Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

Supplement to: Villar L, Dayan GH, Arredondo-García JL, et al. Efficacy of a tetravalent dengue vaccine in children in Latin America. N Engl J Med. DOI: 10.1056/NEJMoa1411037

Supplementary Appendix
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CYD15 Study Group

Sanofi Pasteur Nicolas Jackson, PhD, Anna Skipetrova, MD, Florence Sellier-Sandrin, BTEC, Jean Lang, MD, Vincent Canouet, MSc, Lyon, France; Linda Urcuyo MD, Guatemala, Guatemala, José Noguera MD, Washington USA; Pedro Garbes, MD, Brazil; (during the study; current affiliation: Takeda vaccines, Brazil), Tom Papa, MD (during the study; currently retired); Brazil: Flávio Henrique Alves de Lima, MD, Amanda Queiroz Soares, Pharmacist, Hospital Clínicas, Universidade Federal de Goiás; Eveline Pipolo Milan, MD, Universidade Federal do Río Grande do Norte; Manoella do Monte Alves, MD, Universidade de Potiguar, Maria Fabiana da Silva Nascimento, Social Worker, Instituto de Biomedicina, Universidade Federal do Ceará, Lilia Maraia Carneiro Camara, MD, Departamento de Patología e Medicina Legal, Universidade Federal do Ceará, Ana Daniela Azoton de Sadovsky, MD, Patricia Marquez Rodrigues, Study Nurse Coordinator, Camila Giuberti, Pharmacist, MSc, Núcleo de Doenças Infecciosas - Universidade Federal do Espirito Santo (UFES), Anamaría Mello M. Paniago, MD, Vanessa Gubert Matos, Pharmacist, MSc, Universidade Federal de Mato Grosso do Sul (UFMS); Colombia: Juliana Quintero, MD, Centro de Estudios de Investigación en Salud (CEIS), Fundación Santa Fe de Bogotá; Jaime Carrillo, MD, Nueva Clínica San Sebastian; Víctor Osorio, MD, Hospital Pío X; Héctor Pachón, MD, Hospital San Vicente; Reynaldo López, MD, Hospital La Misericordia, Erwin Pardo, MD, Centro de Salud Fundadores; Victor Sierra, MD, Centro de Atención en Investigación Médica CAIMED Yopal, Edith Rodríguez, MD, CAIMED Aguazul, Héctor Velasquez, MD, CAIMED Acacías; Libia M Hernández M, MD, Centro de Atención y Diagnóstico de Enfermedades Infecciosas (CDI); Elsa Rojas, MD, Universidad Industrial de Santander; Jurg Niederbacher, MD, Universidad Industrial de Santander; Honduras: Elham B Mandegari F, MD, Myrna L. Vásquez A, MSc, Amalia I Sabillón C, BSc, Organización para el Desarrollo y la Investigación Salud en Honduras (ODISH); Mexico: Leonor Cristina Benist Damian, MD, Servicios de Salud de Tamaulipas; Ismael Martin Valencia Camara, MD, María Concepcion Morales Martin, MD, Servicios de Salud de Yucatán; José Maria Remes Troche, MD, Instituto de Investigaciones Médico Biológicas, Universidad Veracruzana; Puerto Rico: Jaime Deseda Tous, MD, Caribbean Travel Medicine Clinic; Jeffrey Quiñones, MD, Clinical Research Puerto Rico; José Miguel Fors, MD, Clinical Research Puerto Rico.

Contributions

The manuscript was drafted by Margaret Haugh (MediCom Consult) funded by Sanofi Pasteur.

Conflicts of interest

LV declared his institute had received funding from Sanofi Pasteur to support work in CYD15 and he has received honoraria for lecturing activities; DMR, CD, HR declared their institutes had received funding from Sanofi Pasteur to support work in CYD15; GC declared his institute had received funding from Sanofi Pasteur to support work in CYD15, he has received honoraria from his institute for work as principal investigator/coordinator for CYD15 and he has been invited by Sanofi Pasteur to two congresses and one to their headquarters in Lyon, France to discuss issues related to CYD15 and another trial with the same vaccine (CYD35); LCR has received research grants from Sanofi Pasteur; ; JLAG, RV, MSC, JOMR, RD and KL have nothing to disclose; GHD, ER, MCS,BZ, EL, MB, NT, MS and FN are employed by Sanofi Pasteur and hold shares/stock options; MCMM is employed by Sanofi Pasteur.

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In addition they thank Margaret Haugh (MediCom Consult) for medical writing and editorial assistance and Gee Marsh (Sanofi Pasteur) for coordination and editorial assistance for the preparation of this manuscript.

Additional Methods Description

Identification and enrollment of participants

Different strategies for identification of participants were implemented at the sites. Potential participants could be identified from among the patients that attended the clinics (pre-screening lists), or by referral from pediatricians in the area. An information campaign about the disease and the trial was done in the local health centers, schools and community centers, and potential participants and their parents were invited to go to the trial site for specific trial information. Before implementation, representatives of the Ministries of Health and Education and Community Leaders (e.g. Youth Associations) of the areas involved were informed about the activities. Parents could phone the trial site for an appointment or they went directly to the site to initiate the enrollment process. Materials for these activities (posters, flyers with address and telephone numbers of the sites, and power point presentations) were approved by the Sponsor and Ethics Committees before use.

Study Population: Temporary and Definitive Exclusion Criteria

Temporary Exclusion Criteria

Randomization of participants who had received another vaccine was delayed until 4 weeks after vaccination and those with acute febrile disease until resolution.

Definitive Exclusion Criteria

An individual fulfilling any of the following criteria was excluded definitively:

- women who were pregnant, lactating, or of childbearing potential (to be considered of non-childbearing potential, a female had to be pre-menarche, surgically sterile, or using an effective method of contraception or agreed to abstain from intercourse at least 4 weeks prior to the first vaccination until at least 4 weeks after the last vaccination) [a]
- participation in another clinical trial investigating a vaccine, drug, medical device, or a medical procedure in the 4 weeks preceding the first trial vaccination
- planned to participate in another clinical trial during the current trial period
- self-reported or suspected congenital or acquired immunodeficiency; or receipt of immunosuppressive therapy such as anti-cancer chemotherapy or radiation therapy within the preceding 6 months; or long-term systemic corticosteroids therapy (prednisone or equivalent for more than 2 consecutive weeks within the previous 3 months)
- self-reported seropositivity for human immunodeficiency virus (HIV) infection
- self-reported systemic hypersensitivity to any of the vaccine components, or history of a life-threatening reaction to the vaccine used in the trial or to a vaccine containing any of the same substances
- chronic illness that, in the opinion of the investigator, was at a stage where it could interfere with trial conduct or completion [b]
- receipt of blood or blood-derived products in the previous 3 months, which could interfere with assessment of the immune response
- planned receipt of any vaccine in the 4 weeks following any trial vaccination
- deprived of freedom by administrative or court order, or in an emergency setting, or hospitalized involuntarily
- current alcohol abuse or drug addiction that could interfere with the ability to comply with trial procedures
- identified as a site employee of the investigator or study center, with direct involvement in the proposed study or other studies under the direction of that investigator or study center, as well as a family member (i.e., immediate, husband, wife and their children, adopted or natural) of the site employees or the investigator

[a] For pre-menarche females, the young female subjects self-declared that they have not yet started menstruation. If a female subject reached menarche during the study, then she was considered as a woman of childbearing potential from that time forward.
[b] Chronic illnesses could include, but were not limited to, cardiac disorders, renal disorders, auto-immune disorders, or diabetes.

Randomization and Blinding
We used an observer-blind procedure because the presentations of vaccine and placebo were different. During the active surveillance phase, investigators, participants, their parents/guardians and the sponsor were all unaware of which product had been given. The unblinded trial staff, who were responsible for the preparation and administration of the injections, were not involved in the participants' follow-up. The sponsor was unblinded at the end of this phase to perform the analyses. The investigators, participants and the parents/guardians will remain blinded until the ongoing hospital phase of the trial has been terminated (Figure S1).

Laboratory Analysis for Blood Samples Taken for Acute Febrile Illness
Two blood samples were taken from all participants with acute febrile illness; one within five days of fever onset (acute sample), and the other between 7 and 14 days later (convalescent sample). The acute sample was tested for dengue non-structural protein (NS) 1 ELISA antigen (Ag) (PlateliaTM Biorad Laboratories, Marnes-La-Coquette, France); dengue screen (DS) reverse transcriptase-polymerase chain reaction (qRT-PCR); and Simplexa™ Dengue RT-PCR (for samples positive for Dengue NS1 or DS qRT-PCR).[1] The episode was classified as virologically confirmed dengue if any of these tests were positive.
Both the acute and convalescent samples were tested for dengue IgM and IgG (not presented). The dengue-specific assays were managed by the sponsor's Global Clinical Immunology (GCI) laboratories (Swiftwater, PA, USA) under masked conditions with RT-PCR performed at GCI and ELISA assays at Focus Diagnostics Inc. (Cypress, California, USA). Haematocrit; platelet count; aspartate aminotransferase (AST); and alanine aminotransferase (ALT) were also determined using this sample and the convalescent sample in local laboratories available at each study site.

Additional Biological Sampling for Safety Assessment
To rule out viscerotropic or neurotropic disease, the acute blood sample, cerebrospinal fluid (when available), and biological fluids/tissues (when relevant) underwent qRT-PCR testing for either vaccinal or wild-type yellow fever viruses.

Independent Data Monitoring Committee
An Independent Data Monitoring Committee (IDMC) was involved in the regular review of safety data and confirmed dengue cases, including assessment of severity of virologically confirmed dengue (VCD) cases to ensure consistency in classification (see below).

Definition of Severe Virologically-Confirmed Dengue and Dengue Hemorrhagic Fever
The IDMC classified dengue cases as severe using the following criteria:

- Virologically-confirmed dengue fever, i.e. temperature ≥38°C on ≥2 consecutive days and virological confirmation, and at least one of the following:
- Platelet count $\leq 100 \times 100^9$/L *and* bleeding (tourniquet, petechiae or any bleeding) *and* plasma leakage (effusion on chest x-ray or clinically apparent ascites including imaging procedures or hematocrit >20% above baseline recovery level or standard for age if only one reading).

- Shock (pulse pressure ≤ 20 mmHg in a child or adolescent, or hypotension [≤ 90 mmHg] with tachycardia, weak pulse and poor perfusion).
- Bleeding requiring blood transfusion
- Encephalopathy i.e., unconsciousness or poor conscious state (Glasgow Coma Scale (GCS) score) or convulsions not attributable to simple febrile convulsion or focal neurological signs.
- Liver impairment (AST >1000 U/L or prothrombin time, international normalized ratio >1.5)
- Impaired kidney function (serum creatinine ≥1.5 mg/dL)
- Myocarditis, pericarditis or heart failure (clinical heart failure) supported by chest X ray, echocardiography, electrocardiogram or cardiac enzymes where they were available

Every effort was made to identify and document any existing chronic co-morbidity, such as uncontrolled epilepsy, chronic liver disease, of existing cardiac disease or acute co-morbidity, such as acute hepatitis.
Severity of the dengue episodes was also assessed using the following 1997 WHO criteria for defining dengue hemorrhagic fever (DHF), since clinicians are more familiar with this definition.[2] This assessment was done by the Biostatistics Department at Sanofi Pasteur using a program to analyze standardized data collected in the trial database.

Regular review of safety data
On a regular basis throughout the trial, the IDMC reviewed serious adverse events (SAEs) and all dengue cases (including severe dengue) for signal detection purposes. For each review an independent external statistician, not a member of the IDMC and who was not involved in any other aspect of the study, conducted unblinded analyses of the incidence of dengue, severe dengue and SAEs in vaccine and control arms. These analyses were presented to the IDMC in a semi- blinded manner by showing the incidence of SAEs in three equally-sized groups, with two groups representing data from vaccine-recipients, and one representing data from placebo-recipients. The IDMC remained blind as to which groups received vaccine. For each SAE category the IDMC were informed if the incidence of the SAE in the vaccine group was significantly higher than in the control group. Data analyses were also performed to alert the IDMC to any excess of dengue fever or severe dengue among vaccinees. In case of higher incidence of dengue fever or severe dengue, the IDMC would be presented with unblinded analyses.

At the end of the trial in August 2014, when the treatment codes were broken, it became apparent that the data tables provided throughout the trial to the IDMC by the external independent statistician contained errors in treatment assignment, which in many cases did not correspond to the actual treatment received. Therefore the regular systematic reviews conducted based on treatment assignment were invalid. This occurred due to an error in the read-out of a wrong variable in the randomization list by the external independent statistician. The Sponsor verified and confirmed that the subjects had received the treatment as intended. The IDMC re-reviewed the data on SAEs and cases of dengue fever and severe dengue, based on the correct randomization assignment, and concluded there was no material difference in risk of any specific serious adverse events between vaccinated and control groups and no evidence of an increased risk of dengue fever or severe dengue among partially or fully vaccinated trial participants. The IDMC concurred with the sponsor's conclusion that, though this error impacted on the interim safety analyses conducted by the IDMC, it had no impact on the integrity of the data that had been collected in the trial. The error did not impact on the sponsor safety review and reporting to Regulatory Authorities during the trial. This error was

isolated to the phase III efficacy trial in Latin America presented here and had no impact on the ongoing review of all other CYD dengue trials under the IDMC charter, or on previously reported trials.

Description of Trial Analysis Populations

Per-Protocol Analysis Population

The per-protocol analysis population included all participants who had received all three doses as per-protocol, case counting started 28-days post-dose 3, and had none of the following protocol deviations:

- Did not meet at least one of the protocol-specified inclusion/exclusion criteria and did not respect the definite contraindications
- Did not receive the correct number of injections
- Received at least one dose of a product other than the one that he/she was randomized to receive
- Administration of vaccine was not done as per-protocol (site and route of administration)
- Did not receive vaccine in the time window defined in the table of study procedures
- Received a protocol-restricted therapy or vaccine from Category 2
- Emergency unblinding performed by the investigator
- Did not have at least one contact point after 28 days post-Dose 3 and before the end of the active surveillance period
- Severe non-compliance to GCPs
- Severe non-compliance to surveillance system

Participants who met the last two criteria were completely excluded and the other participants remained in the population until they met any of the above criteria.

Modified Per-Protocol Population for Efficacy

The modified per-protocol population for efficacy (mPPPE) included all participants who had received all three injections, regardless of any protocol deviations, except those who had severe non-compliance with GCPs. Case counting started after 28 days post-dose 3.

Intention-to-Treat Population for Efficacy

The intention-to-treat population (ITT) for efficacy included all participants who had received at least one injection, and did not have severe non-compliance to GCPs. Case counting started on day 0.

Intention-to-Treat Population for Immunogenicity

The ITT population for immunogenicity included all participants in the subset who had received at least one injection, who did not have severe non-compliance to GCP and who had a blood sample drawn and a result available after the injection.

Safety Analysis Population

The safety analysis population was defined for each dose as the subset of participants who received the dose and who did not have severe non-compliance to GCP: participants were analyzed according to the treatment received at this dose. For the safety analysis at any dose, participants were analyzed according to the treatment received at the first dose.

Roles and Responsibilities

The sponsor of the study, Sanofi Pasteur, had a role in the study design, sample testing, data analysis, data interpretation, and writing of the report. The investigators were responsible for data collection. GHD, ER, MCMM, MCS, BZ, EL, MB, NT, MS, FN (all employed by Sanofi Pasteur) had complete access to the trial data. These authors all vouch for the data and the analyses. The other authors had access to the statistical analyses but not participant-level data because the observer-blind hospital phase is still ongoing. All authors will have full access to

all data at the end of the study. There are no specific agreements concerning the confidentiality of the data between Sanofi Pasteur and the authors or their institutions. Margaret Haugh (MediCom Consult) funded by Sanofi Pasteur wrote the first draft of the paper; all authors provided critically input for the successive drafts and validated the submitted version. GHD had primary responsibility for the decision to submit for publication.

Description of Tables and Figures

The tables and figures in this supplementary appendix summarize additional results from the CYD15 clinical trial of the CYD-TVD vaccine in children and adolescents aged 9 to 16 years in five Latin American countries.

Figure S1 illustrates the trial design and shows the active phase (terminated and reported here) and the hospital phase, which is ongoing. The periods during which VCD cases were included in the per-protocol and intention-to-treat vaccine efficacy analyses are shown.

Figure S2 summarizes the flow of the participants through the trial.

Table S1 summarizes the country-specific baseline dengue seropositivity rate, VCD incidence density per 100 person-years in the control group, dengue serotypes identified in VCD cases in the control group and vaccine efficacy. The results show there were differences between the countries in terms of these variables.

Table S2 summarizes the results from the exploratory ITT analyses of vaccine efficacy, with case counting starting on day 0, by age strata (9-11 years and 12-16 years), and in the subset and by baseline dengue serostatus. Results for vaccine efficacy between doses is also summarized, with case counting starting 28 days after the injection. In the subset, vaccine efficacy was higher than in the overall ITT population (64.7% [95% CI: 58.7–69.8]) and it was higher in participants who were seropositive at baseline than in those who were seronegative. Vaccine efficacy was seen in the between-dose periods.

Table S3 summarizes the clinical signs and symptoms of all virologically-confirmed dengue episodes due to any serotype in the intention-to-treat population.

Table S4 summarizes all serious adverse events (SAEs) occurring during the active phase by system organ class in the safety analysis set. Only four SAEs were considered as related by the investigators.

Table S5 summarizes all unsolicited adverse reactions occurring within 28 days after each injection in the subset by system organ class and preferred term and grade.

Table S6 summarizes all unsolicited adverse events occurring within 28 days after each injection in the subset by system organ class and preferred term and grade.

Table S7 summarizes the geometric mean $PRNT_{50}$ dengue antibody titers (GMTs) against the vaccine's parental dengue viruses at baseline and 28 days after the second and third dose in the intention-to-treat population for immunogenicity. For the vaccine group, the GMTs are provided by baseline serostatus.

Figure S1: Summary of trial design

Trial design, illustrating the active and hospital trial phases, the three-dose vaccination schedule, and the periods during which cases were included in the per-protocol and intention-to-treat vaccine efficacy analyses.

Reprinted with permission from Elsevier (The Lancet, 2014, pii: S0140-6736(14)61060-6).[3]

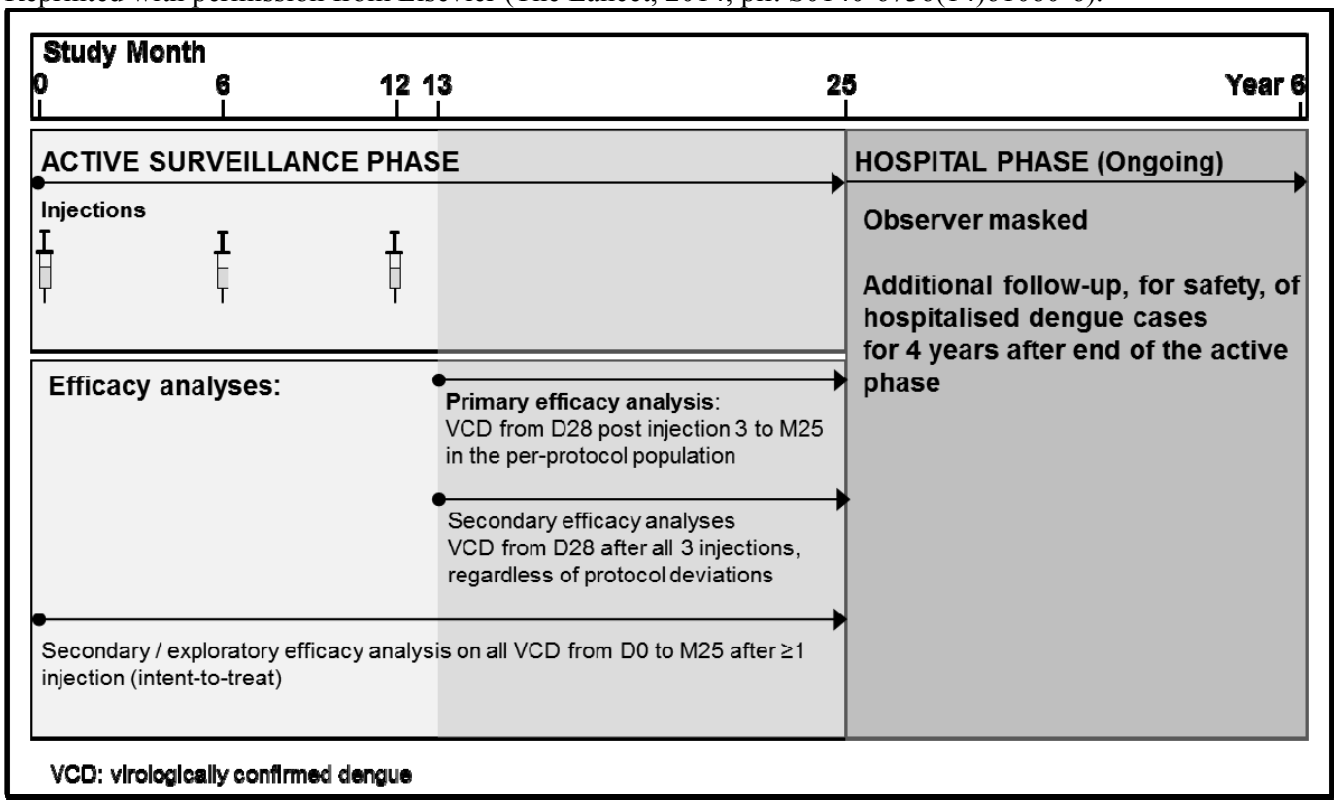

Figure S2: Trial profile
SAE: serious adverse event; AE: adverse event; GCPs: good clinical practices

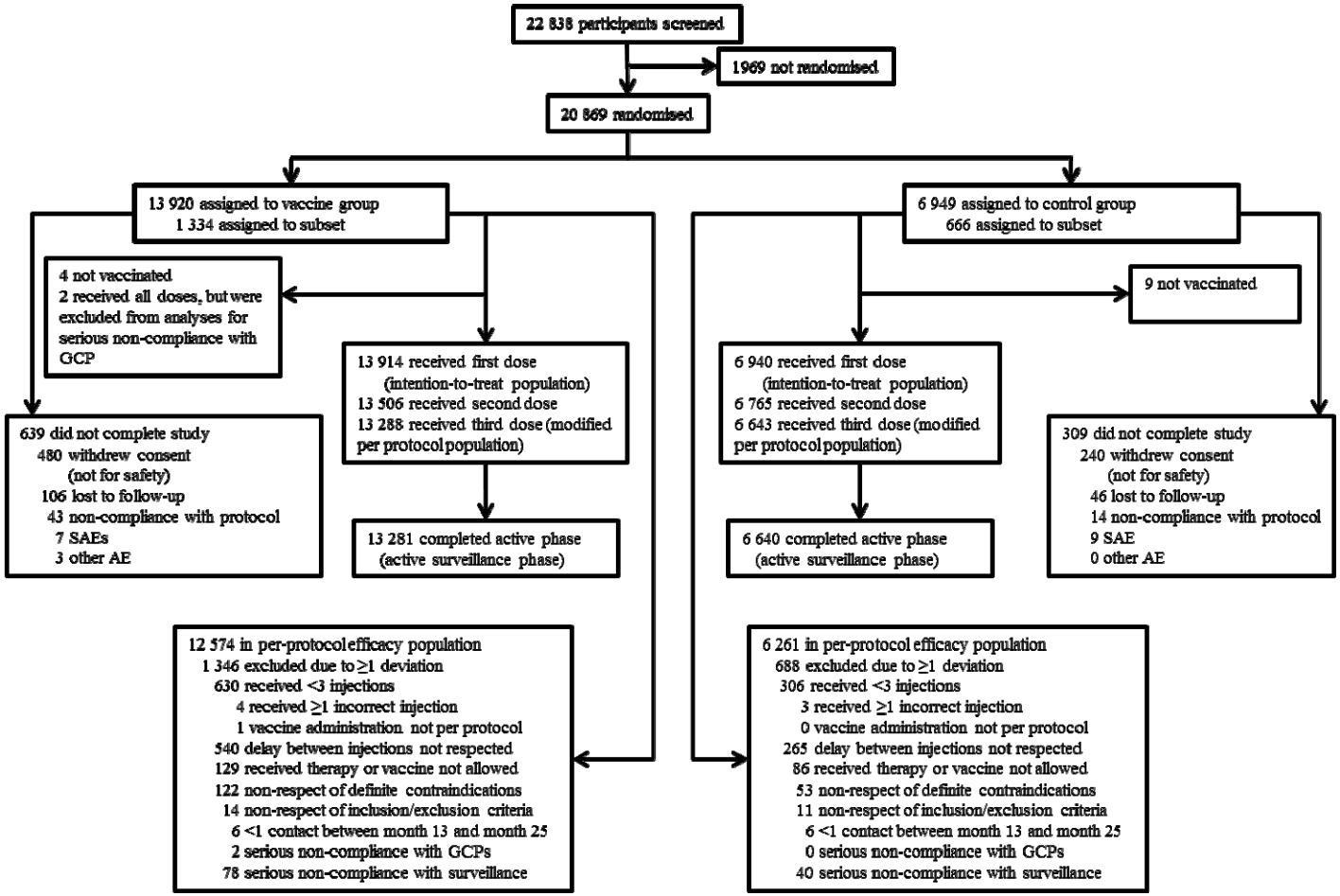

Table S1: Country-specific baseline dengue seropositivity rate, incidence density and infecting serotype of virologically-confirmed dengue in the control group, and vaccine efficacy

Country	N randomized to receive vaccine (V) or placebo control (C)				Baseline dengue seropositivity rate[1]	Incidence density (ID) and infecting serotype of virologically-confirmed dengue in the control group (ITT)[2]							Vaccine Efficacy, (ITT)[3]	
	Overall		Subset											
	V	C	V	C	%	ID	(95%CI)	ST1	ST2	ST3	ST4	ND	%	(95% CI)
All	13920	6949	1334	666	79.4	2.9	(2.6–3.2)	109	84	106	83	14	64.7	(58.7–69.8)
Brazil	2370	1178	202	98	73.5	3.7	(2.9–4.6)	9	0	0	72	0	77.5	(66.5–85.1)
Colombia	6497	3246	613	308	92.2	2.7	(2.3–3.1)	58	33	67	9	2	67.5	(58.3–74.7)
Honduras	1866	933	200	100	85.7	4.0	(3.2–5.0)	6	20	39	0	9	71.1	(57.0–80.7)
Mexico	2312	1152	219	108	53.1	2.5	(1.9–3.2)	25	30	0	1	2	31.3	(1.3–51.9)
Puerto Rico	875	440	100	52	56.2	1.6	(0.8–2.6)	11	1	0	1	1	57.6	(-2.5–82.8)

[1]Anti-dengue seropositivity rate defined as the percentage of participants with a plaque-reduction neutralization test ($PRNT_{50}$) titer of 10 or higher against at least one serotype. [2]Incidence density (ID): number of cases per 100 person-years at risk in the intention-to-treat population; dengue virus serotype (ST) 1–4 determined by Simplexa RT-PCR; ND: not determined in this assay. [3]Intention-to-treat efficacy population included all participants who received at least one injection, and participants were analyzed in the group to which they were randomized, regardless of per-protocol criteria; VCD occurring from D0.

Table S2: Exploratory analyses of vaccine efficacy by age and by baseline dengue serostatus, and between doses

	Vaccine group			Control group			
	Cases (n)	Person-years at risk	Incidence density (95% CI)	Cases (n)	Person-years at risk	Incidence density (95% CI)	Vaccine efficacy % (95% CI)
Age strata							
9 to 11 years	150	12,172	1.2 (1.0–1.4)	192	5,967	3.2 (2.8–3.7)	61.7 (52.3–69.3)
12 to 16 years	127	14,711	0.9 (0.7–1.0)	193	7,237	2.7 (2.3–3.1)	67.6 (59.3–74.3)
Dengue serostatus at baseline							
Seropositive[1]	8	2,116	0.4 (0.2–0.7)	23	994	2.3 (1.5–3.5)	83.7 (62.2–93.7)
Seronegative	9	500	1.8 (0.8–3.4)	9	284	3.2 (1.5–5.9)	43.2 (-61.5–80.0)
Between dose period							
Dose 1 to 2	30	5,554	0.5 (0.4–0.8)	58	2,763	2.1 (1.6–2.7)	74.3 (59.4–84.0)
Dose 2 to 3	42	5,621	0.7 (0.5–1.0)	59	2,806	2.1 (1.6–2.7)	64.5 (46.3–76.7)

A case was defined as a first episode of virologically-confirmed dengue (VCD) by either dengue non-structural protein (NS) 1 antigen ELISA, dengue screen RT-PCR, or a serotype-specific RT-PCR·1 Participants with a plaque-reduction neutralization test (PRNT50) titer of 10 or higher against at least one serotype were considered seropositive. The person-years at risk was the cumulative time (in years) until the participant was diagnosed with VCD or until the end of the active period, whichever came first. The person-years at risk presented in the tables is the sum of individual units of time for which the participants contributed to the analyses. Incidence density (cases per 100 person-years at risk) was calculated as the number of cases divided by the cumulative person-years at risk. For the between dose vaccine efficacy, case counting started 28 days after dose 1 for the period between dose 1 and 2 and 28 days after dose 2 for the period between dose 2 and 3.

Table S3: Summary of clinical signs and symptoms of all virologically-confirmed dengue (VCD) episodes due to any serotype in the intention-to-treat population for efficacy

	Vaccine group	Control group	Relative risk (95% CI)
Number VCD episodes, N	281	389	
Duration of clinical symptoms, days			
Median (min–max)	6.0 (2.0–28.0)	6.0 (2.0–24.0)	
Duration of fever, days			
Median (min–max)	3.0 (2.0–17.0)	3.0 (2.0–17.0)	
Hospitalized VCD episodes			
Any serotype,	17/281 (6.0)	43/389 (11.1)	
Serotype 1, n	7	13	
Serotype 2, n	6	15	
Serotype 3, n	3	9	
Serotype 4, n	1	6	
Unserotyped, n	1	0	
Median duration of hospitalization, days (min–max)	6.0 (2.0–10.0)	4.0 (1.0–11.0)	
Any hemorrhage,	7/281 (2.5)	29/389 (7.5)	0.33 (0.12–0.78)
Any visceral manifestation	0/281 (0.0)	10/389 (2.6)	0.00 (0.00–0.62)
Plasma leakage			
Any	11/281 (3.9)	26/389 (6.7)	0.59 (0.26–1.23)
With clinical signs	0/281 (0.0)	9/389 (2.3)	0.00 (0.00–0.70)
Hematocrit increase ≥20%	11/281 (3.9)	22/389 (5.7)	0.69 (0.30–1.49)
Thrombocytopenia,			
Platelet count $\leq 50 \times 10^9$/L	10/281 (3.6)	22/389 (5.7)	0.63 (0.27–1.38)
Platelet count $\leq 100 \times 10^9$/L	31/281 (11.0)	61/389 (15.7)	0.70 (0.44–1.10)
Shock	0/281 (0.0)	0/389 (0.0)	–

Numbers are n/N (%), unless indicated otherwise

Table S4: All and related serious adverse events during the active phase, by system organ class - Safety Analysis Set

	Vaccine Group (N=13915)				Control Group (N=6939)			
	All SAEs		SAEs within 28 days after any injection		All SAEs		SAEs within 28 days after any injection	
Subjects experiencing at least one:	n (%) [95% CI]	n SAEs	n (%) [95% CI]	n SAEs	n (%) [95% CI]	n SAEs	n (%) [95% CI]	n SAEs
SAE	565 (4.1) [3.7; 4.4]	630	81 (0.6) [0.5; 0.7]	84	308 (4.4) [4.0; 4.9]	35	40 (0.6) [0.4; 0.8]	42
Infections and infestations	293 (2.1) [1.9; 2.4]	306	37 (0.3) [0.2; 0.4]	37	188 (2.7) [2.3; 3.1]	20	16 (0.2) [0.1; 0.4]	17
Injury, poisoning and procedural complications	102 (0.7) [0.6; 0.9]	103	14 (0.1) [0.1; 0.2]	14	35 (0.5) [0.4; 0.7]	35	4 (<0.1) [0.0; 0.1]	4
Pregnancy, puerperium and perinatal conditions	38 (0.3) [0.2; 0.4]	41	1 (<0.0) [0.0; 0.0]	1	17 (0.2) [0.1; 0.4]	21	0 (0.0) [0.0; 0.1]	0
Gastrointestinal disorders	32 (0.2) [0.2; 0.3]	33	7 (<0.1) [0.0; 0.1]	7	14 (0.2) [0.1; 0.3]	14	2 (<0.1) [0.0; 0.1]	2
Nervous system disorders	26* (0.2) [0.1; 0.3]	37	7* (<0.1) [0.0; 0.1]	8	14 (0.2) [0.1; 0.3]	14	4 (<0.1) [0.0; 0.1]	4
Psychiatric disorders	26 (0.2) [0.1; 0.3]	27	3 (<0.1) [0.0; 0.1]	3	12 (0.2) [0.1; 0.3]	15	3 (<0.1) [0.0; 0.1]	3
Respiratory, thoracic and mediastinal disorders	18* (0.1) [0.1; 0.2]	21	4* (<0.1) [0.0; 0.1]	4	15 (0.2) [0.1; 0.4]	17	4 (<0.1) [0.0; 0.1]	4
Reproductive system and breast disorders	12 (<0.1) [0.0; 0.2]	12	1 (<0.1) [0.0; 0.0]	1	4 (<0.1) [0.0; 0.1]	4	0 (0.0) [0.0; 0.1]	0
Hepatobiliary disorders	10 (<0.1) [0.0; 0.1]	10	1 (<0.1) [0.0; 0.0]	1	5 (<0.1) [0.0; 0.2]	7	0 (0.0) [0.0; 0.1]	0
Musculoskeletal and connective tissue disorders	7 (<0.1) [0.0; 0.1]	7	1 (<0.1) [0.0; 0.0]	1	3 (<0.1) [0.0; 0.1]	3	1 (<0.1) [0.0; 0.1]	1
General disorders and administration site conditions	6 (<0.1) [0.0; 0.1]	6	1 (<0.1) [0.0; 0.0]	1	2 (<0.1) [0.0; 0.1]	2	1 (<0.1) [0.0; 0.1]	1
Renal and urinary disorders	6 (<0.1) [0.0; 0.1]	6	0 (0.0) [0.0; 0.0]	0	5 (<0.1) [0.0; 0.2]	7	1 (<0.1) [0.0; 0.1]	1
Skin and subcutaneous tissue disorders	6* (<0.1) [0.0; 0.1]	6	4* (<0.1) [0.0; 0.1]	4	1 (<0.1) [0.0; 0.1]	1	0 (0.0) [0.0; 0.1]	0
Blood and lymphatic system disorders	4 (<0.1) [0.0; 0.1]	4	1 (<0.1) [0.0; 0.0]	1	4 (<0.1) [0.0; 0.1]	4	1 (<0.1) [0.0; 0.1]	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (<0.1) [0.0; 0.1]	3	1 (<0.1) [0.0; 0.0]	1	2 (<0.1) [0.0; 0.1]	2	1 (<0.1) [0.0; 0.1]	1
Immune system disorders	2 (<0.1) [0.0; 0.1]	2	0 (0.0) [0.0; 0.0]	0	1 (<0.1) [0.0; 0.1]	1	1 (<0.1) [0.0; 0.1]	1
Metabolism and nutrition disorders	2 (<0.1) [0.0; 0.1]	2	0 (0.0) [0.0; 0.0]	0	2 (<0.1) [0.0; 0.1]	2	1 (<0.1) [0.0; 0.1]	1
Surgical and medical procedures	2 (<0.1) [0.0; 0.1]	2	0 (0.0) [0.0; 0.0]		1 (<0.1) [0.0; 0.1]	1	0 (0.0) [0.0; 0.0]	
Ear and labyrinth disorders	1 (<0.1) [0.0; 0.1]	1	0 (0.0) [0.0; 0.0]		0 (0.0) [0.0; 0.1]	0	0 (0.0) [0.0; 0.0]	
Social circumstances	1 (<0.1) [0.0; 0.1]	1	0 (0.0) [0.0; 0.0]		0 (0.0) [0.0; 0.1]	0	0 (0.0) [0.0; 0.0]	
Congenital, familial and genetic disorders	0 (0.0) [0.0; 0.0]	0	0 (0.0) [0.0; 0.0]		2 (<0.1) [0.0; 0.1]	2	0 (0.0) [0.0; 0.0]	
Eye disorders	0 (0.0) [0.0; 0.0]	0	0 (0.0) [0.0; 0.0]	0	1* (<0.1) [0.0; 0.1]	1	1* (<0.1) [0.0; 0.1]	1

n: number of subjects experiencing the endpoint listed in the first column. *Including one related SAE (total: 3 in vaccine group; 1 in control group) Related: relationship reported by investigator as related.

Table S5: Reactogenicity after each injection, by maximum grade reported

Reactogenicity after each injection, by maximum grade[1] reported. Data are proportion of participants reporting solicited injection site reactions within 7 days after injection, and solicited system reactions within 14 days after injection.

		Vaccine Group (N=1333)						Control Group (N=664)					
		1st injection		2nd injection		3rd injection		1st injection		2nd injection		3rd injection	
Injection site reactions within 7 days		%	95% CI	%	95% CI	%	95% CI	%	95% CI	%	95% CI	%	95% CI
Pain	Any intensity grade	32.4	(29.9; 35.0)	25.6	(23.2; 28.1)	22.5	(20.3; 24.9)	26.3	(23.0; 29.9)	16.4	(13.6; 19.5)	16.5	(13.7; 19.6)
	Grade 1	26.8	(24.4; 29.2)	21.7	(19.5; 24.0)	18.3	(16.2; 20.5)	21.9	(18.8; 25.3)	13.6	(11.1; 16.5)	14.0	(11.4; 16.9)
	Grade 2	4.8	(3.7; 6.1)	3.4	(2.5; 4.5)	3.4	(2.4; 4.5)	3.5	(2.2; 5.2)	2.8	(1.7; 4.4)	2.2	(1.2; 3.7)
	Grade 3	0.8	(0.4; 1.5)	0.5	(0.2; 1.1)	0.9	(0.4; 1.5)	0.9	(0.3; 2.0)	0.0	(0.0; 0.6)	0.3	(0.0; 1.1)
Erythema	Any intensity grade	4.1	(3.1; 5.4)	1.9	(1.3; 2.8)	1.5	(0.9; 2.3)	4.7	(3.2; 6.6)	1.7	(0.9; 3.1)	1.6	(0.8; 2.9)
	Grade 1	3.6	(2.7; 4.8)	1.7	(1.1; 2.6)	1.4	(0.8; 2.2)	4.6	(3.1; 6.5)	1.7	(0.9; 3.1)	1.4	(0.7; 2.7)
	Grade 2	0.5	(0.2; 1.1)	0.2	(0.0; 0.6)	<0.1	(0.0; 0.4)	0.0	(0.0; 0.6)	0.0	(0.0; 0.6)	0.2	(0.0; 0.9)
	Grade 3	0.0	(0.0; 0.3)	<0.1	(0.0; 0.4)	0.0	(0.0; 0.3)	0.2	(0.0; 0.8)	0.0	(0.0; 0.6)	0.0	(0.0; 0.6)
Swelling	Any intensity grade	3.5	(2.6; 4.7)	1.9	(1.3; 2.8)	1.6	(1.0; 2.4)	2.7	(1.6; 4.3)	0.9	(0.3; 2.0)	1.3	(0.5; 2.5)
	Grade 1	2.9	(2.0; 3.9)	1.9	(1.2; 2.7)	1.6	(1.0; 2.4)	2.4	(1.4; 3.9)	0.9	(0.3; 2.0)	1.3	(0.5; 2.5)
	Grade 2	0.7	(0.3; 1.3)	<0.1	(0.0; 0.4)	0.0	(0.0; 0.3)	0.2	(0.0; 0.8)	0.0	(0.0; 0.6)	0.0	(0.0; 0.6)
	Grade 3	0.0	(0.0; 0.3)	0.0	(0.0; 0.3)	0.0	(0.0; 0.3)	0.2	(0.0; 0.8)	0.0	(0.0; 0.6)	0.0	(0.0; 0.6)
Systemic reactions within 14 days													
Fever	Any intensity grade	6.8	(5.5; 8.3)	5.9	(4.6; 7.3)	7.3	(5.9; 8.9)	6.6	(4.8; 8.8)	7.1	(5.1; 9.4)	8.7	(6.6; 11.3)
	Grade 1	3.2	(2.3; 4.3)	2.9	(2.0; 3.9)	3.1	(2.2; 4.3)	3.8	(2.4; 5.6)	4.5	(3.0; 6.5)	5.0	(3.4; 7.1)
	Grade 2	2.0	(1.3; 2.9)	2.2	(1.5; 3.2)	3.1	(2.2; 4.3)	1.7	(0.9; 3.1)	1.3	(0.6; 2.6)	2.8	(1.7; 4.5)
	Grade 3	1.7	(1.0; 2.5)	0.8	(0.4; 1.5)	1.1	(0.6; 1.8)	1.1	(0.4; 2.3)	1.2	(0.5; 2.4)	0.8	(0.3; 1.9)
Headache	Any intensity grade	39.9	(37.2; 42.6)	29.8	(27.3; 32.3)	29.6	(27.1; 32.2)	41.6	(37.8; 45.4)	28.5	(25.0; 32.2)	25.0	(21.7; 28.6)
	Grade 1	24.8	(22.5; 27.3)	19.0	(16.9; 21.2)	18.2	(16.2; 20.5)	25.6	(22.3; 29.1)	18.6	(15.7; 21.9)	15.4	(12.6; 18.4)
	Grade 2	10.0	(8.4; 11.7)	8.7	(7.2; 10.4)	8.8	(7.3; 10.5)	11.9	(9.5; 14.6)	7.5	(5.6; 9.8)	7.8	(5.8; 10.1)
	Grade 3	5.1	(3.9; 6.4)	2.1	(1.4; 3.0)	2.6	(1.8; 3.6)	4.1	(2.7; 5.9)	2.3	(1.3; 3.8)	1.9	(1.0; 3.3)
Malaise	Any intensity grade	24.5	(22.2; 26.9)	20.8	(18.6; 23.1)	19.3	(17.1; 21.5)	25.9	(22.6; 29.4)	16.6	(13.8; 19.7)	15.2	(12.5; 18.3)
	Grade 1	15.9	(13.9; 18.0)	13.9	(12.1; 15.9)	12.5	(10.8; 14.5)	17.5	(14.7; 20.6)	10.2	(7.9; 12.8)	10.3	(8.0; 12.9)
	Grade 2	6.2	(5.0; 7.6)	5.5	(4.4; 6.9)	5.3	(4.2; 6.7)	6.1	(4.4; 8.2)	5.2	(3.6; 7.2)	3.8	(2.5; 5.6)
	Grade 3	2.4	(1.7; 3.4)	1.3	(0.8; 2.1)	1.4	(0.8; 2.2)	2.3	(1.3; 3.7)	1.3	(0.5; 2.5)	1.1	(0.4; 2.3)
Myalgia	Any intensity grade	29.2	(26.7; 31.7)	21.0	(18.8; 23.4)	20.0	(17.8; 22.3)	27.4	(24.0; 31.0)	15.8	(13.1; 18.9)	18.4	(15.4; 21.6)
	Grade 1	18.4	(16.3; 20.6)	14.7	(12.8; 16.8)	13.2	(11.4; 15.2)	18.3	(15.4; 21.4)	9.2	(7.1; 11.7)	12.2	(9.8; 15.0)
	Grade 2	8.6	(7.2; 10.3)	4.7	(3.6; 6.0)	5.2	(4.1; 6.6)	7.6	(5.7; 9.9)	5.8	(4.1; 7.9)	5.4	(3.8; 7.4)

	Grade 3	2.2	(1.5; 3.1)	1.6	(1.0; 2.5)	1.5	(0.9; 2.3)	1.5	(0.7; 2.8)	0.8	(0.3; 1.8)	0.8	(0.3; 1.8)
Asthenia	Any intensity grade	24.6	(22.3; 27.1)	17.8	(15.8; 20.0)	16.3	(14.3; 18.4)	22.5	(19.4; 25.9)	16.4	(13.6; 19.5)	17.4	(14.6; 20.6)
	Grade 1	14.8	(12.9; 16.8)	11.2	(9.6; 13.1)	10.1	(8.5; 11.9)	15.4	(12.7; 18.4)	10.6	(8.4; 13.3)	12.8	(10.3; 15.7)
	Grade 2	7.1	(5.8; 8.6)	4.7	(3.6; 6.0)	4.9	(3.7; 6.2)	4.6	(3.1; 6.5)	4.7	(3.2; 6.6)	3.3	(2.1; 5.0)
	Grade 3	2.7	(1.9; 3.7)	1.8	(1.2; 2.7)	1.3	(0.8; 2.1)	2.6	(1.5; 4.1)	1.1	(0.4; 2.2)	1.3	(0.5; 2.5)

[1]Injection site pain in: Grade 1: easily tolerated, Grade 2: Sufficiently discomforting to interfere with normal behavior or activities, Grade 3: Incapacitating - unable to perform usual activities; Injection site pain in 12–18 year-olds: Grade 1: no interference with activity, Grade 2: some interference with activity, Grade 3: significant - prevents daily activity; Injection site erythema or swelling in 9–11 year-olds: Grade 1: 0–25 mm, Grade 2: ≥25–50 mm, Grade 3: ≥50 mm, and in 12–16 year-olds: Grade 1: ≥25–50 mm, Grade 2: ≥51–100 mm, Grade 3: >100 mm; Solicited systemic reactions, all ages: Fever: Grade 1: 38.0–38.4°C, Grade 2: 38.5°C–38.9°C, Grade 3: ≥39.0°C; Headache, Malaise, Myalgia, Asthenia reactions: Grade 1=no interference with activity, Grade 2=some interference with activity, Grade 3=significant prevents daily activity.

Table S6 Unsolicited adverse reactions occurring within 28 days after each injection in the subset
Listing of all unsolicited adverse reactions[1] (ARs) occurring within 28 days after each injection in the subset, by MedDRA system organ class, preferred term, and maximum intensity grade[2]

	Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one unsolicited AR:	n subjects	% subjects	(95% CI)	n ARs	n subjects	% subjects	(95% CI)	n ARs
First injection								
Any	10	0.8	(0.4; 1.4)	13	3	0.5	(0.1; 1.3)	3
General disorders and administration site conditions	6	0.5	(0.2; 1.0)	8	2	0.3	(0.0; 1.1)	2
Injection site pain	3	0.2	(0.0; 0.7)	5	1	0.2	(0.0; 0.8)	1
Grade 1	3	0.2	(0.0; 0.7)	5	0	0.0	(0.0; 0.6)	0
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Injection site anesthesia	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Injection site hematoma	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Missing	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Malaise	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Injection site induration	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Skin and subcutaneous tissue disorders	2	0.2	(0.0; 0.5)	2	1	0.2	(0.0; 0.8)	1
Generalized erythema	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Urticaria	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Pruritus	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Ear and labyrinth disorders	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0

	Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one unsolicited AR:	n subjects	% subjects	(95% CI)	n ARs	n subjects	% subjects	(95% CI)	n ARs
Vertigo	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Gastrointestinal disorders	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Abdominal pain	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Respiratory, thoracic and mediastinal disorders	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Asthmatic crisis	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Second injection								
Any	6	0.5	(0.2; 1.0)	6	2	0.3	(0.0; 1.1)	2
General disorders and administration site conditions	4	0.3	(0.1; 0.8)	4	1	0.2	(0.0; 0.9)	1
Injection site pruritus	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Injection site hematoma	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Missing	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Injection site pain	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.9)	1
Grade 2	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.9)	1
Gastrointestinal disorders	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Vomiting	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Respiratory, thoracic and mediastinal disorders	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Dyspnoea	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Blood and lymphatic system disorders	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Lymphadenitis	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1

Third injection:								
Any	0	0.0	(0.0; 0.3)	0	0	0.0	(0.0; 0.6)	0

[1] Unsolicited adverse reactions are adverse events that were classified as related to vaccine by the investigator; Serious Adverse Events are excluded from this listing and presented separately. MedDRA=Medical Dictionary for Regulatory Activities. Intensity was graded using the grading scale described above (Table S5) where applicable, otherwise as follows: Intensity Grade 1=No interference with activity; Grade 2=Some interference with activity; Grade 3=Significant; prevents daily activity.

Table S7: Unsolicited adverse events occurring within 28 days after each injection in the subset
Unsolicited adverse events[1] (AEs) occurring within 28 days after each injection in the subset, by MedDRA system organ class, preferred term, and maximum intensity grade[2]

	CYD Dengue Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one:	n subjects	% subjects	(95% CI)	n AEs	n subjects	% subjects	(95% CI)	n AEs
First injection:								
Any	313	23.5	(21.2; 25.9)	461	166	25.0	(21.7; 28.5)	251
Infections and infestations	143	10.7	(9.1; 12.5)	157	83	12.5	(10.1; 15.3)	98
Nasopharyngitis	58	4.4	(3.3; 5.6)	59	27	4.1	(2.7; 5.9)	27
Grade 1	39	2.9	(2.1; 4.0)	40	21	3.2	(2.0; 4.8)	21
Grade 2	16	1.2	(0.7; 1.9)	16	6	0.9	(0.3; 2.0)	6
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Missing	2	0.2	(0.0; 0.5)	2	0	0.0	(0.0; 0.6)	0
Influenza	31	2.3	(1.6; 3.3)	32	15	2.3	(1.3; 3.7)	15
Grade 1	21	1.6	(1.0; 2.4)	22	8	1.2	(0.5; 2.4)	8
Grade 2	6	0.5	(0.2; 1.0)	6	4	0.6	(0.2; 1.5)	4
Missing	4	0.3	(0.1; 0.8)	4	3	0.5	(0.1; 1.3)	3
Pharyngitis	12	0.9	(0.5; 1.6)	12	11	1.7	(0.8; 2.9)	11
Grade 1	10	0.8	(0.4; 1.4)	10	7	1.1	(0.4; 2.2)	7
Grade 2	0	0.0	(0.0; 0.3)	0	4	0.6	(0.2; 1.5)	4
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Missing	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Rhinitis	8	0.6	(0.3; 1.2)	8	6	0.9	(0.3; 2.0)	6
Grade 1	7	0.5	(0.2; 1.1)	7	6	0.9	(0.3; 2.0)	6
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0

	CYD Dengue Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one:	n subjects	% subjects	(95% CI)	n AEs	n subjects	% subjects	(95% CI)	n AEs
Tonsillitis	6	0.5	(0.2; 1.0)	6	3	0.5	(0.1; 1.3)	3
Grade 1	4	0.3	(0.1; 0.8)	4	2	0.3	(0.0; 1.1)	2
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Missing	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Bronchitis	4	0.3	(0.1; 0.8)	4	1	0.2	(0.0; 0.8)	1
Grade 1	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.8)	1
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 3	2	0.2	(0.0; 0.5)	2	0	0.0	(0.0; 0.6)	0
Sinusitis	4	0.3	(0.1; 0.8)	4	0	0.0	(0.0; 0.6)	0
Grade 1	3	0.2	(0.0; 0.7)	3	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Viral pharyngitis	4	0.3	(0.1; 0.8)	4	1	0.2	(0.0; 0.8)	1
Grade 1	3	0.2	(0.0; 0.7)	3	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.8)	1
Pharyngotonsillitis	3	0.2	(0.0; 0.7)	3	0	0.0	(0.0; 0.6)	0
Grade 2	2	0.2	(0.0; 0.5)	2	0	0.0	(0.0; 0.6)	0
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Viral infection	3	0.2	(0.0; 0.7)	3	4	0.6	(0.2; 1.5)	4
Grade 1	3	0.2	(0.0; 0.7)	3	3	0.5	(0.1; 1.3)	3
Grade 3	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Gastroenteritis	2	0.2	(0.0; 0.5)	2	3	0.5	(0.1; 1.3)	3
Grade 1	2	0.2	(0.0; 0.5)	2	3	0.5	(0.1; 1.3)	3
Upper respiratory tract infection	2	0.2	(0.0; 0.5)	2	2	0.3	(0.0; 1.1)	2
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.8)	1
Grade 3	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1

	CYD Dengue Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one:	n subjects	% subjects	(95% CI)	n AEs	n subjects	% subjects	(95% CI)	n AEs
Urinary tract infection	2	0.2	(0.0; 0.5)	2	5	0.8	(0.2; 1.7)	5
Grade 1	0	0.0	(0.0; 0.3)	0	2	0.3	(0.0; 1.1)	2
Grade 2	1	<0.1	(0.0; 0.4)	1	3	0.5	(0.1; 1.3)	3
Missing	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Varicella	2	0.2	(0.0; 0.5)	2	2	0.3	(0.0; 1.1)	2
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.8)	1
Missing	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Croup infectious	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Cystitis	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Dermatophytosis	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Ear infection	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Fungal infection	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Furuncle	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Gastroenteritis viral	1	<0.1	(0.0; 0.4)	1	4	0.6	(0.2; 1.5)	5
Grade 1	1	<0.1	(0.0; 0.4)	1	4	0.6	(0.2; 1.5)	5
Gastrointestinal viral infection	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Herpes simplex	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Hordeolum	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0

	CYD Dengue Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one:	n subjects	% subjects	(95% CI)	n AEs	n subjects	% subjects	(95% CI)	n AEs
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Infection parasitic	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Laryngitis	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.8)	1
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Oral herpes	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.8)	1
Grade 1	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.8)	1
Tonsillitis bacterial	1	<0.1	(0.0; 0.4)	1	2	0.3	(0.0; 1.1)	2
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	0	0.0	(0.0; 0.3)	0	2	0.3	(0.0; 1.1)	2
Abscess limb	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Acarodermatitis	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Amoebic dysentery	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Bronchitis viral	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Cellulitis	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Otitis externa	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Grade 3	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Otitis media acute	0	0.0	(0.0; 0.3)	0	2	0.3	(0.0; 1.1)	2
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Grade 3	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Viral tonsillitis	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1

	CYD Dengue Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one:	n subjects	% subjects	(95% CI)	n AEs	n subjects	% subjects	(95% CI)	n AEs
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Gastrointestinal disorders	71	5.3	(4.2; 6.7)	81	37	5.6	(4.0; 7.6)	44
Abdominal pain	24	1.8	(1.2; 2.7)	25	5	0.8	(0.2; 1.7)	5
Grade 1	14	1.1	(0.6; 1.8)	14	2	0.3	(0.0; 1.1)	2
Grade 2	9	0.7	(0.3; 1.3)	10	3	0.5	(0.1; 1.3)	3
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Diarrhea	20	1.5	(0.9; 2.3)	20	14	2.1	(1.2; 3.5)	15
Grade 1	14	1.1	(0.6; 1.8)	14	8	1.2	(0.5; 2.4)	9
Grade 2	4	0.3	(0.1; 0.8)	4	5	0.8	(0.2; 1.7)	5
Grade 3	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.8)	1
Missing	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Vomiting	13	1.0	(0.5; 1.7)	13	8	1.2	(0.5; 2.4)	9
Grade 1	9	0.7	(0.3; 1.3)	9	6	0.9	(0.3; 2.0)	6
Grade 2	4	0.3	(0.1; 0.8)	4	1	0.2	(0.0; 0.8)	1
Missing	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	2
Toothache	7	0.5	(0.2; 1.1)	8	2	0.3	(0.0; 1.1)	3
Grade 1	0	0.0	(0.0; 0.3)	0	0	0.0	(0.0; 0.6)	1
Grade 2	4	0.3	(0.1; 0.8)	4	0	0.0	(0.0; 0.6)	0
Grade 3	1	<0.1	(0.0; 0.4)	1	2	0.3	(0.0; 1.1)	2
Missing	2	0.2	(0.0; 0.5)	3	0	0.0	(0.0; 0.6)	0
Abdominal pain upper	4	0.3	(0.1; 0.8)	4	4	0.6	(0.2; 1.5)	5
Grade 1	0	0.0	(0.0; 0.3)	0	4	0.6	(0.2; 1.5)	5
Grade 2	3	0.2	(0.0; 0.7)	3	0	0.0	(0.0; 0.6)	0
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Odynophagia	4	0.3	(0.1; 0.8)	4	2	0.3	(0.0; 1.1)	2
Grade 1	3	0.2	(0.0; 0.7)	3	1	0.2	(0.0; 0.8)	1
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1

	CYD Dengue Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one:	n subjects	% subjects	(95% CI)	n AEs	n subjects	% subjects	(95% CI)	n AEs
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Constipation	2	0.2	(0.0; 0.5)	2	3	0.5	(0.1; 1.3)	3
Grade 1	0	0.0	(0.0; 0.3)	0	3	0.5	(0.1; 1.3)	3
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Nausea	2	0.2	(0.0; 0.5)	2	1	0.2	(0.0; 0.8)	1
Grade 2	2	0.2	(0.0; 0.5)	2	1	0.2	(0.0; 0.8)	1
Food poisoning	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Gastrointestinal disorder	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Rectal hemorrhage	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Gastritis	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Grade 3	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Respiratory, thoracic and mediastinal disorders	59	4.4	(3.4; 5.7)	72	24	3.6	(2.3; 5.3)	29
Cough	27	2.0	(1.3; 2.9)	27	16	2.4	(1.4; 3.9)	16
Grade 1	18	1.4	(0.8; 2.1)	18	8	1.2	(0.5; 2.4)	8
Grade 2	8	0.6	(0.3; 1.2)	8	7	1.1	(0.4; 2.2)	7
Missing	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.8)	1
Oropharyngeal pain	11	0.8	(0.4; 1.5)	11	2	0.3	(0.0; 1.1)	2
Grade 1	7	0.5	(0.2; 1.1)	7	0	0.0	(0.0; 0.6)	0
Grade 2	3	0.2	(0.0; 0.7)	3	1	0.2	(0.0; 0.8)	1
Grade 3	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.8)	1
Epistaxis	10	0.8	(0.4; 1.4)	11	2	0.3	(0.0; 1.1)	2
Grade 1	8	0.6	(0.3; 1.2)	9	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	2	0.3	(0.0; 1.1)	2

	CYD Dengue Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one:	n subjects	% subjects	(95% CI)	n AEs	n subjects	% subjects	(95% CI)	n AEs
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Rhinorrhea	9	0.7	(0.3; 1.3)	9	3	0.5	(0.1; 1.3)	3
Grade 1	7	0.5	(0.2; 1.1)	7	2	0.3	(0.0; 1.1)	2
Grade 2	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.8)	1
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Nasal congestion	3	0.2	(0.0; 0.7)	3	2	0.3	(0.0; 1.1)	2
Grade 1	1	<0.1	(0.0; 0.4)	1	2	0.3	(0.0; 1.1)	2
Grade 2	2	0.2	(0.0; 0.5)	2	0	0.0	(0.0; 0.6)	0
Productive cough	3	0.2	(0.0; 0.7)	3	0	0.0	(0.0; 0.6)	0
Grade 1	2	0.2	(0.0; 0.5)	2	0	0.0	(0.0; 0.6)	0
Missing	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Nasal obstruction	2	0.2	(0.0; 0.5)	2	0	0.0	(0.0; 0.6)	0
Grade 1	2	0.2	(0.0; 0.5)	2	0	0.0	(0.0; 0.6)	0
Allergic respiratory disease	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Asthma	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.8)	1
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 3	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Asthma exercise induced	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Asthmatic crisis	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Rhinitis allergic	1	<0.1	(0.0; 0.4)	1	2	0.3	(0.0; 1.1)	2
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Grade 2	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.8)	1
Sneezing	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Missing	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0

	CYD Dengue Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one:	n subjects	% subjects	(95% CI)	n AEs	n subjects	% subjects	(95% CI)	n AEs
Dysphonia	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Nervous system disorders	34	2.6	(1.8; 3.5)	36	18	2.7	(1.6; 4.3)	20
Headache	27	2.0	(1.3; 2.9)	28	14	2.1	(1.2; 3.5)	15
Grade 1	14	1.1	(0.6; 1.8)	15	8	1.2	(0.5; 2.4)	9
Grade 2	11	0.8	(0.4; 1.5)	11	5	0.8	(0.2; 1.7)	5
Grade 3	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.8)	1
Missing	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Dizziness	7	0.5	(0.2; 1.1)	7	3	0.5	(0.1; 1.3)	3
Grade 1	4	0.3	(0.1; 0.8)	4	1	0.2	(0.0; 0.8)	1
Grade 2	2	0.2	(0.0; 0.5)	2	1	0.2	(0.0; 0.8)	1
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Missing	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Migraine	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Somnolence	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Grade 3	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Syncope	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
General disorders and administration site conditions	24	1.8	(1.2; 2.7)	28	12	1.8	(0.9; 3.1)	13
Pyrexia	10	0.8	(0.4; 1.4)	10	3	0.5	(0.1; 1.3)	3
Grade 1	4	0.3	(0.1; 0.8)	4	2	0.3	(0.0; 1.1)	2
Grade 2	3	0.2	(0.0; 0.7)	3	1	0.2	(0.0; 0.8)	1
Grade 3	3	0.2	(0.0; 0.7)	3	0	0.0	(0.0; 0.6)	0
Malaise	5	0.4	(0.1; 0.9)	5	4	0.6	(0.2; 1.5)	4
Grade 1	3	0.2	(0.0; 0.7)	3	1	0.2	(0.0; 0.8)	1
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1

	CYD Dengue Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one:	n subjects	% subjects	(95% CI)	n AEs	n subjects	% subjects	(95% CI)	n AEs
Grade 3	2	0.2	(0.0; 0.5)	2	1	0.2	(0.0; 0.8)	1
Missing	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Chest pain	3	0.2	(0.0; 0.7)	3	3	0.5	(0.1; 1.3)	3
Grade 1	0	0.0	(0.0; 0.3)	0	2	0.3	(0.0; 1.1)	2
Grade 2	2	0.2	(0.0; 0.5)	2	1	0.2	(0.0; 0.8)	1
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Injection site pain	3	0.2	(0.0; 0.7)	5	1	0.2	(0.0; 0.8)	1
Grade 1	3	0.2	(0.0; 0.7)	5	0	0.0	(0.0; 0.6)	0
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Asthenia	2	0.2	(0.0; 0.5)	2	1	0.2	(0.0; 0.8)	1
Grade 1	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.8)	1
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Face edema	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Injection site anesthesia	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Injection site hematoma	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Missing	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Injection site induration	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Skin and subcutaneous tissue disorders	20	1.5	(0.9; 2.3)	21	9	1.4	(0.6; 2.6)	9
Dermatitis contact	3	0.2	(0.0; 0.7)	3	1	0.2	(0.0; 0.8)	1
Grade 1	2	0.2	(0.0; 0.5)	2	1	0.2	(0.0; 0.8)	1
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Urticaria	3	0.2	(0.0; 0.7)	4	0	0.0	(0.0; 0.6)	0
Grade 1	2	0.2	(0.0; 0.5)	3	0	0.0	(0.0; 0.6)	0
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0

	CYD Dengue Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one:	n subjects	% subjects	(95% CI)	n AEs	n subjects	% subjects	(95% CI)	n AEs
Dermatitis atopic	2	0.2	(0.0; 0.5)	2	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Rash	2	0.2	(0.0; 0.5)	2	0	0.0	(0.0; 0.6)	0
Grade 1	2	0.2	(0.0; 0.5)	2	0	0.0	(0.0; 0.6)	0
Rash generalized	2	0.2	(0.0; 0.5)	2	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Dermatitis	1	<0.1	(0.0; 0.4)	1	2	0.3	(0.0; 1.1)	2
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Grade 3	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Dermatosis	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Ecchymosis	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Generalized erythema	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Hyperkeratosis	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Missing	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Ingrowing nail	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Prurigo	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Skin lesion	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Dermatitis allergic	0	0.0	(0.0; 0.3)	0	2	0.3	(0.0; 1.1)	2

	CYD Dengue Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one:	n subjects	% subjects	(95% CI)	n AEs	n subjects	% subjects	(95% CI)	n AEs
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Hidradenitis	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Hyperhidrosis	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Pruritus	0	0.0	(0.0; 0.3)	0	2	0.3	(0.0; 1.1)	2
Grade 1	0	0.0	(0.0; 0.3)	0	2	0.3	(0.0; 1.1)	2
Musculoskeletal and connective tissue disorders	16	1.2	(0.7; 1.9)	17	6	0.9	(0.3; 2.0)	6
Pain in extremity	5	0.4	(0.1; 0.9)	5	2	0.3	(0.0; 1.1)	2
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Grade 2	5	0.4	(0.1; 0.9)	5	0	0.0	(0.0; 0.6)	0
Grade 3	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Bone pain	3	0.2	(0.0; 0.7)	3	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Missing	2	0.2	(0.0; 0.5)	2	0	0.0	(0.0; 0.6)	0
Myalgia	3	0.2	(0.0; 0.7)	3	2	0.3	(0.0; 1.1)	2
Grade 1	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.8)	1
Grade 2	2	0.2	(0.0; 0.5)	2	1	0.2	(0.0; 0.8)	1
Arthralgia	2	0.2	(0.0; 0.5)	2	1	0.2	(0.0; 0.8)	1
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.8)	1
Back pain	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.8)	1
Grade 2	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.8)	1
Chondritis	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Costochondritis	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0

	CYD Dengue Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one:	n subjects	% subjects	(95% CI)	n AEs	n subjects	% subjects	(95% CI)	n AEs
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Neck pain	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Reproductive system and breast disorders	12	0.9	(0.5; 1.6)	12	5	0.8	(0.2; 1.7)	5
Dysmenorrhea	10	0.8	(0.4; 1.4)	10	4	0.6	(0.2; 1.5)	4
Grade 1	3	0.2	(0.0; 0.7)	3	0	0.0	(0.0; 0.6)	0
Grade 2	7	0.5	(0.2; 1.1)	7	4	0.6	(0.2; 1.5)	4
Pelvic pain	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.8)	1
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Missing	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Vaginal discharge	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Injury, poisoning and procedural complications	11	0.8	(0.4; 1.5)	11	8	1.2	(0.5; 2.4)	8
Limb injury	3	0.2	(0.0; 0.7)	3	1	0.2	(0.0; 0.8)	1
Grade 1	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.8)	1
Grade 2	2	0.2	(0.0; 0.5)	2	0	0.0	(0.0; 0.6)	0
Contusion	2	0.2	(0.0; 0.5)	2	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Back injury	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Excoriation	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Face injury	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.8)	1
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Head injury	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0

	CYD Dengue Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one:	n subjects	% subjects	(95% CI)	n AEs	n subjects	% subjects	(95% CI)	n AEs
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Laceration	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Upper limb fracture	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Animal bite	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Arthropod sting	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Eye penetration	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Joint injury	0	0.0	(0.0; 0.3)	0	2	0.3	(0.0; 1.1)	2
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Grade 3	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Wound	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Ear and labyrinth disorders	8	0.6	(0.3; 1.2)	8	6	0.9	(0.3; 2.0)	6
Ear pain	7	0.5	(0.2; 1.1)	7	4	0.6	(0.2; 1.5)	4
Grade 1	3	0.2	(0.0; 0.7)	3	2	0.3	(0.0; 1.1)	2
Grade 2	3	0.2	(0.0; 0.7)	3	2	0.3	(0.0; 1.1)	2
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Vertigo	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.8)	1
Grade 1	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.8)	1
Cerumen impaction	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Eye disorders	6	0.5	(0.2; 1.0)	7	2	0.3	(0.0; 1.1)	2
Conjunctivitis	3	0.2	(0.0; 0.7)	4	1	0.2	(0.0; 0.8)	1

	CYD Dengue Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one:	n subjects	% subjects	(95% CI)	n AEs	n subjects	% subjects	(95% CI)	n AEs
Grade 2	2	0.2	(0.0; 0.5)	3	1	0.2	(0.0; 0.8)	1
Missing	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Eye pain	2	0.2	(0.0; 0.5)	2	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Missing	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Chalazion	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Refraction disorder	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Blood and lymphatic system disorders	5	0.4	(0.1; 0.9)	5	1	0.2	(0.0; 0.8)	1
Lymphadenopathy	3	0.2	(0.0; 0.7)	3	0	0.0	(0.0; 0.6)	0
Grade 1	2	0.2	(0.0; 0.5)	2	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Anemia	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.8)	1
Grade 1	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.8)	1
Iron deficiency anemia	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Immune system disorders	4	0.3	(0.1; 0.8)	4	2	0.3	(0.0; 1.1)	5
Allergy to arthropod bite	2	0.2	(0.0; 0.5)	2	1	0.2	(0.0; 0.8)	4
Grade 1	2	0.2	(0.0; 0.5)	2	1	0.2	(0.0; 0.8)	4
Food allergy	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Hypersensitivity	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.8)	1
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Metabolism and nutrition disorders	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Hypoglycemic unconsciousness	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0

	CYD Dengue Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one:	n subjects	% subjects	(95% CI)	n AEs	n subjects	% subjects	(95% CI)	n AEs
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Skin papilloma	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Endocrine disorders	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	2
Endocrine disorder	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	2
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	2
Psychiatric disorders	0	0.0	(0.0; 0.3)	0	2	0.3	(0.0; 1.1)	2
Anxiety disorder	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Mood altered	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Grade 3	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Vascular disorders	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Pallor	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.8)	1
Second injection:								
Any	256	19.7	(17.5; 21.9)	364	131	20.4	(17.3; 23.7)	176
Infections and infestations	134	10.3	(8.7; 12.1)	141	66	10.3	(8.0; 12.9)	71
Nasopharyngitis	51	3.9	(2.9; 5.1)	51	28	4.4	(2.9; 6.2)	28
Grade 1	31	2.4	(1.6; 3.4)	31	18	2.8	(1.7; 4.4)	18
Grade 2	18	1.4	(0.8; 2.2)	18	8	1.2	(0.5; 2.4)	8
Grade 3	2	0.2	(0.0; 0.6)	2	1	0.2	(0.0; 0.9)	1
Missing	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Influenza	29	2.2	(1.5; 3.2)	29	12	1.9	(1.0; 3.2)	13

	CYD Dengue Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one:	n subjects	% subjects	(95% CI)	n AEs	n subjects	% subjects	(95% CI)	n AEs
Grade 1	21	1.6	(1.0; 2.5)	21	10	1.6	(0.7; 2.8)	11
Grade 2	8	0.6	(0.3; 1.2)	8	2	0.3	(0.0; 1.1)	2
Rhinitis	10	0.8	(0.4; 1.4)	10	5	0.8	(0.3; 1.8)	5
Grade 1	9	0.7	(0.3; 1.3)	9	4	0.6	(0.2; 1.6)	4
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Missing	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Pharyngitis	8	0.6	(0.3; 1.2)	8	4	0.6	(0.2; 1.6)	4
Grade 1	4	0.3	(0.1; 0.8)	4	2	0.3	(0.0; 1.1)	2
Grade 2	3	0.2	(0.0; 0.7)	3	2	0.3	(0.0; 1.1)	2
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Tonsillitis	7	0.5	(0.2; 1.1)	7	0	0.0	(0.0; 0.6)	0
Grade 1	3	0.2	(0.0; 0.7)	3	0	0.0	(0.0; 0.6)	0
Grade 2	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Missing	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Upper respiratory tract infection	4	0.3	(0.1; 0.8)	4	0	0.0	(0.0; 0.6)	0
Grade 1	3	0.2	(0.0; 0.7)	3	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Gastroenteritis	3	0.2	(0.0; 0.7)	3	0	0.0	(0.0; 0.6)	0
Grade 1	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Abscess limb	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0
Grade 1	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0
Acute tonsillitis	2	0.2	(0.0; 0.6)	2	1	0.2	(0.0; 0.9)	1
Grade 1	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Gastroenteritis viral	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0

	CYD Dengue Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one:	n subjects	% subjects	(95% CI)	n AEs	n subjects	% subjects	(95% CI)	n AEs
Grade 1	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0
Oral herpes	2	0.2	(0.0; 0.6)	2	1	0.2	(0.0; 0.9)	1
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 2	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0
Pharyngotonsillitis	2	0.2	(0.0; 0.6)	2	2	0.3	(0.0; 1.1)	2
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	2	0.3	(0.0; 1.1)	2
Viral infection	2	0.2	(0.0; 0.6)	2	3	0.5	(0.1; 1.4)	3
Grade 1	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.9)	1
Grade 3	1	<0.1	(0.0; 0.4)	1	2	0.3	(0.0; 1.1)	2
Fungal infection	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.9)	1
Grade 1	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.9)	1
Furuncle	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.9)	1
Grade 1	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.9)	1
Hordeolum	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Impetigo	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Infectious mononucleosis	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Laryngitis	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Otitis media acute	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Pneumonia	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Pyoderma	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0

	CYD Dengue Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one:	n subjects	% subjects	(95% CI)	n AEs	n subjects	% subjects	(95% CI)	n AEs
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Respiratory tract infection	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.9)	1
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Missing	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Skin infection	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Subcutaneous abscess	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Tinea versicolor	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Tooth abscess	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Viral diarrhea	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Viral pharyngitis	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.9)	1
Grade 1	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.9)	1
Viral tonsillitis	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Acarodermatitis	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Amoebiasis	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Bronchitis	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Conjunctivitis viral	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Ear infection	0	0.0	(0.0; 0.3)	0	2	0.3	(0.0; 1.1)	2

	CYD Dengue Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one:	n subjects	% subjects	(95% CI)	n AEs	n subjects	% subjects	(95% CI)	n AEs
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Missing	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Helminthic infection	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Sinusitis	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Missing	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Urinary tract infection	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 3	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Vulvovaginal candidiasis	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Gastrointestinal disorders	57	4.4	(3.3; 5.6)	70	28	4.4	(2.9; 6.2)	29
Abdominal pain	21	1.6	(1.0; 2.5)	22	7	1.1	(0.4; 2.2)	7
Grade 1	9	0.7	(0.3; 1.3)	9	3	0.5	(0.1; 1.4)	3
Grade 2	7	0.5	(0.2; 1.1)	8	4	0.6	(0.2; 1.6)	4
Grade 3	3	0.2	(0.0; 0.7)	3	0	0.0	(0.0; 0.6)	0
Missing	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0
Diarrhea	16	1.2	(0.7; 2.0)	17	3	0.5	(0.1; 1.4)	3
Grade 1	8	0.6	(0.3; 1.2)	9	1	0.2	(0.0; 0.9)	1
Grade 2	7	0.5	(0.2; 1.1)	7	2	0.3	(0.0; 1.1)	2
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Vomiting	9	0.7	(0.3; 1.3)	9	6	0.9	(0.3; 2.0)	6
Grade 1	4	0.3	(0.1; 0.8)	4	4	0.6	(0.2; 1.6)	4
Grade 2	2	0.2	(0.0; 0.6)	2	1	0.2	(0.0; 0.9)	1
Grade 3	3	0.2	(0.0; 0.7)	3	0	0.0	(0.0; 0.6)	0
Missing	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Odynophagia	8	0.6	(0.3; 1.2)	8	5	0.8	(0.3; 1.8)	5
Grade 1	3	0.2	(0.0; 0.7)	3	3	0.5	(0.1; 1.4)	3

	CYD Dengue Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one:	n subjects	% subjects	(95% CI)	n AEs	n subjects	% subjects	(95% CI)	n AEs
Grade 2	5	0.4	(0.1; 0.9)	5	2	0.3	(0.0; 1.1)	2
Abdominal pain upper	6	0.5	(0.2; 1.0)	6	1	0.2	(0.0; 0.9)	1
Grade 1	6	0.5	(0.2; 1.0)	6	1	0.2	(0.0; 0.9)	1
Nausea	3	0.2	(0.0; 0.7)	3	0	0.0	(0.0; 0.6)	0
Grade 1	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Constipation	2	0.2	(0.0; 0.6)	3	0	0.0	(0.0; 0.6)	0
Grade 1	0	0.0	(0.0; 0.3)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Gastritis	2	0.2	(0.0; 0.6)	2	2	0.3	(0.0; 1.1)	2
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	2	0.3	(0.0; 1.1)	2
Dental caries	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Dyspepsia	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Food poisoning	0	0.0	(0.0; 0.3)	0	2	0.3	(0.0; 1.1)	2
Grade 1	0	0.0	(0.0; 0.3)	0	2	0.3	(0.0; 1.1)	2
Toothache	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Nervous system disorders	42	3.2	(2.3; 4.3)	46	17	2.6	(1.5; 4.2)	18
Headache	32	2.5	(1.7; 3.5)	34	15	2.3	(1.3; 3.8)	15
Grade 1	17	1.3	(0.8; 2.1)	19	10	1.6	(0.7; 2.8)	10
Grade 2	7	0.5	(0.2; 1.1)	7	5	0.8	(0.3; 1.8)	5
Grade 3	7	0.5	(0.2; 1.1)	7	0	0.0	(0.0; 0.6)	0
Missing	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0

	CYD Dengue Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one:	n subjects	% subjects	(95% CI)	n AEs	n subjects	% subjects	(95% CI)	n AEs
Dizziness	6	0.5	(0.2; 1.0)	7	1	0.2	(0.0; 0.9)	2
Grade 1	3	0.2	(0.0; 0.7)	4	0	0.0	(0.0; 0.6)	0
Grade 2	2	0.2	(0.0; 0.6)	2	1	0.2	(0.0; 0.9)	2
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Migraine	3	0.2	(0.0; 0.7)	3	1	0.2	(0.0; 0.9)	1
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 2	3	0.2	(0.0; 0.7)	3	0	0.0	(0.0; 0.6)	0
Somnolence	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Syncope	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Respiratory, thoracic and mediastinal disorders	39	3.0	(2.1; 4.1)	46	19	3.0	(1.8; 4.6)	22
Cough	15	1.2	(0.6; 1.9)	15	11	1.7	(0.9; 3.0)	11
Grade 1	9	0.7	(0.3; 1.3)	9	6	0.9	(0.3; 2.0)	6
Grade 2	6	0.5	(0.2; 1.0)	6	4	0.6	(0.2; 1.6)	4
Grade 3	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Oropharyngeal pain	8	0.6	(0.3; 1.2)	8	6	0.9	(0.3; 2.0)	6
Grade 1	4	0.3	(0.1; 0.8)	4	5	0.8	(0.3; 1.8)	5
Grade 2	3	0.2	(0.0; 0.7)	3	1	0.2	(0.0; 0.9)	1
Missing	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Rhinitis allergic	6	0.5	(0.2; 1.0)	7	0	0.0	(0.0; 0.6)	0
Grade 1	5	0.4	(0.1; 0.9)	5	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	2	0	0.0	(0.0; 0.6)	0
Asthma	3	0.2	(0.0; 0.7)	3	1	0.2	(0.0; 0.9)	2
Grade 1	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.9)	2
Grade 2	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0
Epistaxis	3	0.2	(0.0; 0.7)	4	1	0.2	(0.0; 0.9)	1

	CYD Dengue Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one:	n subjects	% subjects	(95% CI)	n AEs	n subjects	% subjects	(95% CI)	n AEs
Grade 1	1	<0.1	(0.0; 0.4)	2	1	0.2	(0.0; 0.9)	1
Grade 2	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0
Rhinorrhea	3	0.2	(0.0; 0.7)	3	1	0.2	(0.0; 0.9)	1
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	2	0.2	(0.0; 0.6)	2	1	0.2	(0.0; 0.9)	1
Asthmatic crisis	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Allergic cough	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Dyspnea	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Productive cough	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Sneezing	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.9)	1
Grade 1	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.9)	1
General disorders and administration site conditions	14	1.1	(0.6; 1.8)	15	9	1.4	(0.6; 2.6)	9
Malaise	3	0.2	(0.0; 0.7)	3	5	0.8	(0.3; 1.8)	5
Grade 1	1	<0.1	(0.0; 0.4)	1	4	0.6	(0.2; 1.6)	4
Grade 2	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.9)	1
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Injection site pruritus	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Pain	2	0.2	(0.0; 0.6)	2	1	0.2	(0.0; 0.9)	1
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 3	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0

	CYD Dengue Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one:	n subjects	% subjects	(95% CI)	n AEs	n subjects	% subjects	(95% CI)	n AEs
Pyrexia	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0
Grade 1	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0
Asthenia	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.9)	1
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Chest pain	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.9)	1
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Face edema	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Injection site hematoma	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Missing	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Injection site pain	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.9)	1
Grade 2	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.9)	1
Nodule	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Musculoskeletal and connective tissue disorders	13	1.0	(0.5; 1.7)	18	4	0.6	(0.2; 1.6)	4
Pain in extremity	5	0.4	(0.1; 0.9)	5	3	0.5	(0.1; 1.4)	3
Grade 1	1	<0.1	(0.0; 0.4)	1	2	0.3	(0.0; 1.1)	2
Grade 2	4	0.3	(0.1; 0.8)	4	1	0.2	(0.0; 0.9)	1
Arthralgia	2	0.2	(0.0; 0.6)	4	0	0.0	(0.0; 0.6)	0
Grade 2	2	0.2	(0.0; 0.6)	4	0	0.0	(0.0; 0.6)	0
Myalgia	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Back pain	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.9)	1
Grade 1	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.9)	1

	CYD Dengue Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one:	n subjects	% subjects	(95% CI)	n AEs	n subjects	% subjects	(95% CI)	n AEs
Bone pain	1	<0.1	(0.0; 0.4)	2	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	2	0	0.0	(0.0; 0.6)	0
Costochondritis	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Joint swelling	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Neck pain	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Torticollis	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Injury, poisoning and procedural complications	9	0.7	(0.3; 1.3)	9	5	0.8	(0.3; 1.8)	6
Limb injury	4	0.3	(0.1; 0.8)	4	1	0.2	(0.0; 0.9)	1
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 2	4	0.3	(0.1; 0.8)	4	0	0.0	(0.0; 0.6)	0
Animal bite	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Chest injury	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Procedural pain	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Radius fracture	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Traumatic fracture	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Contusion	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Head injury	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1

	CYD Dengue Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one:	n subjects	% subjects	(95% CI)	n AEs	n subjects	% subjects	(95% CI)	n AEs
Grade 3	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Joint injury	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Laceration	0	0.0	(0.0; 0.3)	0	2	0.3	(0.0; 1.1)	2
Grade 1	0	0.0	(0.0; 0.3)	0	2	0.3	(0.0; 1.1)	2
Reproductive system and breast disorders	5	0.4	(0.1; 0.9)	5	3	0.5	(0.1; 1.4)	4
Dysmenorrhea	5	0.4	(0.1; 0.9)	5	3	0.5	(0.1; 1.4)	4
Grade 1	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.9)	1
Grade 2	4	0.3	(0.1; 0.8)	4	1	0.2	(0.0; 0.9)	2
Grade 3	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Immune system disorders	4	0.3	(0.1; 0.8)	4	1	0.2	(0.0; 0.9)	1
Allergy to arthropod bite	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0
Grade 2	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0
Drug hypersensitivity	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Hypersensitivity	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Food allergy	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Skin and subcutaneous tissue disorders	4	0.3	(0.1; 0.8)	4	3	0.5	(0.1; 1.4)	3
Dermatitis	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Dermatitis contact	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Missing	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Skin ulcer	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Urticaria	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.9)	1

	CYD Dengue Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one:	n subjects	% subjects	(95% CI)	n AEs	n subjects	% subjects	(95% CI)	n AEs
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Alopecia	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Dermatitis allergic	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Blood and lymphatic system disorders	2	0.2	(0.0; 0.6)	2	1	0.2	(0.0; 0.9)	1
Lymphadenopathy	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0
Grade 1	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0
Lymphadenitis	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Ear and labyrinth disorders	2	0.2	(0.0; 0.6)	2	6	0.9	(0.3; 2.0)	6
Ear pain	1	<0.1	(0.0; 0.4)	1	6	0.9	(0.3; 2.0)	6
Grade 1	0	0.0	(0.0; 0.3)	0	3	0.5	(0.1; 1.4)	3
Grade 2	1	<0.1	(0.0; 0.4)	1	2	0.3	(0.0; 1.1)	2
Grade 3	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Vertigo	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Eye disorders	1	<0.1	(0.0; 0.4)	1	2	0.3	(0.0; 1.1)	2
Eye irritation	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.9)	1
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Conjunctivitis	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Vascular disorders	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Orthostatic hypotension	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0

	CYD Dengue Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one:	n subjects	% subjects	(95% CI)	n AEs	n subjects	% subjects	(95% CI)	n AEs
Third injection:								
Any	249	19.4	(17.3; 21.7)	336	106	16.7	(13.9; 19.9)	151
Infections and infestations	126	9.8	(8.2; 11.6)	135	52	8.2	(6.2; 10.6)	54
Nasopharyngitis	53	4.1	(3.1; 5.4)	53	14	2.2	(1.2; 3.7)	15
Grade 1	39	3.0	(2.2; 4.1)	39	8	1.3	(0.5; 2.5)	8
Grade 2	13	1.0	(0.5; 1.7)	13	5	0.8	(0.3; 1.8)	6
Missing	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.9)	1
Influenza	19	1.5	(0.9; 2.3)	19	12	1.9	(1.0; 3.3)	12
Grade 1	14	1.1	(0.6; 1.8)	14	9	1.4	(0.7; 2.7)	9
Grade 2	5	0.4	(0.1; 0.9)	5	3	0.5	(0.1; 1.4)	3
Pharyngitis	10	0.8	(0.4; 1.4)	10	4	0.6	(0.2; 1.6)	4
Grade 1	4	0.3	(0.1; 0.8)	4	0	0.0	(0.0; 0.6)	0
Grade 2	6	0.5	(0.2; 1.0)	6	4	0.6	(0.2; 1.6)	4
Rhinitis	8	0.6	(0.3; 1.2)	8	5	0.8	(0.3; 1.8)	5
Grade 1	3	0.2	(0.0; 0.7)	3	4	0.6	(0.2; 1.6)	4
Grade 2	4	0.3	(0.1; 0.8)	4	1	0.2	(0.0; 0.9)	1
Missing	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Viral infection	8	0.6	(0.3; 1.2)	8	2	0.3	(0.0; 1.1)	2
Grade 1	3	0.2	(0.0; 0.7)	3	1	0.2	(0.0; 0.9)	1
Grade 2	2	0.2	(0.0; 0.6)	2	1	0.2	(0.0; 0.9)	1
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Missing	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0
Gastroenteritis	4	0.3	(0.1; 0.8)	4	1	0.2	(0.0; 0.9)	1
Grade 1	4	0.3	(0.1; 0.8)	4	0	0.0	(0.0; 0.6)	0
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Acarodermatitis	3	0.2	(0.0; 0.7)	3	0	0.0	(0.0; 0.6)	0

	CYD Dengue Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one:	n subjects	% subjects	(95% CI)	n AEs	n subjects	% subjects	(95% CI)	n AEs
Grade 1	3	0.2	(0.0; 0.7)	3	0	0.0	(0.0; 0.6)	0
Pharyngotonsillitis	3	0.2	(0.0; 0.7)	3	1	0.2	(0.0; 0.9)	1
Grade 1	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.9)	1
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Urinary tract infection	3	0.2	(0.0; 0.7)	3	2	0.3	(0.0; 1.1)	2
Grade 1	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	2	0.3	(0.0; 1.1)	2
Furuncle	2	0.2	(0.0; 0.6)	2	1	0.2	(0.0; 0.9)	1
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Gastroenteritis viral	2	0.2	(0.0; 0.6)	2	1	0.2	(0.0; 0.9)	1
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 3	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.9)	1
Respiratory tract infection	2	0.2	(0.0; 0.6)	2	1	0.2	(0.0; 0.9)	1
Grade 1	2	0.2	(0.0; 0.6)	2	1	0.2	(0.0; 0.9)	1
Tonsillitis bacterial	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Upper respiratory tract infection	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Abscess limb	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Acute sinusitis	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0

	CYD Dengue Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one:	n subjects	% subjects	(95% CI)	n AEs	n subjects	% subjects	(95% CI)	n AEs
Cellulitis	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Enterobiasis	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Missing	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Folliculitis	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Missing	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Fungal infection	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Fungal skin infection	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Infection	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Oral herpes	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Otitis media acute	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Sinusitis	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Tonsillitis	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.9)	1
Grade 1	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.9)	1
Varicella	1	<0.1	(0.0; 0.4)	1	2	0.3	(0.0; 1.1)	2
Grade 2	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.9)	1
Grade 3	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Viral pharyngitis	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Missing	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Acute tonsillitis	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1

	CYD Dengue Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one:	n subjects	% subjects	(95% CI)	n AEs	n subjects	% subjects	(95% CI)	n AEs
Bronchitis	0	0.0	(0.0; 0.3)	0	2	0.3	(0.0; 1.1)	2
Grade 1	0	0.0	(0.0; 0.3)	0	2	0.3	(0.0; 1.1)	2
Otitis externa	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Subcutaneous abscess	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Wound infection	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Gastrointestinal disorders	51	4.0	(3.0; 5.2)	64	26	4.1	(2.7; 6.0)	33
Abdominal pain	17	1.3	(0.8; 2.1)	18	8	1.3	(0.5; 2.5)	8
Grade 1	11	0.9	(0.4; 1.5)	11	6	0.9	(0.3; 2.0)	6
Grade 2	3	0.2	(0.0; 0.7)	4	2	0.3	(0.0; 1.1)	2
Grade 3	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0
Missing	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Vomiting	12	0.9	(0.5; 1.6)	12	7	1.1	(0.4; 2.3)	7
Grade 1	6	0.5	(0.2; 1.0)	6	5	0.8	(0.3; 1.8)	5
Grade 2	5	0.4	(0.1; 0.9)	5	2	0.3	(0.0; 1.1)	2
Missing	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Diarrhea	11	0.9	(0.4; 1.5)	11	5	0.8	(0.3; 1.8)	6
Grade 1	7	0.5	(0.2; 1.1)	7	3	0.5	(0.1; 1.4)	3
Grade 2	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.9)	2
Grade 3	3	0.2	(0.0; 0.7)	3	1	0.2	(0.0; 0.9)	1
Odynophagia	9	0.7	(0.3; 1.3)	9	6	0.9	(0.3; 2.0)	6
Grade 1	4	0.3	(0.1; 0.8)	4	3	0.5	(0.1; 1.4)	3
Grade 2	3	0.2	(0.0; 0.7)	3	2	0.3	(0.0; 1.1)	2
Grade 3	2	0.2	(0.0; 0.6)	2	1	0.2	(0.0; 0.9)	1
Abdominal pain upper	4	0.3	(0.1; 0.8)	4	1	0.2	(0.0; 0.9)	1

	CYD Dengue Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one:	n subjects	% subjects	(95% CI)	n AEs	n subjects	% subjects	(95% CI)	n AEs
Grade 1	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0
Grade 2	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0
Grade 3	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Toothache	4	0.3	(0.1; 0.8)	4	2	0.3	(0.0; 1.1)	2
Grade 1	3	0.2	(0.0; 0.7)	3	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.9)	1
Grade 3	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Nausea	3	0.2	(0.0; 0.7)	3	1	0.2	(0.0; 0.9)	1
Grade 1	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.9)	1
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Gastritis	2	0.2	(0.0; 0.6)	2	1	0.2	(0.0; 0.9)	1
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Mouth ulceration	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Food poisoning	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Respiratory, thoracic and mediastinal disorders	35	2.7	(1.9; 3.8)	37	18	2.8	(1.7; 4.5)	19
Cough	18	1.4	(0.8; 2.2)	18	8	1.3	(0.5; 2.5)	8
Grade 1	14	1.1	(0.6; 1.8)	14	7	1.1	(0.4; 2.3)	7
Grade 2	4	0.3	(0.1; 0.8)	4	1	0.2	(0.0; 0.9)	1
Oropharyngeal pain	5	0.4	(0.1; 0.9)	5	5	0.8	(0.3; 1.8)	5
Grade 1	2	0.2	(0.0; 0.6)	2	2	0.3	(0.0; 1.1)	2
Grade 2	2	0.2	(0.0; 0.6)	2	3	0.5	(0.1; 1.4)	3
Missing	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0

	CYD Dengue Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one:	n subjects	% subjects	(95% CI)	n AEs	n subjects	% subjects	(95% CI)	n AEs
Asthma	3	0.2	(0.0; 0.7)	3	1	0.2	(0.0; 0.9)	1
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 2	3	0.2	(0.0; 0.7)	3	0	0.0	(0.0; 0.6)	0
Epistaxis	3	0.2	(0.0; 0.7)	3	1	0.2	(0.0; 0.9)	1
Grade 1	2	0.2	(0.0; 0.6)	2	1	0.2	(0.0; 0.9)	1
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Allergic cough	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Asthmatic crisis	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Dysphonia	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Dyspnea	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Nasal obstruction	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Nasal polyps	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Productive cough	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Rhinitis allergic	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Rhinorrhea	0	0.0	(0.0; 0.3)	0	2	0.3	(0.0; 1.1)	3
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	2
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Status asthmaticus	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1

	CYD Dengue Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one:	n subjects	% subjects	(95% CI)	n AEs	n subjects	% subjects	(95% CI)	n AEs
Nervous system disorders	34	2.6	(1.8; 3.7)	37	13	2.1	(1.1; 3.5)	15
Headache	29	2.3	(1.5; 3.2)	31	9	1.4	(0.7; 2.7)	9
Grade 1	19	1.5	(0.9; 2.3)	21	2	0.3	(0.0; 1.1)	2
Grade 2	8	0.6	(0.3; 1.2)	8	6	0.9	(0.3; 2.0)	6
Grade 3	2	0.2	(0.0; 0.6)	2	1	0.2	(0.0; 0.9)	1
Dizziness	2	0.2	(0.0; 0.6)	2	3	0.5	(0.1; 1.4)	3
Grade 1	1	<0.1	(0.0; 0.4)	1	2	0.3	(0.0; 1.1)	2
Grade 2	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.9)	1
Hypoesthesia	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Migraine	1	<0.1	(0.0; 0.4)	1	2	0.3	(0.0; 1.1)	3
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	2
Missing	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Migraine with aura	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Syncope	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
General disorders and administration site conditions	18	1.4	(0.8; 2.2)	22	5	0.8	(0.3; 1.8)	7
Pyrexia	11	0.9	(0.4; 1.5)	11	3	0.5	(0.1; 1.4)	3
Grade 1	5	0.4	(0.1; 0.9)	5	2	0.3	(0.0; 1.1)	2
Grade 2	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.9)	1
Grade 3	4	0.3	(0.1; 0.8)	4	0	0.0	(0.0; 0.6)	0
Missing	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Malaise	4	0.3	(0.1; 0.8)	5	2	0.3	(0.0; 1.1)	2
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	2	0.2	(0.0; 0.6)	3	2	0.3	(0.0; 1.1)	2

	CYD Dengue Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one:	n subjects	% subjects	(95% CI)	n AEs	n subjects	% subjects	(95% CI)	n AEs
Missing	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Asthenia	2	0.2	(0.0; 0.6)	3	1	0.2	(0.0; 0.9)	1
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 3	2	0.2	(0.0; 0.6)	3	0	0.0	(0.0; 0.6)	0
Chest pain	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Chills	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Influenza like illness	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Pain	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Musculoskeletal and connective tissue disorders	11	0.9	(0.4; 1.5)	12	4	0.6	(0.2; 1.6)	5
Pain in extremity	4	0.3	(0.1; 0.8)	4	1	0.2	(0.0; 0.9)	1
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	2	0.2	(0.0; 0.6)	2	1	0.2	(0.0; 0.9)	1
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Arthralgia	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0
Grade 1	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0
Back pain	2	0.2	(0.0; 0.6)	2	1	0.2	(0.0; 0.9)	1
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.9)	1
Myalgia	2	0.2	(0.0; 0.6)	2	1	0.2	(0.0; 0.9)	1
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Costochondritis	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0

	CYD Dengue Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one:	n subjects	% subjects	(95% CI)	n AEs	n subjects	% subjects	(95% CI)	n AEs
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Neck pain	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.9)	1
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Joint swelling	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Eye disorders	8	0.6	(0.3; 1.2)	8	0	0.0	(0.0; 0.6)	0
Conjunctivitis	3	0.2	(0.0; 0.7)	3	0	0.0	(0.0; 0.6)	0
Grade 1	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0
Missing	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Chalazion	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Conjunctival hemorrhage	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Eye irritation	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Eye pain	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Eye swelling	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Ear and labyrinth disorders	5	0.4	(0.1; 0.9)	5	2	0.3	(0.0; 1.1)	2
Ear pain	5	0.4	(0.1; 0.9)	5	1	0.2	(0.0; 0.9)	1
Grade 1	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0
Grade 2	3	0.2	(0.0; 0.7)	3	1	0.2	(0.0; 0.9)	1
Vertigo	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Skin and subcutaneous tissue disorders	5	0.4	(0.1; 0.9)	5	6	0.9	(0.3; 2.0)	6

	CYD Dengue Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one:	n subjects	% subjects	(95% CI)	n AEs	n subjects	% subjects	(95% CI)	n AEs
Dermatitis allergic	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0
Grade 1	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0
Dermatitis	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.9)	1
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Dermatitis contact	1	<0.1	(0.0; 0.4)	1	2	0.3	(0.0; 1.1)	2
Grade 1	1	<0.1	(0.0; 0.4)	1	1	0.2	(0.0; 0.9)	1
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Urticaria	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Dermatosis	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Pruritus generalized	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Rash	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Immune system disorders	3	0.2	(0.0; 0.7)	3	1	0.2	(0.0; 0.9)	1
Allergy to arthropod bite	3	0.2	(0.0; 0.7)	3	1	0.2	(0.0; 0.9)	1
Grade 1	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Missing	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Injury, poisoning and procedural complications	3	0.2	(0.0; 0.7)	3	5	0.8	(0.3; 1.8)	6
Abdominal injury	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 1	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Humerus fracture	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Joint injury	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0

	CYD Dengue Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one:	n subjects	% subjects	(95% CI)	n AEs	n subjects	% subjects	(95% CI)	n AEs
Grade 2	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Back injury	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Face injury	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Laceration	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Limb injury	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 1	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Muscle strain	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 3	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Procedural pain	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Reproductive system and breast disorders	3	0.2	(0.0; 0.7)	3	1	0.2	(0.0; 0.9)	1
Dysmenorrhea	3	0.2	(0.0; 0.7)	3	1	0.2	(0.0; 0.9)	1
Grade 2	2	0.2	(0.0; 0.6)	2	1	0.2	(0.0; 0.9)	1
Grade 3	1	<0.1	(0.0; 0.4)	1	0	0.0	(0.0; 0.6)	0
Renal and urinary disorders	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0
Dysuria	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0
Grade 1	2	0.2	(0.0; 0.6)	2	0	0.0	(0.0; 0.6)	0
Metabolism and nutrition disorders	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Decreased appetite	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Fibroadenoma of breast	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1
Grade 2	0	0.0	(0.0; 0.3)	0	1	0.2	(0.0; 0.9)	1

	CYD Dengue Vaccine Group (N=1333)				Control Group (N=664)			
Subjects experiencing at least one:	n subjects	% subjects	(95% CI)	n AEs	n subjects	% subjects	(95% CI)	n AEs

1 Unsolicited adverse events listed here excludes Serious Adverse Events that are presented separately. MedDRA=Medical Dictionary for Regulatory Activities. Intensity was graded using the grading scale described above (Table S5) where applicable, otherwise as follows: Intensity Grade 1=No interference with activity; Grade 2=Some interference with activity; Grade 3=Significant; prevents daily activity.

Table S8: Summary of dengue virus serotype-specific $PRNT_{50}$ antibody responses
Geometric mean titers (and 95% confidence intervals) against the CYD vaccine's parental dengue virus strains at baseline and 28 days after the second and third injections (intention-to-treat population for immunogenicity)

	Vaccine group			Control group
	Dengue seropositive at baseline (N=1048*)	Dengue seronegative at baseline (N=251*)	All (N=1301)	All (N=643)
Baseline				
Serotype 1	278 (247–313)	5 (ND)	128 (112–145)	119 (99–142)
Serotype 2	306 (277–338)	5 (ND)	138 (123–156)	115 (97–136)
Serotype 3	261 (235–289)	5 (ND)	121 (108–136)	114 (96–136)
Serotype 4	73.3 (66.6–80.7)	5 (ND)	44 (40–48)	39.0 (34–45)
28 days after second injection (Month 7)				
Serotype 1	912 (820–1016)	25.5 (21.3–30.5)	458 (406–517)	128 (106–154)
Serotype 2	1050 (967–1139)	69.4 (58.1–83.0)	622 (566–684)	124 (104–148)
Serotype 3	907 (832–989)	71.2 (61.4–82.5)	556 (506–610)	117 (98–139)
Serotype 4	353 (328–380)	72.9 (61.1–87.1)	261 (242–281)	40.9 (36–47)
28 days after third injection (Month 13)				
Serotype 1	703 (634–781)	35.3 (29.8–41.9)	395 (353–441)	121 (101–145)
Serotype 2	860 (796–930)	105 (89.3–125)	574 (528–624)	129 (109–152)
Serotype 3	762 (699–830)	93.6 (80.3–109)	508 (465–555)	124 (105–147)
Serotype 4	306 (286–328)	89.5 (76.1–105)	241 (226–258)	44.3 (39–51)

N: number of participants in the intention-to-treat population for immunogenicity. Dengue seropositivity was defined as the percentage of participants with a plaque-reduction neutralization test ($PRNT_{50}$) titer of 10 or higher against at least one serotype. GMT: geometric mean titer, calculated using a titer of 5 for samples below the assay detection limit of 10. ND: not determined. Numbers in parentheses: 95% confidence interval. *Dengue serostatus at baseline was undetermined for 2 participants.

Supplementary References

1. Boaz M, Janosczyk H, Garg S, et al. Virological confirmation of suspected dengue in a Phase 2 Latin American vaccine trial: Implications for vaccine efficacy evaluation. Trials Vaccinol 2014;3:127-33.
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3. Capeding MR, Tran NH, Hadinegoro SR, et al. Clinical efficacy and safety of a novel tetravalent dengue vaccine in healthy children in Asia: a phase 3, randomised, observer-masked, placebo-controlled trial. Lancet 2014.