5 mL: Panama: CD4+ T Cells
Subject analysis set type	Sub-group analysis
Subject analysis set description: TDV 0.5 mL, SC injection, on Day 1 (Month 0) and Day 90 (Month 3): Participants from Panama, CD4+ T cells.	
Subject analysis set title	TDV 0.5 mL: Philippines: CD4+ T Cells
Subject analysis set type	Sub-group analysis
Subject analysis set description: TDV 0.5 mL, SC injection, on Day 1 (Month 0) and Day 90 (Month 3): Participants from Philippines, CD4+ T cells.	
Subject analysis set title	TDV 0.5 mL: Panama: CD8+ T Cells
Subject analysis set type	Sub-group analysis
Subject analysis set description: TDV 0.5 mL, SC injection, on Day 1 (Month 0) and Day 90 (Month 3): Participants from Panama, CD8+ T cells.	
Subject analysis set title	TDV 0.5 ml: Philippines: CD8+ T Cells
Subject analysis set type	Sub-group analysis
Subject analysis set description: TDV 0.5 mL, SC injection, on Day 1 (Month 0) and Day 90 (Month 3): Participants from Philippines, CD8+ T cells.	
Subject analysis set title	TDV 0.5 mL: Seropositive: CD4+ T-Cells

Subject analysis set type	Sub-group analysis
Subject analysis set description:	
TDV 0.5 mL, SC injection, on Day 1 (Month 0) and Day 90 (Month 3): Participants seropositive at Baseline, CD4+ T cells.	
Subject analysis set title	TDV 0.5 mL: Seronegative: CD4+ T-Cells
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
TDV 0.5 mL, SC injection, on Day 1 (Month 0) and Day 90 (Month 3): Participants seronegative at Baseline, CD4+ T cells.	
Subject analysis set title	TDV 0.5 mL: Seropositive: CD8+ T- Cells
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
TDV 0.5 mL, SC injection, on Day 1 (Month 0) and Day 90 (Month 3): Participants seropositive at Baseline, CD8+ T cells.	
Subject analysis set title	TDV 0.5 mL: Seronegative: CD8+ T-Cells
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
TDV 0.5 mL, SC injection, on Day 1 (Month 0) and Day 90 (Month 3): Participants seronegative at Baseline, CD8+ T cells.	

Reporting group values	Tetravalent Dengue Vaccine (TDV) 0.5 mL: Panama	Tetravalent Dengue Vaccine (TDV) 0.5 mL: Philippines	Tetravalent Dengue Vaccine (TDV) 0.5 mL: Seropositive
Number of subjects	97	98	109
Age Categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Male Female			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Black or African American White More than one race			
Baseline Seropositivity Status			
Seropositive at Baseline was defined as a reciprocal neutralizing titer >=10 for one or more dengue serotypes. Seronegative at Baseline was defined as having a reciprocal neutralizing titer <10 for all dengue serotypes. The 4 dengue virus serotypes were dengue virus (DENV)-1, DENV-2, DENV-3 and DENV-4.			
Units: Subjects			
Seropositive Seronegative			

Height Units: Cm arithmetic mean standard deviation	± 	± 	±
Weight Units: Kg arithmetic mean standard deviation	± 	± 	±
Body Mass Index (BMI)			
BMI = weight (kg)/[height (m)^2]			
Units: Kg/m^2 arithmetic mean standard deviation	± 	± 	±

Reporting group values	Tetravalent Dengue Vaccine (TDV) 0.5 mL: Seronegative	Tetravalent Dengue Vaccine (TDV) 0.5 mL: CD4+ T Cells	Tetravalent Dengue Vaccine (TDV) 0.5 mL: CD8+ T Cells
Number of subjects	86	79	79
Age Categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	± 	± 	±
Gender categorical Units: Subjects			
Male Female			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Black or African American White More than one race			
Baseline Seropositivity Status			
Seropositive at Baseline was defined as a reciprocal neutralizing titer >=10 for one or more dengue serotypes. Seronegative at Baseline was defined as having a reciprocal neutralizing titer <10 for all dengue serotypes. The 4 dengue virus serotypes were dengue virus (DENV)-1, DENV-2, DENV-3 and DENV-4.			
Units: Subjects			
Seropositive Seronegative			
Height Units: Cm arithmetic mean standard deviation	± 	± 	±
Weight			

Units: Kg arithmetic mean standard deviation	± 	± 	±
Body Mass Index (BMI)			
BMI = weight (kg)/[height (m)^2]			
Units: Kg/m^2 arithmetic mean standard deviation	± 	± 	±

Reporting group values	TDV 0.5 mL: Panama: CD4+ T Cells	TDV 0.5 mL: Philippines: CD4+ T Cells	TDV 0.5 mL: Panama: CD8+ T Cells
Number of subjects	33	46	33
Age Categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	± 	± 	±
Gender categorical Units: Subjects			
Male Female			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Black or African American White More than one race			
Baseline Seropositivity Status			
Seropositive at Baseline was defined as a reciprocal neutralizing titer >=10 for one or more dengue serotypes. Seronegative at Baseline was defined as having a reciprocal neutralizing titer <10 for all dengue serotypes. The 4 dengue virus serotypes were dengue virus (DENV)-1, DENV-2, DENV-3 and DENV-4.			
Units: Subjects			
Seropositive Seronegative			
Height Units: Cm arithmetic mean standard deviation	± 	± 	±
Weight Units: Kg arithmetic mean standard deviation	± 	± 	±
Body Mass Index (BMI)			
BMI = weight (kg)/[height (m)^2]			

Units: Kg/m^2			
arithmetic mean			
standard deviation	±	±	±

Reporting group values	TDV 0.5 ml: Philippines: CD8+ T Cells	TDV 0.5 mL: Seropositive: CD4+ T-Cells	TDV 0.5 mL: Seronegative: CD4+ T-Cells
Number of subjects	46	44	35
Age Categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean		0	0
standard deviation	±	±	±
Gender categorical			
Units: Subjects			
Male		0	0
Female		0	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino		0	0
Not Hispanic or Latino		0	0
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native		0	0
Asian		0	0
Black or African American		0	0
White		0	0
More than one race		0	0
Baseline Seropositivity Status			
Seropositive at Baseline was defined as a reciprocal neutralizing titer >=10 for one or more dengue serotypes. Seronegative at Baseline was defined as having a reciprocal neutralizing titer <10 for all dengue serotypes. The 4 dengue virus serotypes were dengue virus (DENV)-1, DENV-2, DENV-3 and DENV-4.			
Units: Subjects			
Seropositive		0	0
Seronegative		0	0
Height			
Units: Cm			
arithmetic mean		0	0
standard deviation	±	±	±
Weight			
Units: Kg			
arithmetic mean		0	0
standard deviation	±	±	±
Body Mass Index (BMI)			
BMI = weight (kg)/[height (m)^2]			
Units: Kg/m^2			
arithmetic mean		0	0
standard deviation	±	±	±

Reporting group values	TDV 0.5 mL:	TDV 0.5 mL:	

	Seropositive: CD8+ T- Cells	Seronegative: CD8+ T-Cells	
Number of subjects	44	35	
Age Categorical Units: Subjects			

Age continuous Units: years			
arithmetic mean	0	0	
standard deviation	±	±	
Gender categorical Units: Subjects			
Male	0	0	
Female	0	0	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	
Not Hispanic or Latino	0	0	
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	0	0	
Black or African American	0	0	
White	0	0	
More than one race	0	0	
Baseline Seropositivity Status			
Seropositive at Baseline was defined as a reciprocal neutralizing titer >=10 for one or more dengue serotypes. Seronegative at Baseline was defined as having a reciprocal neutralizing titer <10 for all dengue serotypes. The 4 dengue virus serotypes were dengue virus (DENV)-1, DENV-2, DENV-3 and DENV-4.			
Units: Subjects			
Seropositive	0	0	
Seronegative	0	0	
Height Units: Cm			
arithmetic mean	0	0	
standard deviation	±	±	
Weight Units: Kg			
arithmetic mean	0	0	
standard deviation	±	±	
Body Mass Index (BMI)			
BMI = weight (kg)/[height (m)^2]			
Units: Kg/m^2			
arithmetic mean	0	0	
standard deviation	±	±	

End points

End points reporting groups

Reporting group title	Tetravalent Dengue Vaccine (TDV) 0.5 mL
Reporting group description: TDV 0.5 mL, subcutaneous (SC) injection, on Day 1 (Month 0) and Day 90 (Month 3).	
Subject analysis set title	Tetravalent Dengue Vaccine (TDV) 0.5 mL: Panama
Subject analysis set type	Sub-group analysis
Subject analysis set description: TDV 0.5 mL, SC injection, on Day 1 (Month 0) and Day 90 (Month 3): Participants from Panama.	
Subject analysis set title	Tetravalent Dengue Vaccine (TDV) 0.5 mL: Philippines
Subject analysis set type	Sub-group analysis
Subject analysis set description: TDV 0.5 mL, SC injection, on Day 1 (Month 0) and Day 90 (Month 3): Participants from Philippines.	
Subject analysis set title	Tetravalent Dengue Vaccine (TDV) 0.5 mL: Seropositive
Subject analysis set type	Sub-group analysis
Subject analysis set description: TDV 0.5 mL, SC injection, on Day 1 (Month 0) and Day 90 (Month 3): Participants seropositive at Baseline.	
Subject analysis set title	Tetravalent Dengue Vaccine (TDV) 0.5 mL: Seronegative
Subject analysis set type	Sub-group analysis
Subject analysis set description: TDV 0.5 mL, SC injection, on Day 1 (Month 0) and Day 90 (Month 3): Participants seronegative status at Baseline.	
Subject analysis set title	Tetravalent Dengue Vaccine (TDV) 0.5 mL: CD4+ T Cells
Subject analysis set type	Sub-group analysis
Subject analysis set description: TDV 0.5 mL, SC injection, on Day 1 (Month 0) and Day 90 (Month 3): CD4+ T cells.	
Subject analysis set title	Tetravalent Dengue Vaccine (TDV) 0.5 mL: CD8+ T Cells
Subject analysis set type	Sub-group analysis
Subject analysis set description: TDV 0.5 mL, SC injection, on Day 1 (Month 0) and Day 90 (Month 3): CD8+ T cells.	
Subject analysis set title	TDV 0.5 mL: Panama: CD4+ T Cells
Subject analysis set type	Sub-group analysis
Subject analysis set description: TDV 0.5 mL, SC injection, on Day 1 (Month 0) and Day 90 (Month 3): Participants from Panama, CD4+ T cells.	
Subject analysis set title	TDV 0.5 mL: Philippines: CD4+ T Cells
Subject analysis set type	Sub-group analysis
Subject analysis set description: TDV 0.5 mL, SC injection, on Day 1 (Month 0) and Day 90 (Month 3): Participants from Philippines, CD4+ T cells.	
Subject analysis set title	TDV 0.5 mL: Panama: CD8+ T Cells
Subject analysis set type	Sub-group analysis
Subject analysis set description: TDV 0.5 mL, SC injection, on Day 1 (Month 0) and Day 90 (Month 3): Participants from Panama, CD8+ T cells.	
Subject analysis set title	TDV 0.5 ml: Philippines: CD8+ T Cells
Subject analysis set type	Sub-group analysis
Subject analysis set description: TDV 0.5 mL, SC injection, on Day 1 (Month 0) and Day 90 (Month 3): Participants from Philippines, CD8+ T cells.	

Subject analysis set title	TDV 0.5 mL: Seropositive: CD4+ T-Cells
Subject analysis set type	Sub-group analysis

Subject analysis set description:

TDV 0.5 mL, SC injection, on Day 1 (Month 0) and Day 90 (Month 3): Participants seropositive at Baseline, CD4+ T cells.

Subject analysis set title	TDV 0.5 mL: Seronegative: CD4+ T-Cells
Subject analysis set type	Sub-group analysis

Subject analysis set description:

TDV 0.5 mL, SC injection, on Day 1 (Month 0) and Day 90 (Month 3): Participants seronegative at Baseline, CD4+ T cells.

Subject analysis set title	TDV 0.5 mL: Seropositive: CD8+ T- Cells
Subject analysis set type	Sub-group analysis

Subject analysis set description:

TDV 0.5 mL, SC injection, on Day 1 (Month 0) and Day 90 (Month 3): Participants seropositive at Baseline, CD8+ T cells.

Subject analysis set title	TDV 0.5 mL: Seronegative: CD8+ T-Cells
Subject analysis set type	Sub-group analysis

Subject analysis set description:

TDV 0.5 mL, SC injection, on Day 1 (Month 0) and Day 90 (Month 3): Participants seronegative at Baseline, CD8+ T cells.

Primary: Percentage of Participants With Cellular Immune Response to 2 Doses of Tetravalent Dengue Vaccine (TDV) at 1 Month Post Second Vaccination

End point title	Percentage of Participants With Cellular Immune Response to 2 Doses of Tetravalent Dengue Vaccine (TDV) at 1 Month Post Second Vaccination[1]

End point description:

Percentage of participants with cellular immune response were reported. Cellular immune response was defined as an interferon-gamma (IFN-γ) enzyme-linked immunospot (ELISPOT) response that was >3 times higher compared to Baseline (Day 1) and ≥ 5 spots per well. Cellular immune response to any peptide pool was reported. The peptide pool included non-structural proteins (NS) NS3 and NS5 for each of the dengue serotype: DENV-1, DENV-2, DENV-3 and DENV-4 and NS1 for DENV-2. Percentage of participants with cellular immune response were reported. Percentages are rounded off to the nearest decimal point. Per-Protocol Set (PPS) included all participants from the Full Analysis Set (FAS) who have no major protocol violations. Participants analysed are participants with data available for analysis.

End point type	Primary

End point timeframe:

1 month post second vaccination (Day 120)

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: No statistical analysis was performed for this outcome measure.

End point values	Tetravalent Dengue Vaccine (TDV) 0.5 mL			
Subject group type	Reporting group			
Number of subjects analysed	173			
Units: percentage of participants				
number (confidence interval 95%)	97.1 (93.4 to 99.1)			

Statistical analyses

No statistical analyses for this end point

Secondary: Magnitude of Cellular Immune Response Assessed by Number of Spot Forming Cells (SFC)/Million Peripheral Blood Mononuclear Cells (PBMCs) Measured by IFN-γ ELISPOT at 1 Month Post Second Vaccination

End point title	Magnitude of Cellular Immune Response Assessed by Number of Spot Forming Cells (SFC)/Million Peripheral Blood Mononuclear Cells (PBMCs) Measured by IFN-γ ELISPOT at 1 Month Post Second Vaccination

End point description:

The magnitude of cellular immune response was assessed by the number of SFC/million PBMCs for participants with a cellular immune response. Cellular immune response was defined as IFN-γ ELISPOT response that was >3 times higher compared to Baseline (Day 1) and ≥ 5 spots per well. Data (SFC/million PBMC) for participants with a cellular immune response to any peptide pool is reported. The peptide pool included NS3 and NS5 for each of the dengue serotype: DENV-1, DENV-2, DENV-3 and DENV-4 and NS1 for DENV-2. PPS included all participants from the FAS who have no major protocol violations. Participants analysed are participants with data available for analysis.

End point type	Secondary

End point timeframe:

1 month post second vaccination (Day 120)

End point values	Tetravalent Dengue Vaccine (TDV) 0.5 mL			
Subject group type	Reporting group			
Number of subjects analysed	168			
Units: SFC/million PBMCs				
median (inter-quartile range (Q1-Q3))	846.5 (378.5 to 1968.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Cellular Immune Response to TDV at 1 Month Post First Vaccination, Pre-second Vaccination, 6 Months Post Second Vaccination, and Annually at Years 1, 2, and 3

End point title	Percentage of Participants With Cellular Immune Response to TDV at 1 Month Post First Vaccination, Pre-second Vaccination, 6 Months Post Second Vaccination, and Annually at Years 1, 2, and 3

End point description:

Percentage of participants with cellular immune response were reported. Cellular immune response was defined as an IFN-γ ELISPOT response that was >3 times higher compared to Baseline (Day 1 [M0]) and >=5 spots per well. Cellular immune response to any peptide pool was reported. The peptide pool included NS3 and NS5 for each of the dengue serotype: DENV-1, DENV-2, DENV-3 and DENV-4 and NS1 for DENV-2. Percentages are rounded off to the nearest decimal point. PPS included all participants from the FAS who have no major protocol violations. Number analysed is the number of participants with data available for analysis at the given timepoint.

End point type	Secondary

End point timeframe:

1 month post first vaccination (Day 30); pre-second vaccination (Day 90); 6 months post second

End point values	Tetravalent Dengue Vaccine (TDV) 0.5 mL			
Subject group type	Reporting group			
Number of subjects analysed	195			
Units: percentage of participants				
number (confidence interval 95%)				
Day 30 (n=171)	95.3 (91.0 to 98.0)			
Day 90 (n=183)	95.1 (90.9 to 97.7)			
Day 270 (n=173)	95.4 (91.1 to 98.0)			
Year 1 (n=174)	90.8 (85.5 to 94.7)			
Year 2 (n=150)	84.0 (77.1 to 89.5)			
Year 3 (n=171)	77.8 (70.8 to 83.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Magnitude of Cellular Immune Response Assessed by Number of SFC/Million PBMCs Measured by IFN-γ ELISPOT at 1 Month Post First Vaccination, Pre-second Vaccination, 6 Months Post Second Vaccination, and Annually at Years 1, 2, and 3

End point title	Magnitude of Cellular Immune Response Assessed by Number of SFC/Million PBMCs Measured by IFN-γ ELISPOT at 1 Month Post First Vaccination, Pre-second Vaccination, 6 Months Post Second Vaccination, and Annually at Years 1, 2, and 3

End point description:

The magnitude of cellular immune response was assessed by the number of SFC/million PBMCs for participants with a cellular immune response. Cellular immune response was defined as IFN-γ ELISPOT response that was >3 times higher compared to Baseline (Day 1) and ≥ 5 spots per well. Data (SFC/million PBMC) for participants with a cellular immune response to any peptide pool is reported. The peptide pool included NS3 and NS5 for each of the dengue serotype: DENV-1, DENV-2, DENV-3 and DENV-4 and NS1 for DENV-2. PPS included all participants from the FAS who have no major protocol violations. Number analysed is the number of participants with data available for analysis at the given timepoint.

End point type	Secondary

End point timeframe:

1 month post first vaccination (Day 30); pre-second vaccination (Day 90); 6 months post second vaccination (Days 120 and 270); Years 1, 2 and 3

End point values	Tetravalent Dengue Vaccine (TDV) 0.5 mL			
Subject group type	Reporting group			
Number of subjects analysed	195			
Units: SFC/million PBMCs				
median (inter-quartile range (Q1-Q3))				
Day 30 (n=163)	1019.0 (418.0 to 2542.0)			
Day 90 (n=174)	536.5 (254.0 to 1212.0)			
Day 270 (n=165)	486.0 (203.0 to 1252.0)			
Year 1 (n=158)	193.0 (76.0 to 482.0)			
Year 2 (n=126)	104.0 (41.0 to 560.0)			
Year 3 (n=133)	136.0 (47.0 to 577.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Cellular Immune Responses to TDV at 1 Month Post First Vaccination, Pre-second Vaccination, 1 and 6 Months Post Second Vaccination, and Annually at Years 1, 2, and 3 Assessed by Country

End point title	Percentage of Participants With Cellular Immune Responses to TDV at 1 Month Post First Vaccination, Pre-second Vaccination, 1 and 6 Months Post Second Vaccination, and Annually at Years 1, 2, and 3 Assessed by Country

End point description:

Percentage of participants with cellular immune response by country (Panama and Philippines) were reported. Cellular immune response was defined as an IFN-γ ELISPOT response that was >3 times higher compared to Baseline (Day 1 [M0]) and >=5 spots per well. Cellular immune response to any peptide pool was reported. The peptide pool included NS3 and NS5 for each of the dengue serotype: DENV-1, DENV-2, DENV-3 and DENV-4 and NS1 for DENV-2. Data is reported as per enrollment by country (Panama and Philippines). Percentages are rounded off to the nearest decimal point. PPS 'by country' included all participants from the FAS who have no major protocol violations. Number analysed is the number of participants with data available for analysis at the given timepoint.

End point type	Secondary

End point timeframe:

1 month post first vaccination (Day 30); pre-second vaccination (Day 90) 1 and 6 months post second vaccination (Days 120 and 270); Years 1, 2, 3

End point values	Tetravalent Dengue Vaccine (TDV) 0.5 mL: Panama	Tetravalent Dengue Vaccine (TDV) 0.5 mL: Philippines		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	97	98		
Units: percentage of participants				

number (confidence interval 95%)				
Day 30 (n=76,95)	96.1 (88.9 to 99.2)	94.7 (88.1 to 98.3)		
Day 90 (n=85,98)	96.5 (90.0 to 99.3)	93.9 (87.1 to 97.7)		
Day 120 (n-75,98)	97.3 (90.7 to 99.7)	96.9 (91.3 to 99.4)		
Day 270 (n=75,98)	94.7 (86.9 to 98.5)	95.9 (89.9 to 98.9)		
Year 1 (n=83,91)	91.6 (83.4 to 96.5)	90.1 (82.1 to 95.4)		
Year 2 (n=52,98)	86.5 (74.2 to 94.4)	82.7 (73.7 to 89.6)		
Year 3 (n=79,92)	79.7 (69.2 to 88.0)	76.1 (66.1 to 84.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Cellular Immune Responses to TDV:1 Month Post First Vaccination, Pre-second Vaccination, 1 and 6 Months Post Second Vaccination, and Annually at Years 1, 2, and 3, by Dengue Baseline Seropositivity Status

End point title	Percentage of Participants With Cellular Immune Responses to TDV:1 Month Post First Vaccination, Pre-second Vaccination, 1 and 6 Months Post Second Vaccination, and Annually at Years 1, 2, and 3, by Dengue Baseline Seropositivity Status

End point description:

Percentage of participants with cellular immune response by dengue Baseline seropositivity status (Seropositive and Seronegative) were reported. Cellular immune response was defined as an IFN-γ ELISPOT response that was >3 times higher compared to Baseline (Day 1[M0]) and >=5 spots per well. Seropositive at Baseline was defined as a reciprocal neutralizing titer >=10 for one or more dengue serotypes. Seronegative at Baseline was defined as having a reciprocal neutralizing titer <10 for all dengue serotypes. The 4 dengue virus serotypes were dengue virus (DENV)-1, DENV-2, DENV-3 and DENV-4. Cellular immune response to any peptide pool was reported. The peptide pool included NS3 and NS5 for each of the dengue serotype: DENV-1,DENV-2,DENV-3 and DENV-4 and NS1 for DENV-2. PPS 'by Baseline seropositivity status' included all participants from the FAS who have no major protocol violations. Number analysed is the number of participants with data available for analysis at the given timepoint.

End point type	Secondary

End point timeframe:

1 month post first vaccination (Day 30); pre-second vaccination (Day 90); 1 and 6 months post second vaccination (Days 120 and 270); Years 1, 2, and 3

End point values	Tetravalent Dengue Vaccine (TDV) 0.5 mL: Seropositive	Tetravalent Dengue Vaccine (TDV) 0.5 mL: Seronegative		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	109	86		
Units: percentage of participants				
number (confidence interval 95%)				

Day 30 (n= 97,74)	91.8 (84.4 to 96.4)	100.0 (95.1 to 100.0)		
Day 90 (n=104,79)	93.3 (86.6 to 97.3)	97.5 (91.2 to 99.7)		
Day 120 (n=100,73)	96.0 (90.1 to 98.9)	98.6 (92.6 to 100.0)		
Day 270 (n=101,72)	93.1 (86.2 to 97.2)	98.6 (92.5 to 100.0)		
Year 1 (n=98,76)	87.8 (79.6 to 93.5)	94.7 (87.1 to 98.5)		
Year 2 (n=93,57)	80.6 (71.1 to 88.1)	89.5 (78.5 to 96.0)		
Year 3 (n=97,74)	74.2 (64.3 to 82.6)	82.4 (71.8 to 90.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Magnitude of Cellular Immune Response Assessed by Number of SFC/Million PBMCs Measured by IFN-γ ELISPOT at 1 Month Post First, Pre- Second Vaccination, 1 and 6 Months Post Second Vaccination, and Annually at Years 1, 2, and 3 by Country

End point title	Magnitude of Cellular Immune Response Assessed by Number of SFC/Million PBMCs Measured by IFN-γ ELISPOT at 1 Month Post First, Pre- Second Vaccination, 1 and 6 Months Post Second Vaccination, and Annually at Years 1, 2, and 3 by Country

End point description:

The magnitude of cellular immune response by country (Panama and Philippines) was assessed by the number of SFC/million PBMCs for participants with a cellular immune response. Cellular immune response was defined as IFN-γ ELISPOT response that was >3 times higher compared to Baseline (Day 1) and ≥ 5 spots per well. Data (SFC/million PBMC) for participants with a cellular immune response to any peptide pool is reported. The peptide pool included NS3 and NS5 for each of the dengue serotype: DENV-1, DENV-2, DENV-3 and DENV-4 and NS1 for DENV-2. Data is reported as per enrollment by country (Panama and Philippines). PPS 'by country' included all participants from the FAS who have no major protocol violations. Number analysed is the number of participants with data available at the given timepoint.

End point type	Secondary

End point timeframe:

1 month post first vaccination (Day 30); pre-second vaccination (Day 90); 1 and 6 months post second vaccination (Days 120 and 270); Years 1, 2, and 3

End point values	Tetravalent Dengue Vaccine (TDV) 0.5 mL: Panama	Tetravalent Dengue Vaccine (TDV) 0.5 mL: Philippines		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	97	98		
Units: SFC/million PBMCs				
median (inter-quartile range (Q1-Q3))				
Day 30 (n=73,90)	1019.0 (437.0 to 2228.0)	1065.0 (418.0 to 2546.0)		

Day 90 (n=82,92)	531.5 (252.0 to 1116.0)	577.5 (255.5 to 1396.0)		
Day 120 (n=73,95)	780.0 (322.0 to 1525.0)	1003.0 (437.0 to 2304.0)		
Day 270 (n=71,94)	426.0 (184.0 to 1382.0)	512.5 (210.0 to 1130.0)		
Year 1 (n=76,82)	209.0 (81.5 to 494.0)	178.5 (73.0 to 451.0)		
Year 2 (n=45,81)	76.0 (45.0 to 229.0)	124.0 (41.0 to 615.0)		
Year 3 (n=63,70)	147.0 (51.0 to 280.0)	117.0 (43.0 to 659.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Magnitude of Cellular Immune Response Assessed by Number of SFC/Million PBMCs Measured by IFN-γ ELISPOT 1Month Post First Vaccination,Pre-second Vaccination;1,6Months Post Second Vaccination, Annually at Years1,2,3 by Dengue Baseline Seropositivity Status

End point title	Magnitude of Cellular Immune Response Assessed by Number of SFC/Million PBMCs Measured by IFN-γ ELISPOT 1Month Post First Vaccination,Pre-second Vaccination;1,6Months Post Second Vaccination, Annually at Years1,2,3 by Dengue Baseline Seropositivity Status

End point description:

The magnitude of cellular immune response by dengue Baseline seropositivity status (Seropositive and Seronegative) was assessed by the number of SFC/million PBMCs for participants with a cellular immune response. Cellular immune response:IFN-γ ELISPOT response that was >3 times higher compared to Baseline (Day 1) and ≥ 5 spots per well. Seropositive at Baseline:a reciprocal neutralizing titer >=10 for one or more dengue serotypes. Seronegative at Baseline:having a reciprocal neutralizing titer <10 for all dengue serotypes. The 4 dengue virus serotypes were dengue virus (DENV)-1, DENV-2, DENV-3 and DENV-4. Cellular immune response to any peptide pool was reported. The peptide pool included NS3 and NS5 for each of the dengue serotype: DENV-1, DENV-2, DENV-3 and DENV-4 and NS1 for DENV-2. PPS 'by Baseline seropositivity status' included all participants from the FAS who have no major protocol violations. Number analysed:participants with data available for analysis at given time point.

End point type	Secondary

End point timeframe:

1 month post first vaccination (Day 30); pre-second vaccination (Day 90); 1 and 6 months post second vaccination (Days 120 and 270); Years 1, 2, and 3

End point values	Tetravalent Dengue Vaccine (TDV) 0.5 mL: Seropositive	Tetravalent Dengue Vaccine (TDV) 0.5 mL: Seronegative		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	109	86		
Units: SFC/million PBMCs				
median (inter-quartile range (Q1-Q3))				
Day 30 (n=89,74)	1415.0 (529.0 to 3302.0)	840.5 (379.0 to 1844.0)		
Day 90 (n=97,77)	743.0 (257.0 to 1560.0)	473.0 (246.0 to 927.0)		

Day 120 (n=96,72)	1086.0 (429.0 to 2521.0)	700.0 (343.0 to 1476.0)		
Day 270 (n=94,71)	592.0 (184.0 to 1569.0)	400.0 (225.0 to 808.0)		
Year 1 (n=86,72)	275.0 (105.0 to 690.0)	132.0 (69.0 to 247.0)		
Year 2 (n=75,51)	135.0 (46.0 to 615.0)	74.0 (38.0 to 304.0)		
Year 3 (n=72,61)	180.0 (61.0 to 645.5)	103.0 (35.0 to 430.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Cellular Immune Response to TDV in Participants >10 Years of Age

End point title	Percentage of Participants With Cellular Immune Response to TDV in Participants >10 Years of Age

End point description:

Percentage of participants with cellular immune response in participants >10 years of age were reported. Cellular immune response was defined as an IFN-γ ELISPOT response that was >3 times higher compared to Baseline (Day 1 [M0]) and >=5 spots per well. Cellular immune response to any peptide pool was reported. The peptide pool included NS3 and NS5 for each of the dengue serotype: DENV-1, DENV-2, DENV-3 and DENV-4 and NS1 for DENV-2. PPS with participants >10 years of age included all participants from the FAS who have no major protocol violations and are >10 years of age. Participants analysed are the number of participants with data available for analysis at the given timepoint.

End point type	Secondary

End point timeframe:

Day 14

End point values	Tetravalent Dengue Vaccine (TDV) 0.5 mL			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: percentage of participants				
number (confidence interval 95%)	70.0 (34.8 to 93.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Magnitude of Cellular Immune Response Assessed by Number of SFC/Million PBMCs Measured by IFN-γ ELISPOT in Participants >10 Years of Age

End point title	Magnitude of Cellular Immune Response Assessed by Number of SFC/Million PBMCs Measured by IFN-γ ELISPOT in

	Participants >10 Years of Age

End point description:

The magnitude of cellular immune response was assessed by the number of SFC/million PBMCs for participants with a cellular immune response. Cellular immune response was defined as IFN-γ ELISPOT response that was >3 times higher compared to Baseline (Day 1) and ≥ 5 spots per well. Cellular immune response to any peptide pool was reported. The peptide pool included NS for each of the dengue serotype: DENV-1, DENV-2, DENV-3 and DENV-4. SFC/million PBMC for any peptide pool is reported in participants >10 years of age. The analysis of samples collected at Day 90 and annually at Years 1, 2 and 3 for outcome measures related to assessment of the cellular immune response is still ongoing because of the limited testing capacities of the laboratory due to COVID-19; the data will be reported when available.

End point type	Secondary

End point timeframe:

Day 14

End point values	Tetravalent Dengue Vaccine (TDV) 0.5 mL			
Subject group type	Reporting group			
Number of subjects analysed	7			
Units: SFC/million PBMC				
median (inter-quartile range (Q1-Q3))	227.0 (124.0 to 3781.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Phenotype Characterization of Cellular Immune Response Assessed by Percentage of Total T Cells of Cellular Response to DENV-2 NS Peptides at 1Month Post First Vaccination,Pre-second Vaccination;1,6Months Post Second Vaccination, Annually at Years1,2,3

End point title	Phenotype Characterization of Cellular Immune Response Assessed by Percentage of Total T Cells of Cellular Response to DENV-2 NS Peptides at 1Month Post First Vaccination,Pre-second Vaccination;1,6Months Post Second Vaccination, Annually at Years1,2,3

End point description:

The phenotype characterization of cellular immune response was assessed by intracellular cytokine staining (ICS) by the frequency of total cluster of differentiation 4 (CD4)+ and CD8+ T cells and was performed in a subset of participants with IFN- γ ELISPOT responses >500 SFC/million cells and availability of sufficient cells. The peptide pools included NS1, NS3 and NS5 for DENV-2 serotype. Data are presented for the different expression profiles of interferon-gamma (IFN-γ), interleukin-2 (IL-2) and tumor necrosis factor-alpha (TNF-α) cytokines for each peptide pool. Data is reported based on the type of T cells present in participants at the time of analysis (CD4+ T cells and CD8+ T cells). ICS Subset 'by T-cells' included participants from PPS who have IFN-γ ELISPOT responses >500 SFC/million PBMCs and availability of sufficient cells. Number analysed is the number of participants with data available for analysis for specific category.

End point type	Secondary

End point timeframe:

1 month post first vaccination (Day 30); pre-second vaccination (Day 90); 1 and 6 months post second vaccination (Days 120 and 270); Years 1, 2, and 3

End point values	Tetravalent Dengue Vaccine (TDV) 0.5 mL: CD4+ T Cells	Tetravalent Dengue Vaccine (TDV) 0.5 mL: CD8+ T Cells		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	79	79		
Units: percentage of T cells				
median (inter-quartile range (Q1-Q3))				
IFNg+IL2+TNFa+, DENV-2, NS1-2, Day 30 (n=71,71)	0.008260 (0.003050 to 0.020000)	0.001350 (0.000000 to 0.008190)		
IFNg+IL2+TNFa+, DENV-2, NS3-2, Day 30 (n=71,71)	0.005110 (0.001953 to 0.010000)	0.020000 (0.002580 to 0.039350)		
IFNg+IL2+TNFa+, DENV-2, NS5-2, Day 30 (n=71,71)	0.005380 (0.002430 to 0.009420)	0.015580 (0.003084 to 0.043000)		
IFNg+IL2+TNFa-, DENV-2, NS1-2, Day 30 (n=71,71)	0.000000 (0.000000 to 0.001350)	0.000000 (0.000000 to 0.000000)		
IFNg+IL2+TNFa-, DENV-2, NS3-2, Day 30 (n=71,71)	0.000000 (0.000000 to 0.000130)	0.001210 (0.000000 to 0.003000)		
IFNg+IL2+TNFa-, DENV-2, NS5-2, Day 30 (n=71,71)	0.000000 (0.000000 to 0.000120)	0.001610 (0.000000 to 0.004370)		
IFNg+IL2-TNFa+, DENV-2, NS1-2, Day 30 (n=71,71)	0.003720 (0.000580 to 0.006770)	0.018180 (0.000190 to 0.054000)		
IFNg+IL2-TNFa+, DENV-2, NS3-2, Day 30 (n=71,71)	0.002810 (0.000130 to 0.006420)	0.140000 (0.058000 to 0.448100)		
IFNg+IL2-TNFa+, DENV-2, NS5-2, Day 30 (n=71,71)	0.002890 (0.000020 to 0.006240)	0.140790 (0.028940 to 0.382000)		
IFNg-IL2+TNFa+, DENV-2, NS1-2, Day 30 (n=71,71)	0.002310 (0.000000 to 0.007080)	0.000000 (0.000000 to 0.000000)		
IFNg-IL2+TNFa+, DENV-2, NS3-2, Day 30 (n=71,71)	0.002110 (0.000000 to 0.007290)	0.000000 (0.000000 to 0.000760)		
IFNg-IL2+TNFa+, DENV-2, NS5-2, Day 30 (n=71,71)	0.003350 (0.000000 to 0.008360)	0.000000 (0.000000 to 0.000000)		
IFNg+IL2-TNFa-, DENV-2, NS1-2, Day 30 (n=71,71)	0.000850 (0.000000 to 0.004190)	0.007490 (0.002150 to 0.032580)		
IFNg+IL2-TNFa-, DENV-2, NS3-2, Day 30 (n=71,71)	0.000000 (0.000000 to 0.002890)	0.061520 (0.025260 to 0.208580)		
IFNg+IL2-TNFa-, DENV-2, NS5-2, Day 30 (n=71,71)	0.000498 (0.000000 to 0.003520)	0.063490 (0.020000 to 0.222230)		
IFNg-IL2+TNFa-, DENV-2, NS1-2, Day 30 (n=71,71)	0.001000 (0.000000 to 0.009000)	0.002000 (0.000000 to 0.008000)		

IFNg-IL2+TNFa-, DENV-2, NS3-2, Day 30 (n=71,71)	0.000000 (0.000000 to 0.007000)	0.000000 (0.000000 to 0.008000)		
IFNg-IL2+TNFa-, DENV-2, NS5-2, Day 30 (n=71,71)	0.000000 (0.000000 to 0.010000)	0.001700 (0.000000 to 0.010000)		
IFNg-IL2-TNFa+, DENV-2, NS1-2, Day 30 (n=71,71)	0.000000 (0.000000 to 0.020000)	0.000000 (0.000000 to 0.013000)		
IFNg-IL2-TNFa+, DENV-2, NS3-2, Day 30 (n=71,71)	0.010000 (0.000000 to 0.040000)	0.012000 (0.000000 to 0.030000)		
IFNg-IL2-TNFa+, DENV-2, NS5-2, Day 30 (n=71,71)	0.010000 (0.000000 to 0.050000)	0.008000 (0.000000 to 0.030000)		
IFNg+IL2+TNFa+, DENV-2, NS1-2, Day 90 (n=72,72)	0.003825 (0.001215 to 0.009130)	0.000000 (0.000000 to 0.004075)		
IFNg+IL2+TNFa+, DENV-2, NS3-2, Day 90 (n=72,72)	0.002908 (0.000285 to 0.006325)	0.005565 (0.001470 to 0.012500)		
IFNg+IL2+TNFa+, DENV-2, NS5-2, Day 90 (n=72,72)	0.002050 (0.000000 to 0.005690)	0.004020 (0.000622 to 0.013000)		
IFNg+IL2+TNFa-, DENV-2, NS1-2, Day 90 (n=72,72)	0.000615 (0.000000 to 0.001460)	0.000000 (0.000000 to 0.000000)		
IFNg+IL2+TNFa-, DENV-2, NS3-2, Day 90 (n=72,72)	0.000000 (0.000000 to 0.002200)	0.000000 (0.000000 to 0.001566)		
IFNg+IL2+TNFa-, DENV-2, NS5-2, Day 90 (n=72,72)	0.000000 (0.000000 to 0.000980)	0.000000 (0.000000 to 0.001865)		
IFNg+IL2-TNFa+, DENV-2, NS1-2, Day 90 (n=72,72)	0.001045 (0.000000 to 0.002805)	0.005155 (0.000020 to 0.021160)		
IFNg+IL2-TNFa+, DENV-2, NS3-2, Day 90 (n=72,72)	0.001608 (0.000000 to 0.003055)	0.106350 (0.032245 to 0.198546)		
IFNg+IL2-TNFa+, DENV-2, NS5-2, Day 90 (n=72,72)	0.000750 (0.000000 to 0.002583)	0.076145 (0.017500 to 0.156850)		
IFNg-IL2+TNFa+, DENV-2, NS1-2, Day 90 (n=72,72)	0.001050 (0.000000 to 0.008000)	0.000000 (0.000000 to 0.000884)		
IFNg-IL2+TNFa+, DENV-2, NS3-2, Day 90 (n=72,72)	0.000910 (0.000000 to 0.003360)	0.000000 (0.000000 to 0.000340)		
IFNg-IL2+TNFa+, DENV-2, NS5-2, Day 90 (n=72,72)	0.002925 (0.000000 to 0.006000)	0.000000 (0.000000 to 0.000374)		
IFNg+IL2-TNFa-, DENV-2, NS1-2, Day 90 (n=72,72)	0.000000 (0.000000 to 0.001425)	0.001820 (0.000000 to 0.006305)		
IFNg+IL2-TNFa-, DENV-2, NS3-2, Day 90 (n=72,72)	0.000000 (0.000000 to 0.000973)	0.022310 (0.007580 to 0.075184)		
IFNg+IL2-TNFa-, DENV-2, NS5-2, Day 90 (n=72,72)	0.000000 (0.000000 to 0.001251)	0.021455 (0.002945 to 0.045665)		
IFNg-IL2+TNFa-, DENV-2, NS1-2, Day 90 (n=72,72)	0.000000 (0.000000 to 0.009000)	0.001500 (0.000000 to 0.010000)		

IFNg-IL2+TNFa-, DENV-2, NS3-2, Day 90 (n=72,72)	0.000000 (0.000000 to 0.010000)	0.000000 (0.000000 to 0.009000)		
IFNg-IL2+TNFa-, DENV-2, NS5-2, Day 90 (n=72,72)	0.003000 (0.000000 to 0.010500)	0.000000 (0.000000 to 0.010000)		
IFNg-IL2-TNFa+, DENV-2, NS1-2, Day 90 (n=72,72)	0.000000 (0.000000 to 0.020000)	0.000000 (0.000000 to 0.009500)		
IFNg-IL2-TNFa+, DENV-2, NS3-2, Day 90 (n=72,72)	0.000000 (0.000000 to 0.028500)	0.012000 (0.000500 to 0.032470)		
IFNg-IL2-TNFa+, DENV-2, NS5-2, Day 90 (n=72,72)	0.009500 (0.000000 to 0.050000)	0.008500 (0.000000 to 0.026500)		
IFNg+IL2+TNFa+, DENV-2, NS1-2, Day 120 (n=75,75)	0.008340 (0.003340 to 0.017000)	0.001320 (0.000000 to 0.004240)		
IFNg+IL2+TNFa+, DENV-2, NS3-2, Day 120 (n=75,75)	0.003410 (0.001041 to 0.007190)	0.010000 (0.002650 to 0.018000)		
IFNg+IL2+TNFa+, DENV-2, NS5-2, Day 120 (n=75,75)	0.002100 (0.000000 to 0.004710)	0.007850 (0.002230 to 0.027000)		
IFNg+IL2+TNFa-, DENV-2, NS1-2, Day 120 (n=75,75)	0.001050 (0.000000 to 0.002420)	0.000000 (0.000000 to 0.000000)		
IFNg+IL2+TNFa-, DENV-2, NS3-2, Day 120 (n=75,75)	0.000000 (0.000000 to 0.001420)	0.000000 (0.000000 to 0.001800)		
IFNg+IL2+TNFa-, DENV-2, NS5-2, Day 120 (n=75,75)	0.000000 (0.000000 to 0.000935)	0.000960 (0.000000 to 0.002340)		
IFNg+IL2-TNFa+, DENV-2, NS1-2, Day 120 (n=75,75)	0.002110 (0.000000 to 0.005070)	0.007340 (0.000000 to 029850)		
IFNg+IL2-TNFa+, DENV-2, NS3-2, Day 120 (n=75,75)	0.002000 (0.000000 to 0.004160)	0.116110 (0.047000 to 0.317000)		
IFNg+IL2-TNFa+, DENV-2, NS5-2, Day 120 (n=75,75)	0.000860 (0.000000 to 0.002820)	0.096230 (0.030050 to 0.207090)		
IFNg-IL2+TNFa+, DENV-2, NS1-2, Day 120 (n=75,75)	0.007160 (0.002000 to 0.015040)	0.000000 (0.000000 to 0.000000)		
IFNg-IL2+TNFa+, DENV-2, NS3-2, Day 120 (n= 75,75)	0.000000 (0.000000 to 0.004710)	0.000000 (0.000000 to 0.000000)		
IFNg-IL2+TNFa+, DENV-2, NS5-2, Day 120 (n=75,75)	0.003350 (0.000000 to 0.009000)	0.000000 (0.000000 to 0.000000)		
IFNg+IL2-TNFa-, DENV-2, NS1-2, Day 120 (n=75,75)	0.002070 (0.000000 to 0.005030)	0.004080 (0.000000 to 0.011000)		
IFNg+IL2-TNFa-, DENV-2, NS3-2, Day 120 (n=75,75)	0.000990 (0.000000 to 0.002630)	0.038000 (0.013270 to 0.094810)		
IFNg+IL2-TNFa-, DENV-2, NS5-2, Day 120 (n=75,75)	0.000000 (0.000000 to 0.002480)	0.018850 (0.007000 to 0.060560)		
IFNg-IL2+TNFa-, DENV-2, NS1-2, Day 120 (n=75,75)	0.009000 (0.000000 to 0.014000)	0.002000 (0.000000 to 0.014000)		

IFNg-IL2+TNFa-, DENV-2, NS3-2, Day 120 (n=75,75)	0.001000 (0.000000 to 0.010000)	0.001000 (0.000000 to 0.017000)		
IFNg-IL2+TNFa-, DENV-2, NS5-2, Day 120 (n=75,75)	0.000000 (0.000000 to 0.013000)	0.001000 (0.000000 to 0.015000)		
IFNg-IL2-TNFa+, DENV-2, NS1-2, Day 120 (n=75,75)	0.002000 (0.000000 to 0.028000)	0.004000 (0.000000 to 0.020000)		
IFNg-IL2-TNFa+, DENV-2, NS3-2, Day 120 (n=75,75)	0.000000 (0.000000 to 0.030000)	0.012000 (0.000000 to 0.028000)		
IFNg-IL2-TNFa+, DENV-2, NS5-2, Day 120 (n=75,75)	0.020000 (0.000000 to 0.050000)	0.012000 (0.000000 to 0.030000)		
IFNg+IL2+TNFa+, DENV-2, NS1-2, Day 270 (n=71,71)	0.006150 (0.002940 to 0.015000)	0.000000 (0.000000 to 0.002450)		
IFNg+IL2+TNFa+, DENV-2, NS3-2, Day 270 (n=71,71)	0.002520 (0.000050 to 0.006570)	0.004630 (0.001430 to 0.010157)		
IFNg+IL2+TNFa+, DENV-2, NS5-2, Day 270 (n=71,71)	0.002840 (0.000220 to 0.005230)	0.004430 (0.000955 to .019000)		
IFNg+IL2+TNFa-, DENV-2, NS1-2, Day 270 (n=71,71)	0.000000 (0.000000 to 0.000980)	0.000000 (0.000000 to 0.000000)		
IFNg+IL2+TNFa-, DENV-2, NS3-2, Day 270 (n=71,71)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.001830)		
IFNg+IL2+TNFa-, DENV-2, NS5-2, Day 270 (n=71,71)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.001470)		
IFNg+IL2-TNFa+, DENV-2, NS1-2, Day 270 (n=71,71)	0.001100 (0.000000 to 0.003380)	0.004620 (0.000000 to 0.023950)		
IFNg+IL2-TNFa+, DENV-2, NS3-2, Day 270 (n=71,71)	0.001210 (0.000000 to 0.003450)	0.089000 (0.033000 to 0.213910)		
IFNg+IL2-TNFa+, DENV-2, NS5-2, Day 270 (n=71,71)	0.000334 (0.000000 to 0.002500)	0.067000 (0.021000 to 0.197960)		
IFNg-IL2+TNFa+, DENV-2, NS1-2, Day 270 (n=71,71)	0.004010 (0.000000 to 0.010000)	0.000000 (0.000000 to 0.000000)		
IFNg-IL2+TNFa+, DENV-2, NS3-2, Day 270 (n=71,71)	0.000000 (0.000000 to 0.004830)	0.000000 (0.000000 to 0.000000)		
IFNg-IL2+TNFa+, DENV-2, NS5-2, Day 270 (n=71,71)	0.001630 (0.000000 to 0.005000)	0.000000 (0.000000 to 0.000000)		
IFNg+IL2-TNFa-, DENV-2, NS1-2, Day 270 (n=71,71)	0.000000 (0.000000 to 0.002570)	0.003060 (0.000000 to 0.008450)		
IFNg+IL2-TNFa-, DENV-2, NS3-2, Day 270 (n=71,71)	0.000000 (0.000000 to 0.001720)	0.015360 (0.002440 to 0.029940)		
IFNg+IL2-TNFa-, DENV-2, NS5-2, Day 270 (n=71,71)	0.000000 (0.000000 to 0.002320)	0.013000 (0.002000 to 0.029600)		
IFNg-IL2+TNFa-, DENV-2, NS1-2, Day 270 (n=71,71)	0.001000 (0.000000 to 0.008000)	0.001000 (0.000000 to 0.007000)		

IFNg-IL2+TNFa-, DENV-2, NS3-2, Day 270 (n=71,71)	0.000000 (0.000000 to 0.001980)	0.000000 (0.000000 to 0.005000)		
IFNg-IL2+TNFa-, DENV-2, NS5-2, Day 270 (n=71,71)	0.000000 (0.000000 to 0.007000)	0.000000 (0.000000 to 0.006000)		
IFNg-IL2-TNFa+, DENV-2, NS1-2, Day 270 (n=71,71)	0.000000 (0.000000 to 0.014000)	0.002000 (0.000000 to 0.018000)		
IFNg-IL2-TNFa+, DENV-2, NS3-2, Day 270 (n=71,71)	0.005000 (0.000000 to 0.030000)	0.015000 (0.000000 to 0.044000)		
IFNg-IL2-TNFa+, DENV-2, NS5-2, Day 270 (n=71,71)	0.000000 (0.000000 to 0.050000)	0.014000 (0.000000 to 0.033000)		
IFNg+IL2+TNFa+, DENV-2, NS1-2, Year 1 (n=70,70)	0.003980 (0.000000 to 0.007470)	0.000000 (0.000000 to 0.001410)		
IFNg+IL2+TNFa+, DENV-2, NS3-2, Year 1 (n=70,70)	0.001998 (0.000000 to 0.005000)	0.001360 (0.000000 to 0.003970)		
IFNg+IL2+TNFa+, DENV-2, NS5-2, Year 1 (n=70,70)	0.001275 (0.000000 to 0.005900)	0.001600 (0.000000 to 0.006660)		
IFNg+IL2+TNFa-, DENV-2, NS1-2, Year 1 (n=70,70)	0.000105 (0.000000 to 0.001700)	0.000000 (0.000000 to 0.000000)		
IFNg+IL2+TNFa-, DENV-2, NS3-2, Year 1 (n=70,70)	0.000000 (0.000000 to 0.001240)	0.000000 (0.000000 to 0.001120)		
IFNg+IL2+TNFa-, DENV-2, NS5-2, Year 1 (n=70,70)	0.000000 (0.000000 to 0.001370)	0.000000 (0.000000 to 0.000828)		
IFNg+IL2-TNFa+, DENV-2, NS1-2, Year 1 (n=70,70)	0.001085 (0.000000 to 0.003000)	0.000000 (0.000000 to 0.012000)		
IFNg+IL2-TNFa+, DENV-2, NS3-2, Year 1 (n=70,70)	0.001100 (0.000000 to 0.002718)	0.022915 (0.004790 to 0.054750)		
IFNg+IL2-TNFa+, DENV-2, NS5-2, Year 1 (n=70,70)	0.000856 (0.000000 to 0.003000)	0.022135 (0.002010 to 0.069860)		
IFNg-IL2+TNFa+, DENV-2, NS1-2, Year 1 (n=70,70)	0.003000 (0.000000 to 0.009125)	0.000000 (0.000000 to 0.001130)		
IFNg-IL2+TNFa+, DENV-2, NS3-2, Year 1 (n=70,70)	0.001585 (0.000000 to 0.005470)	0.000000 (0.000000 to 0.000968)		
IFNg-IL2+TNFa+, DENV-2, NS5-2, Year 1 (n=70,70)	0.003545 (0.000000 to 0.011000)	0.000000 (0.000000 to 0.001370)		
IFNg+IL2-TNFa-, DENV-2, NS1-2, Year 1 (n=70,70)	0.000587 (0.000000 to 0.002580)	0.000434 (0.000000 to 0.005200)		
IFNg+IL2-TNFa-, DENV-2, NS3-2, Year 1 (n=70,70)	0.000000 (0.000000 to 0.002000)	0.003075 (0.000000 to 0.010870)		
IFNg+IL2-TNFa-, DENV-2, NS5-2, Year 1 (n=70,70)	0.000000 (0.000000 to 0.001880)	0.003400 (0.000000 to 0.016640)		
IFNg-IL2+TNFa-, DENV-2, NS1-2, Year 1 (n=70,70)	0.000000 (0.000000 to 0.011000)	0.000000 (0.000000 to 0.009000)		

IFNg-IL2+TNFa-, DENV-2, NS3-2, Year 1 (n=70,70)	0.000500 (0.000000 to 0.010000)	0.000000 (0.000000 to 0.008000)		
IFNg-IL2+TNFa-, DENV-2, NS5-2, Year 1 (n=70,70)	0.003500 (0.000000 to 0.018000)	0.000000 (0.000000 to 0.010000)		
IFNg-IL2-TNFa+, DENV-2, NS1-2, Year 1 (n=70,70)	0.002500 (0.000000 to 0.060000)	0.000000 (0.000000 to 0.007000)		
IFNg-IL2-TNFa+, DENV-2, NS3-2, Year 1 (n=70,70)	0.000000 (0.000000 to 0.070000)	0.005210 (0.000000 to 0.022000)		
IFNg-IL2-TNFa+, DENV-2, NS5-2, Year 1 (n=70,70)	0.042500 (0.000000 to 0.120000)	0.007000 (0.000000 to 0.020250)		
IFNg+IL2+TNFa+, DENV-2, NS1-2, Year 2 (n=56,56)	0.002920 (0.000140 to 0.006890)	0.000000 (0.000000 to 0.001050)		
IFNg+IL2+TNFa+, DENV-2, NS3-2, Year 2 (n=56,56)	0.000727 (0.000000 to 0.003915)	0.001925 (0.000000 to 0.004043)		
IFNg+IL2+TNFa+, DENV-2, NS5-2, Year 2 (n=56,56)	0.001500 (0.000000 to 0.005815)	0.001535 (0.000000 to 0.005245)		
IFNg+IL2+TNFa-, DENV-2, NS1-2, Year 2 (n=56,56)	0.000000 (0.000000 to 0.001040)	0.000000 (0.000000 to 0.000000)		
IFNg+IL2+TNFa-, DENV-2, NS3-2, Year 2 (n=56,56)	0.000000 (0.000000 to 0.000853)	0.000000 (0.000000 to 0.000000)		
IFNg+IL2+TNFa-, DENV-2, NS5-2, Year 2 (n=56,56)	0.000000 (0.000000 to 0.001435)	0.000000 (0.000000 to 0.000982)		
IFNg+IL2-TNFa+, DENV-2, NS1-2, Year 2 (n=56,56)	0.000871 (0.000000 to 0.002065)	0.001015 (0.000000 to 0.004355)		
IFNg+IL2-TNFa+, DENV-2, NS3-2, Year 2 (n=56,56)	0.000080 (0.000000 to 0.001760)	0.014120 (0.004700 to 0.059078)		
IFNg+IL2-TNFa+, DENV-2, NS5-2, Year 2 (n=56,56)	0.000810 (0.000000 to 0.002310)	0.013923 (0.002940 to 0.052000)		
IFNg-IL2+TNFa+, DENV-2, NS1-2, Year 2 (n=56,56)	0.001000 (0.000000 to 0.005000)	0.000100 (0.000000 to 0.001980)		
IFNg-IL2+TNFa+, DENV-2, NS3-2, Year 2 (n=56,56)	0.000000 (0.000000 to 0.003405)	0.003625 (0.001660 to 0.007235)		
IFNg-IL2+TNFa+, DENV-2, NS5-2, Year 2 (n=56,56)	0.002835 (0.000000 to 0.009205)	0.002915 (0.000000 to 0.008730)		
IFNg+IL2-TNFa-, DENV-2, NS1-2, Year 2 (n=56,56)	0.000420 (0.000000 to 0.002115)	0.000100 (0.000000 to 0.001980)		
IFNg+IL2-TNFa-, DENV-2, NS3-2, Year 2 (n=56,56)	0.000210 (0.000000 to 0.001285)	0.003625 (0.001660 to 0.007235)		
IFNg+IL2-TNFa-, DENV-2, NS5-2, Year 2 (n=56,56)	0.000150 (0.000000 to 0.001500)	0.002915 (0.000000 to 0.008730)		
IFNg-IL2+TNFa-, DENV-2, NS1-2, Year 2 (n=56,56)	0.000000 (0.000000 to 0.001500)	0.000000 (0.000000 to 0.005000)		

IFNg-IL2+TNFa-, DENV-2, NS3-2, Year 2 (n=56,56)	0.000000 (0.000000 to 0.002000)	0.000000 (0.000000 to 0.003180)		
IFNg-IL2+TNFa-, DENV-2, NS5-2, Year 2 (n=56,56)	0.000000 (0.000000 to 0.010000)	0.000000 (0.000000 to 0.008500)		
IFNg-IL2-TNFa+, DENV-2, NS1-2, Year 2 (n=56,56)	0.000000 (0.000000 to 0.039000)	0.000000 (0.000000 to 0.001050)		
IFNg-IL2-TNFa+, DENV-2, NS3-2, Year 2 (n=56,56)	0.009500 (0.000000 to 0.055000)	0.001295 (0.000000 to 0.017150)		
IFNg-IL2-TNFa+, DENV-2, NS5-2, Year 2 (n=56,56)	0.029500 (0.000000 to 0.105000)	0.003000 (0.000000 to 0.017150)		
IFNg+IL2+TNFa+, DENV-2, NS1-2, Year 3 (n=69,69)	0.002450 (0.000000 to 0.005360)	0.000000 (0.000000 to 0.001070)		
IFNg+IL2+TNFa+, DENV-2, NS3-2, Year 3 (n=69,69)	0.000696 (0.000000 to 0.006250)	0.000950 (0.000000 to 0.004030)		
IFNg+IL2+TNFa+, DENV-2, NS5-2, Year 3 (n=69,69)	0.002510 (0.000000 to 0.006480)	0.000856 (0.000000 to 0.005240)		
IFNg+IL2+TNFa-, DENV-2, NS1-2, Year 3 (n=69,69)	0.000000 (0.000000 to 0.000999)	0.000000 (0.000000 to 0.000000)		
IFNg+IL2+TNFa-, DENV-2, NS3-2, Year 3 (n=69,69)	0.000060 (0.000000 to 0.001390)	0.000000 (0.000000 to 0.000647)		
IFNg+IL2+TNFa-, DENV-2, NS5-2, Year 3 (n=69,69)	0.000122 (0.000000 to 0.002741)	0.000000 (0.000000 to 0.000905)		
IFNg+IL2-TNFa+, DENV-2, NS1-2, Year 3 (n=69,69)	0.000160 (0.000000 to 0.001990)	0.000000 (0.000000 to 0.002670)		
IFNg+IL2-TNFa+, DENV-2, NS3-2, Year 3 (n=69,69)	0.000000 (0.000000 to 0.001574)	0.006290 (0.000930 to 0.022070)		
IFNg+IL2-TNFa+, DENV-2, NS5-2, Year 3 (n=69,69)	0.000090 (0.000000 to 0.001980)	0.007770 (0.001000 to 0.040020)		
IFNg-IL2+TNFa+, DENV-2, NS1-2, Year 3 (n=69,69)	0.001670 (0.000000 to 0.005550)	0.000000 (0.000000 to 0.000873)		
IFNg-IL2+TNFa+, DENV-2, NS3-2, Year 3 (n=69,69)	0.001000 (0.000000 to 0.003000)	0.000000 (0.000000 to 0.000980)		
IFNg-IL2+TNFa+, DENV-2, NS5-2, Year 3 (n=69,69)	0.002000 (0.000000 to 0.007000)	0.000000 (0.000000 to 0.001060)		
IFNg+IL2-TNFa-, DENV-2, NS1-2, Year 3 (n=69,69)	0.000048 (0.000000 to 0.001480)	0.000000 (0.000000 to 0.002250)		
IFNg+IL2-TNFa-, DENV-2, NS3-2, Year 3 (n=69,69)	0.000000 (0.000000 to 0.001310)	0.002340 (0.000000 to 0.006260)		
IFNg+IL2-TNFa-, DENV-2, NS5-2, Year 3 (n=69,69)	0.000180 (0.000000 to 0.001630)	0.002380 (0.000000 to 0.010000)		
IFNg-IL2+TNFa-, DENV-2, NS1-2, Year 3 (n=69,69)	0.000000 (0.000000 to 0.008000)	0.000000 (0.000000 to 0.005000)		

IFNg-IL2+TNFa-, DENV-2, NS3-2, Year 3 (n=69,69)	0.000000 (0.000000 to 0.009000)	0.000000 (0.000000 to 0.009000)		
IFNg-IL2+TNFa-, DENV-2, NS5-2, Year 3 (n=69,69)	0.002000 (0.000000 to 0.013000)	0.000000 (0.000000 to 0.007000)		
IFNg-IL2-TNFa+, DENV-2, NS1-2, Year 3 (n=69,69)	0.000000 (0.000000 to 0.013000)	0.000000 (0.000000 to 0.005000)		
IFNg-IL2-TNFa+, DENV-2, NS3-2, Year 3 (n=69,69)	0.000000 (0.000000 to 0.011000)	0.003000 (0.000000 to 0.016000)		
IFNg-IL2-TNFa+, DENV-2, NS5-2, Year 3 (n=69,69)	0.020000 (0.000000 to 0.060000)	0.005000 (0.000000 to 0.017000)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phenotype Characterization of Cellular Immune Response Assessed by Percentage of Total T Cells of Cellular Response DENV-2 NS Peptides,1Month Post First Vaccination,Pre Second Vaccination;1,6Months Post Second Vaccination,Annually at Years1,2,3 by Country

End point title	Phenotype Characterization of Cellular Immune Response Assessed by Percentage of Total T Cells of Cellular Response DENV-2 NS Peptides,1Month Post First Vaccination,Pre Second Vaccination;1,6Months Post Second Vaccination,Annually at Years1,2,3 by Country

End point description:

The phenotype characterization of cellular immune response by country was assessed by ICS by the frequency of total CD4+ and CD8+ T cells and was performed in a subset of participants with IFN- γ ELISPOT responses >500 SFC/million cells and availability of sufficient cells. The peptide pools included NS1, NS3 and NS5 for DENV-2 serotype. Data are presented for the different expression profiles of IFN-γ, IL-2 and TNF-α cytokines for each peptide pool. Data is reported per country (Panama and Philippines) based on the type of T cells present in participants at the time of analysis (CD4+ T cells and CD8+ T cells). ICS Subset 'by country based on T-cells' included participants from PPS who have IFN-γ ELISPOT responses >500 SFC/million PBMCs and availability of sufficient cells. Number analysed is the number of participants with data available for analysis for specific category.

End point type	Secondary

End point timeframe:

1 month post first vaccination (Day 30); pre-second vaccination (Day 90); 1 and 6 months post second vaccination (Days 120 and 270); Years 1, 2, and 3

End point values	TDV 0.5 mL: Panama: CD4+ T Cells	TDV 0.5 mL: Philippines: CD4+ T Cells	TDV 0.5 mL: Panama: CD8+ T Cells	TDV 0.5 ml: Philippines: CD8+ T Cells
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	33	46	33	46
Units: percentage of T cells				
median (inter-quartile range (Q1-Q3))				
IFNg+IL2+TNFa+,DENV-2,NS1-2, Day 30(n=28,43,28,43)	0.005670 (0.001120 to 0.017245)	0.010590 (0.004880 to 0.020000)	0.001655 (0.000000 to 0.023500)	0.001350 (0.000000 to 0.004720)

IFNg+IL2+TNFa+,DENV-2,NS3-2, Day 30(n=28,43,28,43)	0.002700 (0.001651 to 0.006900)	0.006810 (0.002040 to 0.011040)	0.014500 (0.002155 to 0.036000)	0.021000 (0.004490 to 0.040260)
IFNg+IL2+TNFa+,DENV-2,NS5-2, Day 30(n=28,43,28,43)	0.003892 (0.001960 to 0.007760)	0.005450 (0.003160 to 0.012000)	0.021000 (0.002955 to 0.039500)	0.014000 (0.003084 to 0.049000)
IFNg+IL2+TNFa-,DENV-2,NS1-2, Day 30(n=28,43,28,43)	0.000000 (0.000000 to 0.001810)	0.000000 (0.000000 to 0.000850)	0.000000 (0.000000 to 0.000545)	0.000000 (0.000000 to 0.000000)
IFNg+IL2+TNFa-,DENV-2,NS3-2, Day 30(n=28,43,28,43)	0.000000 (0.000000 to 0.000865)	0.000000 (0.000000 to 0.000000)	0.001170 (0.000000 to 0.002990)	0.001210 (0.000000 to 0.003340)
IFNg+IL2+TNFa-,DENV-2,NS5-2, Day 30(n=28,43,28,43)	0.000000 (0.000000 to 0.001013)	0.000000 (0.000000 to 0.000000)	0.001825 (0.000000 to 0.004000)	0.001490 (0.000000 to 0.004640)
IFNg+IL2-TNFa+,DENV-2,NS1-2, Day 30(n=28,43,28,43)	0.003935 (0.000208 to 0.006730)	0.003720 (0.000740 to 0.008820)	0.024675 (0.000530 to 0.144580)	0.014000 (0.000190 to 0.030330)
IFNg+IL2-TNFa+,DENV-2,NS3-2, Day 30(n=28,43,28,43)	0.002880 (0.000202 to 0.004855)	0.002710 (0.000130 to 0.006670)	0.114125 (0.034725 to 0.402570)	0.172000 (0.065720 to 0.588300)
IFNg+IL2-TNFa+,DENV-2,NS5-2, Day 30(n=28,43,28,43)	0.003100 (0.000195 to 0.006109)	0.002890 (0.000010 to 0.006340)	0.129260 (0.037645 to 0.344770)	0.142870 (0.026180 to 0.390000)
IFNg-IL2+TNFa+,DENV-2,NS1-2, Day 30(n=28,43,28,43)	0.001820 (0.000000 to 0.004055)	0.004222 (0.000000 to 0.009470)	0.000000 (0.000000 to 0.000090)	0.000000 (0.000000 to 0.000000)
IFNg-IL2+TNFa+,DENV-2,NS3-2, Day 30(n=28,43,28,43)	0.002110 (0.000000 to 0.009815)	0.001700 (0.000000 to 0.006610)	0.000000 (0.000000 to 0.001004)	0.000000 (0.000000 to 0.000180)
IFNg-IL2+TNFa+,DENV-2,NS5-2, Day 30(n=28,43,28,43)	0.003000 (0.000000 to 0.009500)	0.003350 (0.000000 to 0.008000)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.000000)
IFNg+IL2-TNFa-,DENV-2,NS1-2, Day 30(n=28,43,28,43)	0.001440 (0.000000 to 0.004830)	0.000850 (0.000000 to 0.003260)	0.019265 (0.004200 to 0.078745)	0.006850 (0.000850 to 0.015340)
IFNg+IL2-TNFa-,DENV-2,NS3-2, Day 30(n=28,43,28,43)	0.001240 (0.000000 to 0.002885)	0.000000 (0.000000 to 0.003160)	0.065510 (0.025630 to 0.162840)	0.061520 (0.024540 to 0.287780)
IFNg+IL2-TNFa-,DENV-2,NS5-2, Day 30(n=28,43,28,43)	0.000620 (0.000000 to 0.003105)	0.000498 (0.000000 to 0.003550)	0.074245 (0.021500 to 0.190910)	0.053520 (0.014000 to 0.230980)
IFNg-IL2+TNFa-,DENV-2,NS1-2, Day 30(n=28,43,28,43)	0.005000 (0.000000 to 0.012145)	0.000000 (0.000000 to 0.004000)	0.002000 (0.000000 to 0.010500)	0.001620 (0.000000 to 0.008000)
IFNg-IL2+TNFa-,DENV-2,NS3-2, Day 30(n=28,43,28,43)	0.005000 (0.000000 to 0.011645)	0.000000 (0.000000 to 0.002000)	0.000000 (0.000000 to 0.009000)	0.000000 (0.000000 to 0.005000)
IFNg-IL2+TNFa-,DENV-2,NS5-2, Day 30(n=28,43,28,43)	0.008590 (0.000000 to 0.017500)	0.000000 (0.000000 to 0.004000)	0.007000 (0.000000 to 0.011000)	0.000000 (0.000000 to 0.008000)
IFNg-IL2-TNFa+,DENV-2,NS1-2, Day 30(n=28,43,28,43)	0.000000 (0.000000 to 0.006000)	0.000000 (0.000000 to 0.030000)	0.004000 (0.000000 to 0.020000)	0.000000 (0.000000 to 0.010000)
IFNg-IL2-TNFa+,DENV-2,NS3-2, Day 30(n=28,43,28,43)	0.004500 (0.000000 to 0.025500)	0.010000 (0.000000 to 0.048000)	0.008500 (0.003000 to 0.019000)	0.014000 (0.000000 to 0.040000)
IFNg-IL2-TNFa+,DENV-2,NS5-2, Day 30(n=28,43,28,43)	0.000000 (0.000000 to 0.040000)	0.020000 (0.000000 to 0.050000)	0.009000 (0.000000 to 0.024500)	0.002000 (0.000000 to 0.035000)
IFNg+IL2+TNFa+,DENV-2,NS1-2, Day 90(n=31,41,31,41)	0.001485 (0.000000 to 0.006030)	0.005670 (0.002370 to 0.010370)	0.000000 (0.000000 to 0.002070)	0.001030 (0.000000 to 0.004850)

IFNg+IL2+TNFa+,DENV-2,NS3-2, Day 90(n=31,41,31,41)	0.002448 (0.000000 to 0.007030)	0.003491 (0.000710 to 0.006290)	0.003364 (0.000000 to 0.006120)	0.008860 (0.003110 to 0.016000)
IFNg+IL2+TNFa+,DENV-2,NS5-2, Day 90(n=31,41,31,41)	0.001415 (0.000000 to 0.005600)	0.003270 (0.000791 to 0.005780)	0.003560 (0.001220 to 0.008740)	0.005580 (0.000570 to 0.017770)
IFNg+IL2+TNFa-,DENV-2,NS1-2, Day 90(n=31,41,31,41)	0.000100 (0.000000 to 0.002130)	0.000679 (0.000000 to 0.001300)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.000722)
IFNg+IL2+TNFa-,DENV-2,NS3-2, Day 90(n=31,41,31,41)	0.000000 (0.000000 to 0.002690)	0.000515 (0.000000 to 0.001790)	0.000000 (0.000000 to 0.001320)	0.000837 (0.000000 to 0.001920)
IFNg+IL2+TNFa-,DENV-2,NS5-2, Day 90(n=31,41,31,41)	0.000000 (0.000000 to 0.001360)	0.000000 (0.000000 to 0.000921)	0.000000 (0.000000 to 0.001680)	0.001175 (0.000000 to 0.003450)
IFNg+IL2-TNFa+,DENV-2,NS1-2, Day 90(n=31,41,31,41)	0.000545 (0.000000 to 0.002740)	0.001290 (0.000000 to 0.002870)	0.003760 (0.000000 to 0.042000)	0.005470 (0.000662 to 0.019000)
IFNg+IL2-TNFa+,DENV-2,NS3-2, Day 90(n=31,41,31,41)	0.000645 (0.000000 to 0.002690)	0.002120 (0.000000 to 0.003770)	0.047980 (0.027290 to 0.154680)	0.125320 (0.058820 to 0.213810)
IFNg+IL2-TNFa+,DENV-2,NS5-2, Day 90(n=31,41,31,41)	0.000000 (0.000000 to 0.001810)	0.001120 (0.000000 to 0.003650)	0.077000 (0.015630 to 0.158700)	0.067000 (0.021020 to 0.155000)
IFNg-IL2+TNFa+,DENV-2,NS1-2, Day 90(n=31,41,31,41)	0.000000 (0.000000 to 0.001010)	0.004140 (0.000000 to 0.009000)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.000950)
IFNg-IL2+TNFa+,DENV-2,NS3-2, Day 90(n=31,41,31,41)	0.000793 (0.000000 to 0.003000)	0.001000 (0.000000 to 0.004230)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.000791)
IFNg-IL2+TNFa+,DENV-2,NS5-2, Day 90(n=31,41,31,41)	0.001000 (0.000000 to 0.003000)	0.004530 (0.001220 to 0.008000)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.000725)
IFNg+IL2-TNFa-,DENV-2,NS1-2, Day 90(n=31,41,31,41)	0.000000 (0.000000 to 0.002120)	0.000000 (0.000000 to 0.000968)	0.003210 (0.000000 to 0.019000)	0.001540 (0.000000 to 0.004780)
IFNg+IL2-TNFa-,DENV-2,NS3-2, Day 90(n=31,41,31,41)	0.000000 (0.000000 to 0.001680)	0.000000 (0.000000 to 0.000742)	0.018000 (0.001000 to 0.063760)	0.037000 (0.011370 to 0.080257)
IFNg+IL2-TNFa-,DENV-2,NS5-2, Day 90(n=31,41,31,41)	0.000000 (0.000000 to 0.002290)	0.000000 (0.000000 to 0.000949)	0.020970 (0.003000 to 0.059000)	0.021940 (0.002890 to 0.036310)
IFNg-IL2+TNFa-,DENV-2,NS1-2, Day 90(n=31,41,31,41)	0.000000 (0.000000 to 0.008000)	0.000000 (0.000000 to 0.009000)	0.000000 (0.000000 to 0.008000)	0.002000 (0.000000 to 0.011000)
IFNg-IL2+TNFa-,DENV-2,NS3-2, Day 90(n=31,41,31,41)	0.004000 (0.000000 to 0.010000)	0.000000 (0.000000 to 0.009000)	0.000000 (0.000000 to 0.011000)	0.000000 (0.000000 to 0.007000)
IFNg-IL2+TNFa-,DENV-2,NS5-2, Day 90(n=31,41,31,41)	0.007000 (0.000000 to 0.011000)	0.002000 (0.000000 to 0.010000)	0.000000 (0.000000 to 0.015000)	0.000000 (0.000000 to 0.010000)
IFNg-IL2-TNFa+,DENV-2,NS1-2, Day 90(n=31,41,31,41)	0.000000 (0.000000 to 0.050000)	0.000000 (0.000000 to 0.020000)	0.000000 (0.000000 to 0.010000)	0.000000 (0.000000 to 0.009000)
IFNg-IL2-TNFa+,DENV-2,NS3-2, Day 90(n=31,41,31,41)	0.000000 (0.000000 to 0.019000)	0.000000 (0.000000 to 0.036000)	0.004000 (0.000000 to 0.022000)	0.020000 (0.002000 to 0.042000)
IFNg-IL2-TNFa+,DENV-2,NS5-2, Day 90(n=31,41,31,41)	0.000000 (0.000000 to 0.030000)	0.026000 (0.000000 to 0.060000)	0.005000 (0.000000 to 0.017000)	0.010000 (0.000000 to 0.030000)
IFNg+IL2+TNFa+,DENV-2,NS1-2,Day 120(n=29,46,29,46)	0.005531 (0.003340 to 0.012780)	0.009230 (0.003860 to 0.018610)	0.001590 (0.000000 to 0.006910)	0.001100 (0.000000 to 0.002580)

IFNg+IL2+TNFa+,DENV-2,NS3-2,Day 120(n=29,46,29,46)	0.002690 (0.001041 to 0.007190)	0.003495 (0.001420 to 0.006660)	0.010000 (0.002850 to 0.016000)	0.010000 (0.002650 to 0.019000)
IFNg+IL2+TNFa+,DENV-2,NS5-2,Day 120(n=29.46,29,46)	0.000661 (0.000000 to 0.002990)	0.002598 (0.000000 to 0.005470)	0.013000 (0.004830 to 0.021000)	0.006905 (0.001180 to 0.028000)
IFNg+IL2+TNFa-,DENV-2,NS1-2,Day 120(n=29,46,29,46)	0.000900 (0.000000 to 0.002580)	0.001135 (0.000000 to 0.002180)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.000000)
IFNg+IL2+TNFa-,DENV-2,NS3-2,Day 120(n=29,46,29,46)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.001670)	0.000000 (0.000000 to 0.001440)	0.000000 (0.000000 to 0.001920)
IFNg+IL2+TNFa-,DENV-2,NS5-2,Day 120(n=29,46,29,46)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.001190)	0.000000 (0.000000 to 0.001650)	0.001175 (0.000000 to 0.003450)
IFNg+IL2-TNFa+,DENV-2,NS1-2,Day 120(n=29,46,29,46)	0.002396 (0.000260 to 0.005000)	0.002045 (0.000000 to 0.005070)	0.011000 (0.001100 to 0.066340)	0.005500 (0.000000 to 0.019000)
IFNg+IL2-TNFa+,DENV-2,NS3-2,Day 120(n=29,46,29,46)	0.002456 (0.000250 to 0.005980)	0.001800 (0.000000 to 0.003200)	0.092920 (0.038250 to 0.160000)	0.153500 (0.048520 to 0.353170)
IFNg+IL2-TNFa+,DENV-2,NS5-2,Day 120(n=29,46,29,46)	0.001590 (0.000000 to 0.002636)	0.000702 (0.000000 to 0.002960)	0.094740 (0.030050 to 0.205000)	0.096615 (0.031580 to 0.220000)
IFNg-IL2+TNFa+,DENV-2,NS1-2,Day 120(n=29,46,29,46)	0.005710 (0.000000 to 0.010000)	0.008335 (0.002900 to 0.017000)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.000000)
IFNg-IL2+TNFa+,DENV-2,NS3-2,Day 120(n=29,46,29,46)	0.000000 (0.000000 to 0.005520)	0.000000 (0.000000 to 0.004000)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.000000)
IFNg-IL2+TNFa+,DENV-2,NS5-2,Day 120(n=29,46,29,46)	0.003580 (0.000000 to 0.008000)	0.003275 (0.000000 to 0.010660)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.001250)
IFNg+IL2-TNFa-,DENV-2,NS1-2,Day 120(n=29,46,29,46)	0.002490 (0.000000 to 0.005560)	0.001520 (0.000000 to 0.004380)	0.006000 (0.001770 to 0.019000)	0.003750 (0.000000 to 0.007240)
IFNg+IL2-TNFa-,DENV-2,NS3-2,Day 120(n=29,46,29,46)	0.001620 (0.000000 to 0.002630)	0.000365 (0.000000 to 0.002000)	0.033420 (0.009000 to 0.081860)	0.039000 (0.015000 to 0.104850)
IFNg+IL2-TNFa-,DENV-2,NS5-2,Day 120(n=29,46,29,46)	0.000000 (0.000000 to 0.002000)	0.000205 (0.000000 to 0.002830)	0.022820 (0.012340 to 0.058000)	0.018425 (0.004130 to 0.060560)
IFNg-IL2+TNFa-,DENV-2,NS1-2,Day 120(n=29,46,29,46)	0.010000 (0.000000 to 0.015000)	0.007000 (0.000000 to 0.012000)	0.000000 (0.000000 to 0.008000)	0.002000 (0.000000 to 0.017000)
IFNg-IL2+TNFa-,DENV-2,NS3-2,Day 120(n=29,46,29,46)	0.000000 (0.000000 to 0.005000)	0.001500 (0.000000 to 0.011000)	0.005000 (0.000000 to 0.017000)	0.000000 (0.000000 to 0.012000)
IFNg-IL2+TNFa-,DENV-2,NS5-2,Day 120(n=29,46,29,46)	0.001000 (0.000000 to 0.013000)	0.000000 (0.000000 to 0.013000)	0.005000 (0.000000 to 0.015000)	0.000000 (0.000000 to 0.014000)
IFNg-IL2-TNFa+,DENV-2,NS1-2,Day 120(n=29,46,29,46)	0.001000 (0.000000 to 0.020000)	0.002000 (0.000000 to 0.030000)	0.004000 (0.000000 to 0.017000)	0.003000 (0.000000 to 0.020000)
IFNg-IL2-TNFa+,DENV-2,NS3-2,Day 120(n=29,46,29,46)	0.000000 (0.000000 to 0.030000)	0.000000 (0.000000 to 0.028000)	0.010000 (0.000000 to 0.020000)	0.016500 (0.000000 to 0.033000)
IFNg-IL2-TNFa+,DENV-2,NS5-2,Day 120(n=29,46,29,46)	0.020000 (0.000000 to 0.050000)	0.015000 (0.000000 to 0.049000)	0.013000 (0.000000 to 0.027340)	0.011000 (0.000000 to 0.031000)
IFNg+IL2+TNFa+,DENV-2,NS1-2,Day 270(n=27,44,27,44)	0.006400 (0.002940 to 0.015180)	0.005090 (0.002935 to 0.014500)	0.000000 (0.000000 to 0.003850)	0.000000 (0.000000 to 0.002285)

IFNg+IL2+TNFa+,DENV-2,NS3-2,Day 270(n=27,44,27,44)	0.004470 (0.001750 to 0.007780)	0.001540 (0.000000 to 0.004138)	0.002920 (0.000020 to 0.014000)	0.005090 (0.001570 to 0.009779)
IFNg+IL2+TNFa+,DENV-2,NS5-2,Day 270(n=27,44,27,44)	0.002890 (0.001910 to 0.004530)	0.002393 (0.000000 to 0.005765)	0.006040 (0.001120 to 0.030780)	0.003620 (0.000478 to 0.014160)
IFNg+IL2+TNFa-,DENV-2,NS1-2,Day 270(n=27,44,27,44)	0.000000 (0.000000 to 0.001490)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.000000)
IFNg+IL2+TNFa-,DENV-2,NS3-2,Day 270(n=27,44,27,44)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.002100)	0.000000 (0.000000 to 0.000915)
IFNg+IL2+TNFa-,DENV-2,NS5-2,Day 270(n=27,44,27,44)	0.000000 (0.000000 to 0.001220)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.001220)	0.000000 (0.000000 to 0.001550)
IFNg+IL2-TNFa+,DENV-2,NS1-2,Day 270(n=27,44,27,44)	0.000200 (0.000000 to 0.002270)	0.001386 (0.000000 to 0.003795)	0.004620 (0.001270 to 0.041450)	0.004695 (0.000000 to 0.019500)
IFNg+IL2-TNFa+,DENV-2,NS3-2,Day 270(n=27,44,27,44)	0.002270 (0.000000 to 0.005380)	0.000740 (0.000000 to 0.002175)	0.073630 (0.033000 to 0.140000)	0.099370 (0.034095 to 0.273535)
IFNg+IL2-TNFa+,DENV-2,NS5-2,Day 270(n=27,44,27,44)	0.000000 (0.000000 to 0.001870)	0.000430 (0.000000 to 0.002875)	0.093000 (0.022090 to 0.197960)	0.056525 (0.017440 to 0.183385)
IFNg-IL2+TNFa+,DENV-2,NS1-2,Day 270(n=27,44,27,44)	0.002000 (0.000000 to 0.012000)	0.005400 (0.001685 to 0.009780)	0.000000 (0.000000 to 0.000660)	0.000000 (0.000000 to 0.000000)
IFNg-IL2+TNFa+,DENV-2,NS3-2,Day 270(n=27,44,27,44)	0.000000 (0.000000 to 0.005400)	0.000660 (0.000000 to 0.004630)	0.000000 (0.000000 to 0.001160)	0.000000 (0.000000 to 0.000000)
IFNg-IL2+TNFa+,DENV-2,NS5-2,Day 270(n=27,44,27,44)	0.000000 (0.000000 to 0.004000)	0.001955 (0.000000 to 0.006600)	0.000000 (0.000000 to 0.001350)	0.000000 (0.000000 to 0.000000)
IFNg+IL2-TNFa-,DENV-2,NS1-2,Day 270(n=27,44,27,44)	0.000000 (0.000000 to 0.002780)	0.000000 (0.000000 to 0.002015)	0.004600 (0.000000 to 0.011000)	0.001669 (0.000000 to 0.007810)
IFNg+IL2-TNFa-,DENV-2,NS3-2,Day 270(n=32,44,27,44)	0.000000 (0.000000 to 0.002760)	0.000002 (0.000000 to 0.001615)	0.015000 (0.004570 to 0.028280)	0.016169 (0.001670 to 0.047810)
IFNg+IL2-TNFa-,DENV-2,NS5-2,Day 270(n=32,44,27,44)	0.000000 (0.000000 to 0.003550)	0.000000 (0.000000 to 0.001285)	0.018200 (0.006240 to 0.035000)	0.009090 (0.000030 to 0.025060)
IFNg-IL2+TNFa-,DENV-2,NS1-2,Day 270(n=27,44,27,44)	0.000000 (0.000000 to 0.008000)	0.001000 (0.000000 to 0.007620)	0.002000 (0.000000 to 0.009000)	0.000500 (0.000000 to 0.005680)
IFNg-IL2+TNFa-,DENV-2,NS3-2,Day 270(n=27,44,27,44)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.003000)	0.001000 (0.000000 to 0.011000)	0.000000 (0.000000 to 0.001500)
IFNg-IL2+TNFa-,DENV-2,NS5-2,Day 270(n=27,44,27,44)	0.000000 (0.000000 to 0.007000)	0.000000 (0.000000 to 0.007950)	0.000000 (0.000000 to 0.008000)	0.000000 (0.000000 to 0.006000)
IFNg-IL2-TNFa+,DENV-2,NS1-2,Day 270(n=27,44,27,44)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.020000)	0.005000 (0.000000 to 0.021000)	0.000000 (0.000000 to 0.015000)
IFNg-IL2-TNFa+,DENV-2,NS3-2,Day 270(n=27,44,27,44)	0.000000 (0.000000 to 0.029000)	0.005500 (0.000000 to 0.038500)	0.016000 (0.000000 to 0.040000)	0.010000 (0.000000 to 0.053000)
IFNg-IL2-TNFa+,DENV-2,NS5-2,Day 270(n=27,44,27,44)	0.000000 (0.000000 to 0.050000)	0.000000 (0.000000 to 0.040000)	0.021000 (0.000000 to 0.045000)	0.010000 (0.000000 to 0.029000)
IFNg+IL2+TNFa+,DENV-2,NS1-2,Year 1(n=32,38,32,38)	0.002825 (0.000000 to 0.008700)	0.004303 (0.000000 to 0.007260)	0.000000 (0.000000 to 0.001720)	0.000000 (0.000000 to 0.001160)

IFNg+IL2+TNFa+,DENV-2,NS3-2,Year 1(n=32,38,32,38)	0.001835 (0.000000 to 0.006990)	0.002138 (0.000000 to 0.004780)	0.001970 (0.000005 to 0.004610)	0.000000 (0.000000 to 0.003536)
IFNg+IL2+TNFa+,DENV-2,NS5-2,Year 1(n=32,38,32,38)	0.001486 (0.000000 to 0.004375)	0.000538 (0.000000 to 0.006780)	0.004090 (0.000000 to 0.010820)	0.000935 (0.000000 to 0.004230)
IFNg+IL2+TNFa-,DENV-2,NS1-2,Year 1(n=32,38,32,38)	0.000758 (0.000000 to 0.002335)	0.000000 (0.000000 to 0.001590)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.000000)
IFNg+IL2+TNFa-,DENV-2,NS3-2,Year 1(n=32,38,32,38)	0.000035 (0.000000 to 0.001690)	0.000000 (0.000000 to 0.001140)	0.000000 (0.000000 to 0.000918)	0.000000 (0.000000 to 0.001140)
IFNg+IL2+TNFa-,DENV-2,NS5-2,Year 1(n=32,38,32,38)	0.000000 (0.000000 to 0.001230)	0.000000 (0.000000 to 0.001620)	0.000000 (0.000000 to 0.000950)	0.000000 (0.000000 to 0.000000)
IFNg+IL2-TNFa+,DENV-2,NS1-2,Year 1(n=32,38,32,38)	0.000004 (0.000000 to 0.002130)	0.001599 (0.000010 to 0.005810)	0.001650 (0.000000 to 0.025930)	0.000000 (0.000000 to 0.001790)
IFNg+IL2-TNFa+,DENV-2,NS3-2,Year 1(n=32,38,32,38)	0.001170 (0.000000 to 0.002050)	0.000965 (0.000000 to 0.003340)	0.022915 (0.008465 to 0.046500)	0.022820 (0.004000 to 0.061950)
IFNg+IL2-TNFa+,DENV-2,NS5-2,Year 1(n=32,38,32,38)	0.001065 (0.000000 to 0.001825)	0.000766 (0.000000 to 0.003750)	0.045815 (0.009695 to 0.094410)	0.009520 (0.000000 to 0.036130)
IFNg-IL2+TNFa+,DENV-2,NS1-2,Year 1(n=32,38,32,38)	0.002758 (0.000000 to 0.007000)	0.003735 (0.000000 to 0.011820)	0.000000 (0.000000 to 0.001010)	0.000000 (0.000000 to 0.001590)
IFNg-IL2+TNFa+,DENV-2,NS3-2,Year 1(n=32,38,32,38)	0.000000 (0.000000 to 0.003000)	0.003000 (0.000000 to 0.008620)	0.000000 (0.000000 to 0.000035)	0.000000 (0.000000 to 0.001370)
IFNg-IL2+TNFa+,DENV-2,NS5-2,Year 1(n=32,38,32,38)	0.001053 (0.000000 to 0.006000)	0.004910 (0.000060 to 0.014000)	0.000000 (0.000000 to 0.001315)	0.000795 (0.000000 to 0.001510)
IFNg+IL2-TNFa-,DENV-2,NS1-2,Year 1(n=32,38,32,38)	0.000477 (0.000000 to 0.002413)	0.000788 (0.000000 to 0.002670)	0.002995 (0.000000 to 0.009535)	0.000000 (0.000000 to 0.003210)
IFNg+IL2-TNFa-,DENV-2,NS3-2,Year 1(n=32,38,32,38)	0.000000 (0.000000 to 0.001311)	0.000000 (0.000000 to 0.002250)	0.004390 (0.001090 to 0.012525)	0.002250 (0.000000 to 0.008910)
IFNg+IL2-TNFa-,DENV-2,NS5-2,Year 1(n=32,38,32,38)	0.000456 (0.000000 to 0.002790)	0.000000 (0.000000 to 0.001440)	0.008865 (0.002510 to 0.019285)	0.000465 (0.000000 to 0.006390)
IFNg-IL2+TNFa-,DENV-2,NS1-2, Year 1(n=32,38,32,38)	0.000000 (0.000000 to 0.011000)	0.002000 (0.000000 to 0.011000)	0.000000 (0.000000 to 0.009440)	0.000500 (0.000000 to 0.009000)
IFNg-IL2+TNFa-,DENV-2,NS3-2,Year 1(n=32,38,32,38)	0.000000 (0.000000 to 0.010000)	0.001000 (0.000000 to 0.010000)	0.000000 (0.000000 to 0.004175)	0.000000 (0.000000 to 0.008000)
IFNg-IL2+TNFa-,DENV-2,NS5-2,Year 1(n=32,38,32,38)	0.000000 (0.000000 to 0.014500)	0.005000 (0.000000 to 0.020000)	0.000000 (0.000000 to 013940)	0.000500 (0.000000 to 0.009000)
IFNg-IL2-TNFa+,DENV-2,NS1-2,Year 1(n=32,38,32,38)	0.000000 (0.000000 to 0.021000)	0.020000 (0.000000 to 0.130000)	0.000000 (0.000000 to 0.003000)	0.000895 (0.000000 to 0.009000)
IFNg-IL2-TNFa+,DENV-2,NS3-2,Year 1(n=32,38,32,38)	0.000000 (0.000000 to 0.023500)	0.025500 (0.000000 to 0.100000)	0.003500 (0.000000 to 0.012500)	0.010500 (0.000000 to 0.026000)
IFNg-IL2-TNFa+,DENV-2,NS5-2,Year 1(n=32,38,32,38)	0.006500 (0.000000 to 0.085000)	0.075000 (0.000000 to 0.180000)	0.005500 (0.000000 to 0.018210)	0.010000 (0.000000 to 0.022000)
IFNg+IL2+TNFa+,DENV-2,NS1-2,Year 2(n=16,40,16,40)	0.003832 (0.001292 to 0.007035)	0.002406 (0.000000 to 0.006890)	0.000000 (0.000000 to 0.001050)	0.000000 (0.000000 to 0.000998)

IFNg+IL2+TNFa+,DENV-2,NS3-2,Year 2(n=16,40,16,40)	0.001452 (0.000337 to 0.005767)	0.000503 (0.000000 to 0.002644)	0.002230 (0.000484 to 0.002745)	0.001875 (0.000000 to 0.004790)
IFNg+IL2+TNFa+,DENV-2,NS5-2,Year 2(n=16,40,16,40)	0.002005 (0.000323 to 0.007710)	0.001335 (0.000000 to 0.005545)	0.002595 (0.001290 to 0.005245)	0.000812 (0.000000 to 0.005740)
IFNg+IL2-TNFa+,DENV-2,NS1-2,Year 2(n=16,40,16,40)	0.000261 (0.000000 to 0.001360)	0.001095 (0.000000 to 0.002335)	0.002010 (0.000025 to 0.004425)	0.000000 (0.000000 to 0.004290)
IFNg+IL2-TNFa+,DENV-2,NS3-2,Year 2(n=16,40,16,40)	0.000413 (0.000000 to 0.001012)	0.000050 (0.000000 to 0.002470)	0.012063 (0.003120 to 0.045755)	0.015970 (0.006810 to 0.069945)
IFNg+IL2-TNFa+,DENV-2,NS5-2,Year 2(n=16,40,16,40)	0.000656 (0.000000 to 0.001710)	0.001055 (0.000000 to 0.003220)	0.018930 (0.008160 to 0.050495)	0.009770 (0.002160 to 0.054000)
IFNg-IL2+TNFa+,DENV-2,NS1-2,Year 2(N=16,40,16,40)	0.000895 (0.000000 to 0.003615)	0.001000 (0.000000 to 0.005000)	0.000000 (0.000000 to 0.000535)	0.000000 (0.000000 to 0.000054)
IFNg-IL2+TNFa+,DENV-2,NS3-2,Year 2(N=16,40,16,40)	0.000000 (0.000000 to 0.002060)	0.000380 (0.000000 to 0.003775)	0.000000 (0.000000 to 0.000927)	0.000000 (0.000000 to 0.000908)
IFNg-IL2+TNFa+,DENV-2,NS5-2,Year 2(N=16,40,16,40)	0.001555 (0.000000 to 0.008615)	0.003865 (0.000000 to 0.009705)	0.000000 (0.000000 to 0.000856)	0.000000 (0.000000 to 0.000963)
IFNg+IL2-TNFa-,DENV-2,NS1-2,Year 2(n=16,40,16,40)	0.000702 (0.000000 to 0.002704)	0.000020 (0.000000 to 0.001690)	0.000860 (0.000000 to 0.001435)	0.000030 (0.000000 to 0.002080)
IFNg+IL2-TNFa-,DENV-2,NS3-2,Year 2(n=16,40,16,40)	0.001005 (0.000000 to 0.001785)	0.000050 (0.000000 to 0.001196)	0.004335 (0.002185 to 0.008140)	0.003555 (0.000850 to 0.007200)
IFNg+IL2-TNFa-,DENV-2,NS5-2,Year 2(n=16,40,16,40)	0.000985 (0.000000 to 0.001820)	0.000085 (0.000000 to 0.001405)	0.005735 (0.002780 to 0.016800)	0.001155 (0.000000 to 0.007580)
IFNg-IL2+TNFa-,DENV-2,NS1-2,Year 2(n=16,40,16,40)	0.000000 (0.000000 to 0.000500)	0.000000 (0.000000 to 0.003500)	0.000000 (0.000000 to 0.006325)	0.000000 (0.000000 to 0.005000)
IFNg-IL2+TNFa-,DENV-2,NS3-2,Year 2(n=16,40,16,40)	0.000000 (0.000000 to 0.003500)	0.000000 (0.000000 to 0.002000)	0.002180 (0.000000 to 0.006000)	0.000000 (0.000000 to 0.001500)
IFNg-IL2+TNFa-,DENV-2,NS5-2,Year 2(n=16,40,16,40)	0.000500 (0.000000 to 0.022000)	0.000000 (0.000000 to 0.010000)	0.000000 (0.000000 to 0.004385)	0.000000 (0.000000 to 0.009500)
IFNg-IL2-TNFa+,DENV-2,NS1-2,Year 2(n=16,40,16,40)	0.000000 (0.000000 to 0.020000)	0.003500 (0.000000 to 0.044500)	0.000000 (0.000000 to 0.002870)	0.000000 (0.000000 to 0.001000)
IFNg-IL2-TNFa+,DENV-2,NS3-2,Year 2(n=16,40,16,40)	0.000000 (0.000000 to 0.030500)	0.020000 (0.000000 to 0.070000)	0.004155 (0.000000 to 0.013150)	0.001295 (0.000000 to 0.019500)
IFNg-IL2-TNFa+,DENV-2,NS5-2,Year 2(n=16,40,16,40)	0.000500 (0.000000 to 0.065000)	0.047000 (0.005500 to 0.110000)	0.001370 (0.000000 to 0.013650)	0.003500 (0.000000 to 0.020000)
IFNg+IL2+TNFa+,DENV-2,NS1-2,Year 3(n=30,39,30,39)	0.001810 (0.000000 to 0.007589)	0.002624 (0.000000 to 0.005010)	0.000000 (0.000000 to 0.001030)	0.000000 (0.000000 to 0.001240)
IFNg+IL2+TNFa+,DENV-2,NS3-2,Year 3(n=30,39,30,39)	0.000530 (0.000000 to 0.003668)	0.000760 (0.000000 to 0.007520)	0.000985 (0.000000 to 0.004030)	0.000844295 (0.000000 to 0.006500)
IFNg+IL2+TNFa+,DENV-2,NS5-2,Year 3(n=30,39,30,39)	0.001915 (0.000000 to 0.006970)	0.002884 (0.000000 to 0.006480)	0.001735 (0.000000 to 0.006330)	0.000000 (0.000000 to 0.002690)
IFNg+IL2+TNFa-,DENV-2,NS1-2,Year 3(n=30,39,30,39)	0.000000 (0.000000 to 0.000819)	0.000000 (0.000000 to 0.001137)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.000000)

IFNg+IL2+TNFa-,DENV-2,NS3-2,Year 3(n=30,39,30,39)	0.000000 (0.000000 to 0.001238)	0.000080 (0.000000 to 0.001660)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.000763)
IFNg+IL2+TNFa-,DENV-2,NS5-2,Year 3(n=30,39,30,39)	0.001265 (0.000000 to 0.003710)	0.000000 (0.000000 to 0.001990)	0.000000 (0.000000 to 0.001150)	0.000000 (0.000000 to 0.000905)
IFNg+IL2-TNFa+,DENV-2,NS1-2,Year 3(n=30,39,30,39)	0.000070 (0.000000 to 0.001840)	0.000540 (0.000000 to 0.002410)	0.001065 (0.000000 to 0.006760)	0.000000 (0.000000 to 0.002140)
IFNg+IL2-TNFa+,DENV-2,NS3-2,Year 3(n=30,39,30,39)	0.000000 (0.000000 to 0.001140)	0.000000 (0.000000 to 0.001800)	0.007670 (0.002000 to 0.016000)	0.005610 (0.000600 to 0.025430)
IFNg+IL2-TNFa+,DENV-2,NS5-2,Year 3(n=30,39,30,39)	0.000000 (0.000000 to 0.001120)	0.001050 (0.000000 to 0.002940)	0.011465 (0.000000 to 0.045060)	0.005570 (0.001000 to 0.028163)
IFNg-IL2+TNFa+,DENV-2,NS1-2,Year 3(n=30,39,30,39)	0.001695 (0.000000 to 0.004320)	0.001650 (0.000000 to 0.005570)	0.000000 (0.000000 to 0.001013)	0.000000 (0.000000 to 0.000873)
IFNg-IL2+TNFa+,DENV-2,NS3-2,Year 3(n=30,39,30,39)	0.001013 (0.000000 to 0.003000)	0.001000 (0.000000 to 0.002680)	0.000000 (0.000000 to 0.001090)	0.000000 (0.000000 to 0.000813)
IFNg-IL2+TNFa+,DENV-2,NS5-2,Year 3(n=30,39,30,39)	0.002695 (0.000000 to 0.006000)	0.001330 (0.000000 to 0.009330)	0.000000 (0.000000 to 0.001470)	0.000000 (0.000000 to 0.000617)
IFNg+IL2-TNFa-,DENV-2,NS1-2,Year 3(n=30,39,30,39)	0.000000 (0.000000 to 0.001219)	0.000300 (0.000000 to 0.001630)	0.001048 (0.000000 to 0.002680)	0.000000 (0.000000 to 0.001950)
IFNg+IL2-TNFa-,DENV-2,NS3-2,Year 3(n=30,39,30,39)	0.000025 (0.000000 to 0.001630)	0.000000 (0.000000 to 0.001310)	0.001680 (0.000000 to 0.007000)	0.002390 (0.000000 to 0.006260)
IFNg+IL2-TNFa-,DENV-2,NS5-2,Year 3(n=30,39,30,39)	0.000012 (0.000000 to 0.001820)	0.000584 (0.000000 to 0.001560)	0.002050 (0.000000 to 0.013360)	0.002380 (0.000857 to 0.010000)
IFNg-IL2+TNFa-,DENV-2,NS1-2,Year 3(n=30,39,30,39)	0.000000 (0.000000 to 0.006000)	0.000000 (0.000000 to 0.010000)	0.000000 (0.000000 to 0.005000)	0.000000 (0.000000 to 0.005000)
IFNg-IL2+TNFa-,DENV-2,NS3-2,Year 3(n=30,39,30,39)	0.000000 (0.000000 to 0.005000)	0.001000 (0.000000 to 0.011000)	0.001000 (0.000000 to 0.019000)	0.000000 (0.000000 to 0.007000)
IFNg-IL2+TNFa-,DENV-2,NS5-2,Year 3(n=30,39,30,39)	0.021500 (0.000000 to 0.050000)	0.020000 (0.000000 to 0.090000)	0.008500 (0.000000 to 0.017000)	0.001000 (0.000000 to 0.007000)
IFNg-IL2-TNFa+,DENV-2,NS1-2,Year 3(n=30,39,30,39)	0.000000 (0.000000 to 0.013000)	0.000000 (0.000000 to 0.016000)	0.000500 (0.000000 to 0.011710)	0.000000 (0.000000 to 0.003000)
IFNg-IL2-TNFa+,DENV-2,NS3-2,Year 3(n=30,39,30,39)	0.000000 (0.000000 to 0.013000)	0.000000 (0.000000 to 0.010000)	0.001000 (0.000000 to 0.009000)	0.008000 (0.000000 to 0.022000)
IFNg-IL2-TNFa+,DENV-2,NS5-2,Year 3(n=30,39,30,39)	0.021500 (0.000000 to 0.050000)	0.020000 (0.000000 to 0.090000)	0.008500 (0.000000 to 0.017000)	0.004000 (0.000000 to 0.015000)

Statistical analyses

No statistical analyses for this end point

Secondary: Phenotype Characterization of Cellular Immune Response by Percentage of Total T Cells DENV-2 NS Peptides at 1Month Post First Vaccination,Pre Second Vaccination;1,6Months Post Second Vaccination,Annually at Years1,2,3 by Dengue Baseline Seropositivity

End point title	Phenotype Characterization of Cellular Immune Response by Percentage of Total T Cells DENV-2 NS Peptides at 1Month Post First Vaccination,Pre Second Vaccination;1,6Months Post Second Vaccination,Annually at Years1,2,3 by Dengue Baseline Seropositivity

End point description:

Phenotype characterization of cellular immune response by dengue Baseline seropositivity status assessed by frequency of total CD4+ and CD8+ T cells and was performed in subset of participants with IFN- γ ELISPOT responses >500 SFC/million cells and availability of sufficient cells. Seropositive: reciprocal neutralizing titer (MNT50) >=10 for one or more dengue serotypes. Seronegative: titer value of <10 for all 4 serotypes. Peptide pools included NS for DENV-2 serotype. Data are presented fo different expression profiles of IFN-γ, IL-2 and TNF-α cytokines for each peptide pool. Data is reported per Baseline seropositivity status (Seropositive and Seronegative) based on type of T cells present in participants at time of analysis (CD4+ and CD8+ T cells). ICS Subset 'by Baseline seropositivity status based on T-cells'. Number analysed:participants with data available for analysis for specific category.

End point type	Secondary

End point timeframe:

1 month post first vaccination (Day 30); pre-second vaccination (Day 90); 1 and 6 months post second vaccination (Days 120 and 270); Years 1, 2, and 3

End point values	TDV 0.5 mL: Seropositive: CD4+ T-Cells	TDV 0.5 mL: Seronegative: CD4+ T-Cells	TDV 0.5 mL: Seropositive: CD8+ T- Cells	TDV 0.5 mL: Seronegative: CD8+ T-Cells
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	44	35	44	35
Units: percentage of T cells				
median (inter-quartile range (Q1-Q3))				
IFNg+IL2+TNFa+,DENV-2,NS1-2, Day 30(n=39,32,39,32)	0.013000 (0.004820 to 0.023000)	0.007655 (0.001679 to 0.011295)	0.002170 (0.000000 to 0.007600)	0.000245 (0.000000 to 0.009595)
IFNg+IL2+TNFa+,DENV-2,NS3-2, Day 30(n=39,32,39,32)	0.005140 (0.001960 to 0.014000)	0.004985 (0.001651 to 0.008985)	0.021000 (0.002540 to 0.039350)	0.017000 (0.003855 to 0.038500)
IFNg+IL2+TNFa+,DENV-2,NS5-2, Day 30(n=39,32,39,32)	0.005380 (0.002410 to 0.012000)	0.005255 (0.002660 to 0.009030)	0.018000 (0.002380 to 0.050000)	0.009560 (0.003965 to 0.028500)
IFNg+IL2+TNFa-,DENV-2,NS1-2, Day 30(n=39,32,39,32)	0.000000 (0.000000 to 0.001300)	0.000000 (0.000000 to 0.001475)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.000000)
IFNg+IL2+TNFa-,DENV-2,NS3-2, Day 30(n=39,32,39,32)	0.000000 (0.000000 to 0.001060)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.003340)	0.001330 (0.000000 to 0.002990)
IFNg+IL2+TNFa-,DENV-2,NS5-2, Day 30(n=39,32,39,32)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.001100)	0.001540 (0.000000 to 0.004160)	0.001695 (0.000000 to 0.004990)
IFNg+IL2-TNFa+,DENV-2,NS1-2, Day 30(n=39,32,39,32)	0.004740 (0.000930 to 0.008483)	0.003070 (0.000398 to 0.005920)	0.018190 (0.000000 to 0.066470)	0.015540 (0.001500 to 0.051595)
IFNg+IL2-TNFa+,DENV-2,NS3-2, Day 30(n=39,32,39,32)	0.002710 (0.000000 to 0.006750)	0.002885 (0.000779 to 0.005040)	0.108250 (0.052230 to 0.490000)	0.168175 (0.063270 to 0.431355)
IFNg+IL2-TNFa+,DENV-2,NS5-2, Day 30(n=39,32,39,32)	0.002630 (0.001070 to 0.005530)	0.003785 (0.000000 to 0.007035)	0.150000 (0.034000 to 0.307000)	0.117545 (0.027560 to 0.490450)
IFNg-IL2+TNFa+,DENV-2,NS1-2, Day 30(n=39,32,39,32)	0.003620 (0.000000 to 0.011000)	0.002275 (0.000000 to 0.006070)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.000000)
IFNg-IL2+TNFa+,DENV-2,NS3-2, Day 30(n=39,32,39,32)	0.002150 (0.000000 to 0.008000)	0.001230 (0.000000 to 0.004635)	0.000000 (0.000000 to 0.000310)	0.000000 (0.000000 to 0.001035)

IFNg-IL2+TNFa+,DENV-2,NS5-2, Day 30(n=39,32,39,32)	0.003720 (0.000000 to 0.007610)	0.002270 (0.000000 to 0.009435)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.000488)
IFNg+IL2-TNFa-,DENV-2,NS1-2, Day 30(n=39,32,39,32)	0.000850 (0.000000 to 0.003640)	0.000835 (0.000000 to 0.004635)	0.007750 (0.002150 to 0.035143)	0.007370 (0.002315 to 0.030290)
IFNg+IL2-TNFa-,DENV-2,NS3-2, Day 30(n=39,32,39,32)	0.000000 (0.000000 to 0.003160)	0.000065 (0.000000 to 0.002450)	0.065380 (0.013470 to 0.170000)	0.051500 (0.029850 to 0.238910)
IFNg+IL2-TNFa-,DENV-2,NS5-2, Day 30(n=39,32,39,32)	0.000280 (0.000000 to 0.002940)	0.000900 (0.000000 to 0.004040)	0.053520 (0.022000 to 0.116020)	0.101275 (0.017460 to 0.234760)
IFNg-IL2+TNFa-,DENV-2,NS1-2, Day 30(n=39,32,39,32)	0.001000 (0.000000 to 0.008000)	0.000000 (0.000000 to 0.009590)	0.002000 (0.000000 to 0.008000)	0.002000 (0.000000 to 0.009500)
IFNg-IL2+TNFa-,DENV-2,NS3-2, Day 30(n=39,32,39,32)	0.000000 (0.000000 to 0.009000)	0.000000 (0.000000 to 0.003500)	0.000000 (0.000000 to 0.007730)	0.000000 (0.000000 to 0.008110)
IFNg-IL2+TNFa-,DENV-2,NS5-2, Day 30(n=39,32,39,32)	0.000000 (0.000000 to 0.010000)	0.00050 (0.000000 to 0.009090)	0.000000 (0.000000 to 0.010000)	0.003610 (0.000000 to 0.009500)
IFNg-IL2-TNFa+,DENV-2,NS1-2, Day 30(n=39,32,39,32)	0.003000 (0.000000 to 0.030000)	0.000000 (0.000000 to 0.007000)	0.005000 (0.000000 to 0.018000)	0.000000 (0.000000 to 0.004500)
IFNg-IL2-TNFa+,DENV-2,NS3-2, Day 30(n=39,32,39,32)	0.010000 (0.000000 to 0.045000)	0.001500 (0.000000 to 0.030000)	0.018000 (0.003000 to 0.035000)	0.006000 (0.000000 to 0.020000)
IFNg-IL2-TNFa+,DENV-2,NS5-2, Day 30(n=39,32,39,32)	0.028000 (0.000000 to 0.070000)	0.000000 (0.000000 to 0.031000)	0.015000 (0.000000 to 0.032000)	0.000000 (0.000000 to 0.024500)
IFNg+IL2+TNFa+,DENV-2,NS1-2, Day 90(n=38,34,38,34)	0.005720 (0.002968 to 0.010690)	0.002190 (0.001020 to 0.006030)	0.000013 (0.000000 to 0.004300)	0.000000 (0.000000 to 0.002980)
IFNg+IL2+TNFa+,DENV-2,NS3-2, Day 90(n=38,34,38,34)	0.003592 (0.000811 to 0.007360)	0.001325 (0.000000 to 0.005820)	0.004660 (0.001440 to 0.013770)	0.005880 (0.001600 to 0.008860)
IFNg+IL2+TNFa+,DENV-2,NS5-2, Day 90(n=38,34,38,34)	0.002795 (0.000000 to 0.006900)	0.001420 (0.000000 to 0.005530)	0.00326 (0.000000 to 0.014000)	0.004563 (0.001490 to 0.009010)
IFNg+IL2+TNFa-,DENV-2,NS1-2, Day 90(n=38,34,38,34)	0.000842 (0.000000 to 0.001960)	0.000000 (0.000000 to 0.000888)	0.000000 (0.000000 to 0.000722)	0.000000 (0.000000 to 0.000000)
IFNg+IL2+TNFa-,DENV-2,NS3-2, Day 90(n=38,34,38,34)	0.000544 (0.000000 to 0.002510)	0.000000 (0.000000 to 0.000824)	0.000785 (0.000000 to 0.002560)	0.000000 (0.000000 to 0.001132)
IFNg+IL2+TNFa-,DENV-2,NS5-2, Day 90(n=38,34,38,34)	0.000000 (0.000000 to 0.000921)	0.000000 (0.000000 to 0.001039)	0.000383 (0.000000 to 0.001620)	0.000000 (0.000000 to 0.002050)
IFNg+IL2-TNFa+,DENV-2,NS1-2, Day 90(n=38,34,38,34)	0.001540 (0.000000 to 0.003473)	0.000490 (0.000000 to 0.001370)	0.002893 (0.000040 to 0.019000)	0.006540 (0.000000 to 0.024660)
IFNg+IL2-TNFa+,DENV-2,NS3-2, Day 90(n=38,34,38,34)	0.001583 (0.000000 to 0.003050)	0.001810 (0.000000 to 0.003060)	0.103350 (0.034000 to 0.213810)	0.107000 (0.031000 to 0.178620)
IFNg+IL2-TNFa+,DENV-2,NS5-2, Day 90(n=38,34,38,34)	0.001090 (0.000000 to 0.003265)	0.000410 (0.000000 to 0.002460)	0.081000 (0.012110 to 0.129362)	0.069105 (0.019340 to 0.192000)
IFNg-IL2+TNFa+,DENV-2,NS1-2, Day 90(n=38,34,38,34)	0.001245 (0.000000 to 0.007850)	0.001050 (0.000000 to 0.009000)	0.000000 (0.000000 to 0.000912)	0.000000 (0.000000 to 0.000650)
IFNg-IL2+TNFa+,DENV-2,NS3-2, Day 90(n=38,34,38,34)	0.000000 (0.000000 to 0.002770)	0.001880 (0.000000 to 0.004000)	0.000000 (0.000000 to 0.000791)	0.000000 (0.000000 to 0.000030)

IFNg-IL2+TNFa+,DENV-2,NS5-2, Day 90(n=38,34,38,34)	0.003980 (0.000000 to 0.006330)	0.002055 (0.000000 to 0.005370)	0.000000 (0.000000 to 0.000022)	0.000000 (0.000000 to 0.000725)
IFNg+IL2-TNFa-,DENV-2,NS1-2, Day 90(n=38,34,38,34)	0.000010 (0.000000 to 0.001830)	0.000000 (0.000000 to 0.001080)	0.002390 (0.000000 to 0.006940)	0.001535 (0.000000 to 0.005310)
IFNg+IL2-TNFa-,DENV-2,NS3-2, Day 90(n=38,34,38,34)	0.000000 (0.000000 to 0.001070)	0.000000 (0.000000 to 0.000860)	0.039000 (0.009950 to 0.096152)	0.017000 (0.006240 to 0.043000)
IFNg+IL2-TNFa-,DENV-2,NS5-2, Day 90(n=38,34,38,34)	0.000000 (0.000000 to 0.001520)	0.000000 (0.000000 to 0.000949)	0.026425 (0.002250 to 0.059000)	0.015420 (0.004490 to 0.041610)
IFNg-IL2+TNFa-,DENV-2,NS1-2, Day 90(n=38,34,38,34)	0.000000 (0.000000 to 0.009000)	0.000500 (0.000000 to 0.008000)	0.002000 (0.000000 to 0.006000)	0.000500 (0.000000 to 0.012000)
IFNg-IL2+TNFa-,DENV-2,NS3-2, Day 90(n=38,34,38,34)	0.000000 (0.000000 to 0.009000)	0.002000 (0.000000 to 0.010000)	0.000500 (0.000000 to 0.008000)	0.000000 (0.000000 to 0.011000)
IFNg-IL2+TNFa-,DENV-2,NS5-2, Day 90(n=38,34,38,34)	0.001500 (0.000000 to 0.010000)	0.006500 (0.000000 to 0.013000)	0.000000 (0.000000 to 0.009000)	0.001000 (0.000000 to 0.011000)
IFNg-IL2-TNFa+,DENV-2,NS1-2, Day 90(n=38,34,38,34)	0.000000 (0.000000 to 0.020000)	0.000000 (0.000000 to 0.020000)	0.000000 (0.000000 to 0.008000)	0.000000 (0.000000 to 0.012000)
IFNg-IL2-TNFa+,DENV-2,NS3-2, Day 90(n=38,34,38,34)	0.000000 (0.000000 to 0.036000)	0.001000 (0.000000 to 0.020000)	0.008405 (0.001000 to 0.038000)	0.018000 (0.000000 to 0.032000)
IFNg-IL2-TNFa+,DENV-2,NS5-2, Day 90(n=38,34,38,34)	0.000000 (0.000000 to 0.050000)	0.010405 (0.000000 to 0.050000)	0.005450 (0.000000 to 0.027000)	0.009500 (0.000000 to 0.026000)
IFNg+IL2+TNFa+,DENV-2,NS1-2,Day 120(n=42,33,42,33)	0.011000 (0.003860 to 0.017000)	0.005531 (0.003340 to 0.016010)	0.00140 (0.000000 to 0.004030)	0.001320 (0.000000 to 0.004240)
IFNg+IL2+TNFa+,DENV-2,NS3-2,Day 120(n=42,33,42,33)	0.003480 (0.000000 to 0.008830)	0.003300 (0.001670 to 0.005510)	0.010000 (0.002650 to 0.028000)	0.010000 (0.002740 to 0.015000)
IFNg+IL2+TNFa+,DENV-2,NS5-2,Day 120(n=42,33,42,33)	0.002705 (0.000000 to 0.005470)	0.001460 (0.000000 to 0.003000)	0.012000 (0.002670 to 0.035000)	0.006000 (0.002230 to 0.013000)
IFNg+IL2+TNFa-,DENV-2,NS1-2,Day 120(n=42,33,42,33)	0.000975 (0.000000 to 0.002670)	0.001220 (0.000000 to 0.001840)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.000000)
IFNg+IL2+TNFa-,DENV-2,NS3-2,Day 120(n=42,33,42,33)	0.000000 (0.000000 to 0.001580)	0.000000 (0.000000 to 0.001150)	0.000000 (0.000000 to 0.001920)	0.000000 (0.000000 to 0.001460)
IFNg+IL2+TNFa-,DENV-2,NS5-2,Day 120(n=42,33,42,33)	0.000000 (0.000000 to 0.000908)	0.000000 (0.000000 to 0.000953)	0.001540 (0.000000 to 0.003450)	0.000000 (0.000000 to 0.001650)
IFNg+IL2-TNFa+,DENV-2,NS1-2,Day 120(n=42,33,42,33)	0.002885 (0.000760 to 0.005320)	0.002070 (0.000000 to 0.003680)	0.007155 (0.000000 to 0.036000)	0.007850 (0.000000 to 0.028000)
IFNg+IL2-TNFa+,DENV-2,NS3-2,Day 120(n=42,33,42,33)	0.002915 (0.001090 to 0.004370)	0.000450 (0.000000 to 0.002670)	0.144565 (0.039110 to 0.447000)	0.093000 (0.053410 to 0.163270)
IFNg+IL2-TNFa+,DENV-2,NS5-2,Day 120(n=42,33,42,33)	0.000702 (0.000000 to 0.003690)	0.001570 (0.000000 to 0.002150)	0.102525 (0.039880 to 0.291210)	0.078900 (0.025190 to 0.134400)
IFNg-IL2+TNFa+,DENV-2,NS1-2,Day 120(n=42,33,42,33)	0.004735 (0.000280 to 0.013000)	0.011430 (0.003910 to 0.017000)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.000000)
IFNg-IL2+TNFa+,DENV-2,NS3-2,Day 120(n=42,33,42,33)	0.000530 (0.000000 to 0.005520)	0.000000 (0.000000 to 0.003730)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.001140)

IFNg-IL2+TNFa+,DENV-2,NS5-2,Day 120(n=42,33,42,33)	0.003100 (0.000000 to 0.007000)	0.006490 (0.000000 to 0.010660)	0.000000 (0.000000 to 0.001420)	0.000000 (0.000000 to 0.000000)
IFNg+IL2-TNFa-,DENV-2,NS1-2,Day 120(n=42,33,42,33)	0.001520 (0.000000 to 0.004710)	0.002490 (0.000000 to 0.005030)	0.004280 (0.001060 to 0.009270)	0.004080 (0.000000 to 0.016790)
IFNg+IL2-TNFa-,DENV-2,NS3-2,Day 120(n=42,33,42,33)	0.001235 (0.000000 to 0.002480)	0.000190 (0.000000 to 0.002720)	0.046825 (0.015000 to 0.111210)	0.024000 (0.007000 to 0.056110)
IFNg+IL2-TNFa-,DENV-2,NS5-2,Day 120(n=42,33,42,33)	0.000020 (0.000000 to 0.002480)	0.000000 (0.000000 to 0.002260)	0.034610 (0.011000 to 0.101210)	0.016280 (0.006480 to 0.030630)
IFNg-IL2+TNFa-,DENV-2,NS1-2,Day 120(n=42,33,42,33)	0.009500 (0.000000 to 0.011000)	0.006000 (0.000000 to 0.015000)	0.001500 (0.000000 to 0.017000)	0.002000 (0.000000 to 0.014000)
IFNg-IL2+TNFa-,DENV-2,NS3-2,Day 120(n=42,33,42,33)	0.000000 (0.000000 to 0.007000)	0.002000 (0.000000 to 0.011000)	0.000500 (0.000000 to 0.019000)	0.003000 (0.000000 to 0.012000)
IFNg-IL2+TNFa-,DENV-2,NS5-2,Day 120(n=42,33,42,33)	0.000000 (0.000000 to 0.013000)	0.000000 (0.000000 to 0.013000)	0.000000 (0.000000 to 0.011000)	0.006000 (0.000000 to 0.020000)
IFNg-IL2-TNFa+,DENV-2,NS1-2,Day 120(n=42,33,42,33)	0.007000 (0.000000 to 0.040000)	0.000000 (0.000000 to 0.019000)	0.004500 (0.000000 to 0.028000)	0.000000 (0.000000 to 0.014000)
IFNg-IL2-TNFa+,DENV-2,NS3-2,Day 120(n=42,33,42,33)	0.008000 (0.000000 to 0.030000)	0.000000 (0.000000 to 0.028000)	0.018000 (0.000000 to 0.034000)	0.009000 (0.000000 to 0.019000)
IFNg-IL2-TNFa+,DENV-2,NS5-2,Day 120(n=42,33,42,33)	0.020000 (0.000000 to 0.050000)	0.010000 (0.000000 to 0.040000)	0.016500 (0.000000 to 0.040000)	0.008000 (0.000000 to 0.023050)
IFNg+IL2+TNFa+,DENV-2,NS1-2,Day 270(n=39,32,39,32)	0.008790 (0.002970 to 0.019000)	0.004355 (0.002620 to 0.011890)	0.000000 (0.000000 to 0.002760)	0.000411 (0.000000 to 0.002420)
IFNg+IL2+TNFa+,DENV-2,NS3-2,Day 270(n=39,32,39,32)	0.003410 (0.000000 to 0.006810)	0.002170 (0.000355 to 0.004995)	0.008760 (0.002360 to 0.020000)	0.002605 (0.000010 to 0.008395)
IFNg+IL2+TNFa+,DENV-2,NS5-2,Day 270(n=39,32,39,32)	0.002890 (0.001110 to 0.005160)	0.002720 (0.000059 to 0.005480)	0.003960 (0.001120 to 0.026000)	0.004575 (0.000000 to 0.012420)
IFNg+IL2+TNFa-,DENV-2,NS1-2,Day 270(n=39,32,39,32)	0.000000 (0.000000 to 0.000980)	0.000000 (0.000000 to 0.000505)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.000000)
IFNg+IL2+TNFa-,DENV-2,NS3-2,Day 270(n=39,32,39,32)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.001930)	0.000000 (0.000000 to 0.000000)
IFNg+IL2+TNFa-,DENV-2,NS5-2,Day 270(n=39,32,39,32)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.000635)	0.000000 (0.000000 to 0.001570)	0.000000 (0.000000 to 0.001150)
IFNg+IL2-TNFa+,DENV-2,NS1-2,Day 270(n=39,32,39,32)	0.001650 (0.000000 to 0.004170)	0.000190 (0.000000 to 0.002215)	0.003430 (0.000000 to 0.019000)	0.008115 (0.000030 to 0.024475)
IFNg+IL2-TNFa+,DENV-2,NS3-2,Day 270(n=39,32,39,32)	0.001470 (0.000000 to 0.003600)	0.000803 (0.000000 to 0.003250)	0.099000 (0.036000 to 0.289000)	0.069910 (0.027000 to 0.176500)
IFNg+IL2-TNFa+,DENV-2,NS5-2,Day 270(n=39,32,39,32)	0.000000 (0.000000 to 0.002240)	0.000798 (0.000000 to 0.002785)	0.070000 (0.029000 to 0.258000)	0.055015 (0.016265 to 0.128520)
IFNg-IL2+TNFa+,DENV-2,NS1-2,Day 270(n=39,32,39,32)	0.003230 (0.000000 to 0.009190)	0.005735 (0.001130 to 0.013520)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.000000)
IFNg-IL2+TNFa+,DENV-2,NS3-2,Day 270(n=39,32,39,32)	0.000000 (0.000000 to 0.004920)	0.000515 (0.000000 to 0.004630)	0.000000 (0.000000 to 0.000055)	0.000000 (0.000000 to 0.000000)

IFNg-IL2+TNFa+,DENV-2,NS5-2,Day 270(n=39,32,39,32)	0.001000 (0.000000 to 0.003470)	0.002470 (0.000000 to 0.007075)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.001470)
IFNg+IL2-TNFa-,DENV-2,NS1-2,Day 270(n=39,32,39,32)	0.000000 (0.000000 to 0.002800)	0.000000 (0.000000 to 0.001245)	0.003060 (0.000000 to 0.008450)	0.003350 (0.000000 to 0.008815)
IFNg+IL2-TNFa-,DENV-2,NS3-2,Day 270(n=39,32,39,32)	0.000330 (0.000000 to 0.002550)	0.000000 (0.000000 to 0.001390)	0.022120 (0.002960 to 0.032080)	0.007160 (0.002385 to 0.016904)
IFNg+IL2-TNFa-,DENV-2,NS5-2,Day 270(n=39,32,39,32)	0.000000 (0.000000 to 0.003160)	0.000000 (0.000000 to 0.002085)	0.015270 (0.000620 to 0.033830)	0.008945 (0.002924 to 0.027280)
IFNg-IL2+TNFa-,DENV-2,NS1-2,Day 270(n=39,32,39,32)	0.000000 (0.000000 to 0.006000)	0.001500 (0.000000 to 0.010500)	0.000000 (0.000000 to 0.006000)	0.001000 (0.000000 to 0.008500)
IFNg-IL2+TNFa-,DENV-2,NS3-2,Day 270(n=39,32,39,32)	0.000000 (0.000000 to 0.004000)	0.000000 (0.000000 to 0.001000)	0.000000 (0.000000 to 0.005000)	0.000000 (0.000000 to 0.003500)
IFNg-IL2+TNFa-,DENV-2,NS5-2,Day 270(n=39,32,39,32)	0.000000 (0.000000 to 0.007000)	0.000000 (0.000000 to 0.007500)	0.000000 (0.000000 to 0.007460)	0.000000 (0.000000 to 0.005500)
IFNg-IL2-TNFa+,DENV-2,NS1-2,Day 270(n=39,32,39,32)	0.000000 (0.000000 to 0.020000)	0.000000 (0.000000 to 0.005000)	0.003000 (0.000000 to 0.029000)	0.000000 (0.000000 to 0.015000)
IFNg-IL2-TNFa+,DENV-2,NS3-2,Day 270(n=27,44,27,44)	0.019000 (0.000000 to 0.050000)	0.000000 (0.000000 to 0.011500)	0.026000 (0.006000 to 0.070000)	0.004000 (0.000000 to 0.028500)
IFNg-IL2-TNFa+,DENV-2,NS5-2,Day 270(n=39,32,39,32)	0.009000 (0.000000 to 0.050000)	0.000000 (0.000000 to 0.027000)	0.015000 (0.004000 to 0.047000)	0.006000 (0.000000 to 0.024500)
IFNg+IL2+TNFa+,DENV-2,NS1-2,Year 1(n=39,31,39,31)	0.006710 (0.001620 to 0.010000)	0.000000 (0.000000 to 0.004370)	0.000000 (0.000000 to 0.002310)	0.000000 (0.000000 to 0.000870)
IFNg+IL2+TNFa+,DENV-2,NS3-2,Year 1(n=39,31,39,31)	0.002960 (0.000000 to 0.006980)	0.001590 (0.000000 to 0.004050)	0.000170 (0.000000 to 0.005020)	0.002000 (0.000000 to 0.003420)
IFNg+IL2+TNFa+,DENV-2,NS5-2,Year 1(n=39,31,39,31)	0.003220 (0.000000 to 0.007550)	0.000000 (0.000000 to 0.002285)	0.002460 (0.000000 to 0.010000)	0.001200 (0.000000 to 0.004260)
IFNg+IL2+TNFa-,DENV-2,NS1-2,Year 1(n=39,31,39,31)	0.000745 (0.000000 to 0.001700)	0.000000 (0.000000 to 0.002180)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.000000)
IFNg+IL2+TNFa-,DENV-2,NS3-2,Year 1(n=39,31,39,31)	0.000000 (0.000000 to 0.001240)	0.000000 (0.000000 to 0.001510)	0.000000 (0.000000 to 0.001330)	0.000000 (0.000000 to 0.000060)
IFNg+IL2+TNFa-,DENV-2,NS5-2,Year 1(n=39,31,39,31)	0.000000 (0.000000 to 0.001620)	0.000000 (0.000000 to 0.000789)	0.000000 (0.000000 to 0.000961)	0.000000 (0.000000 to 0.000000)
IFNg+IL2-TNFa+,DENV-2,NS1-2,Year 1(n=39,31,39,31)	0.001110 (0.000000 to 0.004180)	0.000920 (0.000000 to 0.002310)	0.000000 (0.000000 to 0.015000)	0.000000 (0.000000 to 0.007750)
IFNg+IL2-TNFa+,DENV-2,NS3-2,Year 1(n=39,31,39,31)	0.001430 (0.000240 to 0.002718)	0.000170 (0.000000 to 0.002810)	0.033910 (0.007790 to 0.061950)	0.013000 (0.004000 to 0.038490)
IFNg+IL2-TNFa+,DENV-2,NS5-2,Year 1(n=39,31,39,31)	0.001058 (0.000000 to 0.003260)	0.000522 (0.000000 to 0.002760)	0.036130 (0.006450 to 0.126150)	0.010120 (0.001030 to 0.040000)
IFNg-IL2+TNFa+,DENV-2,NS1-2,Year 1(n=39,31,39,31)	0.003000 (0.000000 to 0.011820)	0.003000 (0.000000 to 0.009000)	0.000000 (0.000000 to 0.001260)	0.000000 (0.000000 to 0.001020)
IFNg-IL2+TNFa+,DENV-2,NS3-2,Year 1(n=39,31,39,31)	0.003000 (0.000000 to 0.006820)	0.001000 (0.000000 to 0.005000)	0.000000 (0.000000 to 0.000794)	0.000000 (0.000000 to 0.001130)

IFNg-IL2+TNFa+,DENV-2,NS5-2,Year 1(n=39,31,39,31)	0.002000 (0.000000 to 0.011000)	0.004000 (0.000000 to 0.012000)	0.000000 (0.000000 to 0.001680)	0.000000 (0.000000 to 0.001330)
IFNg+IL2-TNFa-,DENV-2,NS1-2,Year 1(n=39,31,39,31)	0.000190 (0.000000 to 0.002580)	0.000746 (0.000000 to 0.002670)	0.000000 (0.000000 to 0.006880)	0.001300 (0.000000 to 0.005200)
IFNg+IL2-TNFa-,DENV-2,NS3-2,Year 1(n=39,31,39,31)	0.000000 (0.000000 to 0.001802)	0.000000 (0.000000 to 0.002430)	0.003000 (0.000000 to 0.012095)	0.003150 (0.000000 to 0.009260)
IFNg+IL2-TNFa-,DENV-2,NS5-2,Year 1(n=39,31,39,31)	0.000070 (0.000000 to 0.001880)	0.000000 (0.000000 to 0.001900)	0.003000 (0.000000 to 0.025100)	0.003800 (0.000000 to 0.012000)
IFNg-IL2+TNFa-,DENV-2,NS1-2, Year 1(n=39,31,39,31)	0.000000 (0.000000 to 0.011000)	0.000000 (0.000000 to 0.011000)	0.000000 (0.000000 to 0.009000)	0.000000 (0.000000 to 0.010000)
IFNg-IL2+TNFa-,DENV-2,NS3-2,Year 1(n=39,31,39,31)	0.000000 (0.000000 to 0.010000)	0.002000 (0.000000 to 0.015000)	0.000000 (0.000000 to 0.007000)	0.000000 (0.000000 to 0.009000)
IFNg-IL2+TNFa-,DENV-2,NS5-2,Year 1(n=39,31,39,31)	0.000000 (0.000000 to 0.018000)	0.006000 (0.000000 to 0.020000)	0.001000 (0.000000 to 0.010000)	0.000000 (0.000000 to 0.010000)
IFNg-IL2-TNFa+,DENV-2,NS1-2,Year 1(n=39,31,39,31)	0.000000 (0.000000 to 0.060000)	0.020000 (0.000000 to 0.060000)	0.000000 (0.000000 to 0.009000)	0.000000 (0.000000 to 0.003000)
IFNg-IL2-TNFa+,DENV-2,NS3-2,Year 1(n=39,31,39,31)	0.000000 (0.000000 to 0.090000)	0.010000 (0.000000 to 0.060000)	0.006000 (0.000000 to 0.024000)	0.004420 (0.000000 to 0.017000)
IFNg-IL2-TNFa+,DENV-2,NS5-2,Year 1(n=39,31,39,31)	0.057000 (0.000000 to 0.100000)	0.034000 (0.000000 to 0.140000)	0.007000 (0.000000 to 0.031000)	0.007000 (0.000000 to 0.017420)
IFNg+IL2+TNFa+,DENV-2,NS1-2,Year 2(n=31,25,31,25)	0.003744 (0.001870 to 0.009000)	0.001200 (0.000000 to 0.003920)	0.000000 (0.000000 to 0.001040)	0.000000 (0.000000 to 0.001100)
IFNg+IL2+TNFa+,DENV-2,NS3-2,Year 2(n=31,25,31,25)	0.000613 (0.000000 to 0.004954)	0.000860 (0.000000 to 0.002303)	0.002100 (0.000786 to 0.004890)	0.000042 (0.000000 to 0.002950)
IFNg+IL2+TNFa+,DENV-2,NS5-2,Year 2(n=31,25,31,25)	0.001490 (0.000000 to 0.003990)	0.001510 (0.000050 to 0.005870)	0.001700 (0.000000 to 0.005170)	0.001340 (0.000000 to 0.005320)
IFNg+IL2+TNFa-,DENV-2,NS1-2,Year 2(n=31,25,31,25)	0.000000 (0.000000 to 0.001820)	0.000000 (0.000000 to 0.000948)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.000000)
IFNg+IL2+TNFa-,DENV-2,NS3-2,Year 2(n=31,25,31,25)	0.000000 (0.000000 to 0.000751)	0.000000 (0.000000 to 0.000954)	0.000000 (0.000000 to 0.000030)	0.000000 (0.000000 to 0.000000)
IFNg+IL2+TNFa-,DENV-2,NS5-2,Year 2(n=31,25,31,25)	0.000000 (0.000000 to 0.002170)	0.000000 (0.000000 to 0.000803)	0.000000 (0.000000 to 0.000953)	0.000000 (0.000000 to 0.001190)
IFNg+IL2-TNFa+,DENV-2,NS1-2,Year 2(n=31,25,31,25)	0.001190 (0.000045 to 0.001810)	0.000120 (0.000000 to 0.002640)	0.001720 (0.000000 to 0.006280)	0.000000 (0.000000 to 0.002570)
IFNg+IL2-TNFa+,DENV-2,NS3-2,Year 2(n=31,25,31,25)	0.000000 (0.000000 to 0.001950)	0.000150 (0.000000 to 0.000948)	0.025000 (0.008990 to 0.067240)	0.007800 (0.002640 to 0.046410)
IFNg+IL2-TNFa+,DENV-2,NS5-2,Year 2(n=31,25,31,25)	0.000631 (0.000000 to 0.002210)	0.001390 (0.000000 to 0.002410)	0.015650 (0.002880 to 0.054000)	0.012220 (0.003480 to 0.028820)
IFNg-IL2+TNFa+,DENV-2,NS1-2,Year 2(N=31,25,31,25)	0.001000 (0.000000 to 0.005000)	0.000380 (0.000000 to 0.003510)	0.000000 (0.000000 to 0.000835)	0.000000 (0.000000 to 0.000000)
IFNg-IL2+TNFa+,DENV-2,NS3-2,Year 2(N=31,25,31,25)	0.000760 (0.000000 to 0.006670)	0.000000 (0.000000 to 0.003070)	0.000000 (0.000000 to 0.000852)	0.000000 (0.000000 to 0.001130)

IFNg-IL2+TNFa+,DENV-2,NS5-2,Year 2(N=31,25,31,25)	0.002000 (0.000000 to 0.008760)	0.005000 (0.000000 to 0.011000)	0.000000 (0.000000 to 0.000940)	0.000000 (0.000000 to 0.000947)
IFNg+IL2-TNFa-,DENV-2,NS1-2,Year 2(n=31,25,31,25)	0.000320 (0.000000 to 0.002130)	0.000588 (0.000000 to 0.002100)	0.000670 (0.000000 to 0.001940)	0.000000 (0.000000 to 0.002020)
IFNg+IL2-TNFa-,DENV-2,NS3-2,Year 2(n=31,25,31,25)	0.000180 (0.000000 to 0.001130)	0.000578 (0.000000 to 0.001680)	0.004920 (0.002000 to 0.007370)	0.003380 (0.000130 to 0.007030)
IFNg+IL2-TNFa-,DENV-2,NS5-2,Year 2(n=31,25,31,25)	0.000621 (0.000000 to 0.001449)	0.000017 (0.000000 to 0.001550)	0.004580 (0.000000 to 0.009150)	0.001140 (0.000000 to 0.007210)
IFNg-IL2+TNFa-,DENV-2,NS1-2,Year 2(n=31,25,31,25)	0.000000 (0.000000 to 0.004000)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.005000)	0.000000 (0.000000 to 0.007000)
IFNg-IL2+TNFa-,DENV-2,NS3-2,Year 2(n=31,25,31,25)	0.000000 (0.000000 to 0.002000)	0.000000 (0.000000 to 0.002000)	0.000000 (0.000000 to 0.003000)	0.000000 (0.000000 to 0.006000)
IFNg-IL2+TNFa-,DENV-2,NS5-2,Year 2(n=31,25,31,25)	0.000000 (0.000000 to 0.010000)	0.000000 (0.000000 to 0.016000)	0.000000 (0.000000 to 0.005360)	0.000000 (0.000000 to 0.009000)
IFNg-IL2-TNFa+,DENV-2,NS1-2,Year 2(n=31,25,31,25)	0.000000 (0.000000 to 0.049000)	0.000000 (0.000000 to 0.022000)	0.000000 (0.000000 to 0.004640)	0.000000 (0.000000 to 0.000000)
IFNg-IL2-TNFa+,DENV-2,NS3-2,Year 2(n=31,25,31,25)	0.011000 (0.000000 to 0.050000)	0.006000 (0.000000 to 0.060000)	0.008310 (0.000000 to 0.020000)	0.000000 (0.000000 to 0.014000)
IFNg-IL2-TNFa+,DENV-2,NS5-2,Year 2(n=31,25,31,25)	0.044000 (0.001000 to 0.100000)	0.018000 (0.000000 to 0.110000)	0.004000 (0.000000 to 0.020000)	0.000000 (0.000000 to 0.014300)
IFNg+IL2+TNFa+,DENV-2,NS1-2,Year 3(n=38,31,38,31)	0.003110 (0.000000 to 0.008297)	0.001934 (0.000180 to 0.004290)	0.000000 (0.000000 to 0.001070)	0.000000 (0.000000 to 0.001460)
IFNg+IL2+TNFa+,DENV-2,NS3-2,Year 3(n=38,31,38,31)	0.000645 (0.000000 to 0.007000)	0.000760 (0.000000 to 0.006250)	0.000060 (0.000000 to 0.003050)	0.001830 (0.000000 to 0.004090)
IFNg+IL2+TNFa+,DENV-2,NS5-2,Year 3(n=38,31,38,31)	0.002612 (0.000000 to 0.007300)	0.002510 (0.000000 to 0.003800)	0.001420 (0.000000 to 0.006330)	0.000000 (0.000000 to 0.002690)
IFNg+IL2+TNFa-,DENV-2,NS1-2,Year 3(n=38,31,38,31)	0.000000 (0.000000 to 0.000831)	0.000000 (0.000000 to 0.001180)	0.000000 (0.000000 to 0.000000)	0.000000 (0.000000 to 0.000000)
IFNg+IL2+TNFa-,DENV-2,NS3-2,Year 3(n=38,31,38,31)	0.000000 (0.000000 to 0.001240)	0.000778 (0.000000 to 0.001670)	0.000000 (0.000000 to 0.000811)	0.000000 (0.000000 to 0.000000)
IFNg+IL2+TNFa-,DENV-2,NS5-2,Year 3(n=38,31,38,31)	0.000686 (0.000000 to 0.002770)	0.000000 (0.000000 to 0.002070)	0.000000 (0.000000 to 0.001290)	0.000000 (0.000000 to 0.000000)
IFNg+IL2-TNFa+,DENV-2,NS1-2,Year 3(n=38,31,38,31)	0.000070 (0.000000 to 0.002070)	0.000557 (0.000000 to 0.001940)	0.000000 (0.000000 to 0.003040)	0.000000 (0.000000 to 0.002560)
IFNg+IL2-TNFa+,DENV-2,NS3-2,Year 3(n=38,31,38,31)	0.000000 (0.000000 to 0.001660)	0.000000 (0.000000 to 0.001574)	0.012470 (0.002000 to 0.023163)	0.004220 (0.000210 to 0.014900)
IFNg+IL2-TNFa+,DENV-2,NS5-2,Year 3(n=38,31,38,31)	0.000000 (0.000000 to 0.001580)	0.001050 (0.000000 to 0.002364)	0.007735 (0.001000 to 0.053360)	0.007770 (0.000832 to 0.029000)
IFNg-IL2+TNFa+,DENV-2,NS1-2,Year 3(n=38,31,38,31)	0.001740 (0.000000 to 0.005570)	0.001650 (0.000000 to 0.004000)	0.000000 (0.000000 to 0.000873)	0.000000 (0.000000 to 0.000930)
IFNg-IL2+TNFa+,DENV-2,NS3-2,Year 3(n=38,31,38,31)	0.000880 (0.000000 to 0.002680)	0.001000 (0.000000 to 0.003810)	0.000000 (0.000000 to 0.000750)	0.000000 (0.000000 to 0.001890)

IFNg-IL2+TNFa+,DENV-2,NS5-2,Year 3(n=38,31,38,31)	0.001500 (0.000000 to 0.008170)	0.002170 (0.000000 to 0.006000)	0.000000 (0.000000 to 0.001230)	0.000000 (0.000000 to 0.000150)
IFNg+IL2-TNFa-,DENV-2,NS1-2,Year 3(n=38,31,38,31)	0.000000 (0.000000 to 0.000702)	0.000864 (0.000000 to 0.002005)	0.000000 (0.000000 to 0.001820)	0.000090 (0.000000 to 0.002680)
IFNg+IL2-TNFa-,DENV-2,NS3-2,Year 3(n=38,31,38,31)	0.000000 (0.000000 to 0.001637)	0.000000 (0.000000 to 0.001310)	0.002707 (0.000000 to 0.006560)	0.002320 (0.000000 to 0.006260)
IFNg+IL2-TNFa-,DENV-2,NS5-2,Year 3(n=38,31,38,31)	0.000523 (0.000000 to 0.001820)	0.000000 (0.000000 to 0.001560)	0.002955 (0.000000 to 0.011250)	0.001070 (0.000000 to 0.006670)
IFNg-IL2+TNFa-,DENV-2,NS1-2,Year 3(n=38,31,38,31)	0.000000 (0.000000 to 0.006000)	0.000000 (0.000000 to 0.009000)	0.000040 (0.000000 to 0.005000)	0.000000 (0.000000 to 0.003000)
IFNg-IL2+TNFa-,DENV-2,NS3-2,Year 3(n=38,31,38,31)	0.000000 (0.000000 to 0.010000)	0.003000 (0.000000 to 0.009000)	0.000000 (0.000000 to 0.004830)	0.000000 (0.000000 to 0.010000)
IFNg-IL2+TNFa-,DENV-2,NS5-2,Year 3(n=38,31,38,31)	0.000500 (0.000000 to 0.015000)	0.004000 (0.000000 to 0.013000)	0.000500 (0.000000 to 0.007000)	0.000000 (0.000000 to 0.006000)
IFNg-IL2-TNFa+,DENV-2,NS1-2,Year 3(n=38,31,38,31)	0.000000 (0.000000 to 0.030000)	0.000000 (0.000000 to 0.010000)	0.000000 (0.000000 to 0.004000)	0.000000 (0.000000 to 0.011710)
IFNg-IL2-TNFa+,DENV-2,NS3-2,Year 3(n=38,31,38,31)	0.000000 (0.000000 to 0.011000)	0.000000 (0.000000 to 0.012000)	0.004000 (0.000000 to 0.014000)	0.001270 (0.000000 to 0.026000)
IFNg-IL2-TNFa+,DENV-2,NS5-2,Year 3(n=38,31,38,31)	0.023000 (0.000000 to 0.060000)	0.016000 (0.000000 to 0.070000)	0.003000 (0.000000 to 0.016000)	0.008000 (0.000000 to 0.018000)

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers (GMT) of Neutralizing Antibodies for Each of the 4 Dengue Serotypes at 1 Month Post First Vaccination, Pre Second Vaccination, and 1, 6 Months Post Second Vaccination and Then Annually Up to 3 Years

End point title	Geometric Mean Titers (GMT) of Neutralizing Antibodies for Each of the 4 Dengue Serotypes at 1 Month Post First Vaccination, Pre Second Vaccination, and 1, 6 Months Post Second Vaccination and Then Annually Up to 3 Years

End point description:

GMT of neutralizing antibodies was measured by microneutralization test (MTN). The dengue virus serotypes are DENV-1, DENV-2, DENV-3 and DENV-4. PPS included all participants from the FAS who have no major protocol violations. Number analysed is the number of participants with data available for analysis at the given timepoint.

End point type	Secondary

End point timeframe:

1 month post first vaccination (Day 30); pre second vaccination (Day 90); 1 and 6 months post second vaccination (Days 120 and 270); annually up to 3 years (Years 1, 2 and 3)

End point values	Tetravalent Dengue Vaccine (TDV) 0.5 mL			
Subject group type	Reporting group			
Number of subjects analysed	195			
Units: titer				
geometric mean (confidence interval 95%)				
DENV-1, Day 30	402.3 (287.5 to 562.9)			
DENV-2, Day 30	5482.2 (4626.4 to 6496.3)			
DENV-3, Day 30	436.1 (326.9 to 581.7)			
DENV-4, Day 30	253.9 (182.6 to 353.1)			
DENV-1, Day 90	271.7 (193.9 to 380.7)			
DENV-2, Day 90	2736.3 (2295.1 to 3262.5)			
DENV-3, Day 90	218.7 (162.0 to 295.2)			
DENV-4, Day 90	177.4 (129.6 to 242.8)			
DENV-1, Day 120	550.6 (408.0 to 743.1)			
DENV-2, Day 120	2808.2 (2395.0 to 3292.8)			
DENV-3, Day 120	404.2 (312.6 to 522.7)			
DENV-4, Day 120	427.1 (335.4 to 543.8)			
DENV-1, Day 270	343.3 (249.8 to 471.6)			
DENV-2, Day 270	1729.9 (1435.7 to 2084.4)			
DENV-3, Day 270	203.8 (153.5 to 270.7)			
DENV-4, Day 270	186.6 (141.6 to 246.0)			
DENV-1, Year 1	243.8 (176.4 to 337.0)			
DENV-2, Year 1	896.2 (729.9 to 1100.5)			
DENV-3, Year 1	148.6 (111.6 to 197.7)			
DENV-4, Year 1	142.4 (108.8 to 186.3)			
DENV-1, Year 2	290.8 (200.8 to 421.1)			
DENV-2, Year 2	724.7 (564.2 to 930.8)			
DENV-3, Year 2	172.7 (120.6 to 247.1)			
DENV-4, Year 2	157.7 (114.0 to 218.0)			

DENV-1, Year 3	178.7 (127.3 to 250.8)			
DENV-2, Year 3	546.4 (435.2 to 686.0)			
DENV-3, Year 3	125.2 (92.8 to 169.0)			
DENV-4, Year 3	91.6 (69.4 to 120.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Seropositive for Each of the 4 Dengue Serotypes at 1 Month Post First Vaccination, Pre-second Vaccination, and 1, 6 Months Post Second Vaccination and Then Annually up to 3 Years

End point title	Percentage of Participants Seropositive for Each of the 4 Dengue Serotypes at 1 Month Post First Vaccination, Pre-second Vaccination, and 1, 6 Months Post Second Vaccination and Then Annually up to 3 Years

End point description:

Seropositive was defined as a reciprocal neutralizing titer ≥10. The dengue virus serotypes are DENV-1, DENV-2, DENV-3 and DENV-4. PPS included all participants from the FAS who have no major protocol violations. Number analysed is the number of participants with data available at the given timepoint.

End point type	Secondary

End point timeframe:

1 month post first vaccination (Day 30); pre second vaccination (Day 90); 1 and 6 months post second vaccination (Days 120 and 270); annually up to 3 years (Years 1, 2 and 3)

End point values	Tetravalent Dengue Vaccine (TDV) 0.5 mL			
Subject group type	Reporting group			
Number of subjects analysed	195			
Units: percentage of participants				
number (confidence interval 95%)				
DENV-1, Day 30	96.8 (93.1 to 98.8)			
DENV-2, Day 30	99.5 (97.0 to 100.0)			
DENV-3, Day 30	99.5 (97.0 to 100.0)			
DENV-4, Day 30	93.0 (88.3 to 96.2)			
DENV-1, Day 90	90.8 (85.8 to 94.4)			
DENV-2, Day 90	99.5 (97.2 to 100.0)			
DENV-3, Day 90	94.4 (90.1 to 97.2)			
DENV-4, Day 90	91.8 (87.0 to 95.2)			

DENV-1, Day 120	99.5 (97.0 to 100.0)			
DENV-2, Day 120	100.0 (98.0 to 100.0)			
DENV-3, Day 120	100.0 (98.0 to 100.0)			
DENV-4, Day 120	100.0 (98.0 to 100.0)			
DENV-1, Day 270	96.8 (93.1 to 98.8)			
DENV-2, Day 270	100.0 (98.0 to 100.0)			
DENV-3, Day 270	97.9 (94.6 to 99.4)			
DENV-4, Day 270	96.8 (93.1 to 98.8)			
DENV-1, Year 1	91.1 (86.2 to 94.8)			
DENV-2, Year 1	100.0 (98.1 to 100.0)			
DENV-3, Year 1	93.8 (89.3 to 96.7)			
DENV-4, Year 1	96.4 (92.6 to 98.5)			
DENV-1, Year 2	93.5 (88.4 to 96.8)			
DENV-2, Year 2	100.0 (97.6 to 100.0)			
DENV-3, Year 2	89.6 (83.7 to 93.9)			
DENV-4, Year 2	95.5 (90.9 to 98.2)			
DENV-1, Year 3	84.4 (78.3 to 89.4)			
DENV-2, Year 3	100.0 (98.0 to 100.0)			
DENV-3, Year 3	86.7 (80.8 to 91.3)			
DENV-4, Year 3	86.1 (80.2 to 90.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Seropositive for Multiple Dengue Serotypes at 1 Month Post First Vaccination, Pre Second Vaccination, 1, 6 Months Post Second Vaccination and Annually up to 3 Years

End point title	Percentage of Participants Seropositive for Multiple Dengue Serotypes at 1 Month Post First Vaccination, Pre Second Vaccination, 1, 6 Months Post Second Vaccination and Annually up to 3 Years

End point description:

Seropositive was defined as a reciprocal neutralizing titer ≥10. The dengue virus serotypes are DENV-1, DENV-2, DENV-3 and DENV-4. Seropositive for multiple dengue serotypes were summarized in the following categories: tetravalent and at least trivalent. Seropositive was defined as a reciprocal neutralizing titer ≥10. The dengue virus serotypes are DENV-1, DENV-2, DENV-3 and DENV-4. Seropositive for multiple dengue serotypes were summarized in the following categories: tetravalent and

at least trivalent.PPS included all participants from the FAS who have no major protocol violations. Number analysed is the number of participants with data available for analysis at the given timepoint.

End point type	Secondary

End point timeframe:

1 month post first vaccination (Day 30); pre second vaccination (Day 90); 1 and 6 months post second vaccination (Days 120 and 270); annually up to 3 years (Years 1, 2 and 3)

End point values	Tetravalent Dengue Vaccine (TDV) 0.5 mL			
Subject group type	Reporting group			
Number of subjects analysed	195			
Units: percentage of participants				
number (confidence interval 95%)				
Tetravalent, Day 30	90.8 (85.7 to 94.6)			
At Least Trivalent, Day 30	98.4 (95.3 to 99.7)			
Tetravalent, Day 90	83.6 (77.6 to 88.5)			
At Least Trivalent, Day 90	95.4 (91.4 to 97.9)			
Tetravalent, Day 120	99.5 (97.0 to 100.0)			
At Least Trivalent, Day 120	100.0 (98.0 to 100.0)			
Tetravalent, Day 270	93.0 (88.4 to 96.2)			
At Least Trivalent, Day 270	98.4 (95.4 to 99.7)			
Tetravalent, Year 1	87.5 (82.0 to 91.8)			
At Least Trivalent, Year 1	95.3 (91.3 to 97.8)			
Tetravalent, Year 2	86.4 (79.9 to 91.4)			
At Least Trivalent, Year 2	93.5 (88.4 to 96.8)			
Tetravalent, Year 3	76.7 (69.8 to 82.6)			
At Least Trivalent, Year 3	87.2 (81.4 to 91.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Experiencing Unsolicited Adverse Events (AE)

End point title	Percentage of Participants Experiencing Unsolicited Adverse Events (AE)

End point description:

An AE was defined as any untoward medical occurrence in a clinical investigation participant

administered a trial vaccine; it does not necessarily have to have a causal relationship with trial vaccine administration. Safety Set included all enrolled participants who received at least 1 dose of TDV. Number analysed is the number of participants with data available for analysis at the given timepoint.

End point type	Secondary

End point timeframe:

Up to 28 days (day of vaccination + 27 days) after administration of each vaccine dose on Day 1 [Month 0] and Day 90 [Month 3]

End point values	Tetravalent Dengue Vaccine (TDV) 0.5 mL			
Subject group type	Reporting group			
Number of subjects analysed	200			
Units: percentage of participants				
number (not applicable)				
After First Vaccination	26.5			
After Second Vaccination	25.3			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Medically Attended AEs (MAAEs)

End point title	Percentage of Participants With Medically Attended AEs (MAAEs)

End point description:

MAAEs were defined as AEs leading to a medical visit to or by a healthcare professional, including visits to an emergency department, but not fulfilling seriousness criteria. Safety Set included all enrolled participants who received at least 1 dose of TDV.

End point type	Secondary

End point timeframe:

From first vaccination (Day 1) up to 6 months post second vaccination (Day 270)

End point values	Tetravalent Dengue Vaccine (TDV) 0.5 mL			
Subject group type	Reporting group			
Number of subjects analysed	200			
Units: percentage of participants				
number (not applicable)	50.5			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Serious Adverse Events (SAEs)

End point title	Percentage of Participants With Serious Adverse Events (SAEs)

End point description:

A SAE was defined as any untoward medical occurrence or effect that at any dose results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability / incapacity, is a congenital anomaly / birth defect or is medically important due to other reasons than the above mentioned criteria. Safety Set included all enrolled participants who received at least 1 dose of TDV.

End point type	Secondary

End point timeframe:

From first vaccination (Day 1) up to end of study (Approximately 3 years)

End point values	Tetravalent Dengue Vaccine (TDV) 0.5 mL			
Subject group type	Reporting group			
Number of subjects analysed	200			
Units: percentage of participants				
number (not applicable)	5.5			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Virologically Confirmed Dengue

End point title	Percentage of Participants With Virologically Confirmed Dengue

End point description:

Participants with febrile illness defined as fever ≥38°C on any 2 of 3 consecutive days were evaluated for dengue. Virologically confirmed dengue was defined as febrile illness with a positive serotype-specific RT-PCR (i.e. positive dengue detection RT-PCR). Safety Set included all enrolled participants who received at least 1 dose of TDV.

End point type	Secondary

End point timeframe:

From first vaccination (Day 1) up to 6 months post second vaccination (Day 270)

End point values	Tetravalent Dengue Vaccine (TDV) 0.5 mL			
Subject group type	Reporting group			
Number of subjects analysed	200			
Units: percentage of participants				
number (not applicable)	6.0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All-cause mortality and SAEs: From first vaccination(Day 1) up to end of study (Approximately 3 years);Non-SAEs: Up to 28 days (day of vaccination + 27 days) after administration of each vaccine dose on Day 1[Month 0] and Day 90[Month 3]

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	21.0

Reporting groups

Reporting group title	Tetravalent Dengue Vaccine (TDV) 0.5 mL

Reporting group description:

TDV 0.5 mL, subcutaneous (SC) injection, on Day 1 (Month 0) and Day 90 (Month 3).

Serious adverse events	Tetravalent Dengue Vaccine (TDV) 0.5 mL		
Total subjects affected by serious adverse events			
subjects affected / exposed	11 / 200 (5.50%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
Foot fracture			
subjects affected / exposed	1 / 200 (0.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Febrile convulsion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 200 (0.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Social circumstances			
Victim of sexual abuse			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	1 / 200 (0.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Faecaloma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 200 (0.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 200 (0.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Biliary colic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 200 (0.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Asthma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 200 (0.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Cellulitis			
subjects affected / exposed	1 / 200 (0.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia			

subjects affected / exposed	3 / 200 (1.50%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Typhoid fever			
subjects affected / exposed	1 / 200 (0.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urosepsis			
subjects affected / exposed	1 / 200 (0.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Systemic viral infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 200 (0.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dengue fever			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 200 (0.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 200 (0.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	Tetravalent Dengue Vaccine (TDV) 0.5 mL		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	66 / 200 (33.00%)		

Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	29 / 200 (14.50%)		
occurrences (all)	33		
Upper respiratory tract infection			
subjects affected / exposed	20 / 200 (10.00%)		
occurrences (all)	21		
Gastroenteritis			
subjects affected / exposed	12 / 200 (6.00%)		
occurrences (all)	13		
Systemic viral infection			
subjects affected / exposed	9 / 200 (4.50%)		
occurrences (all)	9		
Pneumonia			
subjects affected / exposed	8 / 200 (4.00%)		
occurrences (all)	9		
Conjunctivitis			
subjects affected / exposed	4 / 200 (2.00%)		
occurrences (all)	4		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported