

# A Pregnancy Registry to Evaluate the Safety of Dengue Vaccine among Inadvertently Exposed Pregnant Women and their Offsprings

**First published:** 25/06/2021

**Last updated:** 18/12/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS31210

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### Study ID

46441


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### DARWIN EU® study

No

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### Study countries

 Brazil

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### Study description

This will be a Pregnancy Registry Study that utilizes active identification and enrollment of a cohort of pregnant women of any age and their offsprings who were inadvertently exposed to CYD tetravalent dengue vaccine (CYD-TDV) anytime during the pregnancy or in the 30 days preceding their last menstrual period (i.e., periconceptional period). Data collection will utilize a hybrid approach comprised of the use of structured interviews supplemented by medical records review (primary data sources), and the use of health and mortality databases (secondary data sources).

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

**Sanofi**

**First published:** 01/02/2024

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**Institution**

## Contact details

### **Study institution contact**

Trial Transparency Team Trial Transparency Team Contact-  
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**Study contact**

[Contact-US@sanofi.com](mailto:Contact-US@sanofi.com)

**Primary lead investigator**

Trial Transparency Team Trial Transparency Team

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 07/10/2019

Actual: 26/05/2020

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**Study start date**

Planned: 22/01/2022

Actual: 11/03/2022

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**Date of final study report**

Planned: 21/08/2023

Actual: 08/07/2024

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Sanofi

# Study protocol

[rdct-dng16-protocol.pdf](#) (1.88 MB)

## Regulatory

### **Was the study required by a regulatory body?**

No

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### **Is the study required by a Risk Management Plan (RMP)?**

EU RMP category 3 (required)

## Other study registration identification numbers and links

DNG16,U1111-1212-3443,NCT04023708

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Main study objective:**

To evaluate the safety of CYD-TDV in pregnant women and their offsprings inadvertently exposed during pregnancy or up to 30 days preceding their last menstrual period (LMP) with regards to maternal, pregnancy, birth, neonatal and infant outcomes.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

DENGVAXIA

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**Medical condition to be studied**

Exposure during pregnancy

## Population studied

**Age groups**

- Preterm newborn infants (0 - 27 days)
- Term newborn infants (0 - 27 days)
- Infants and toddlers (28 days - 23 months)

- Adolescents (12 to < 18 years)
  - Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
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### **Special population of interest**

Pregnant women

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### **Estimated number of subjects**

214

## **Study design details**

### **Outcomes**

The primary study endpoints will include all serious and non-serious maternal, pregnancy related, birth outcomes, neonatal and infant events occurring anytime between cohort entry and the end of follow-up for each event.

Participant unique anonymized identifier, relevant maternal baseline characteristics, maternal data (type of conception, date of LMP, and estimated date of delivery), characteristics of prenatal care, characteristics of CYD-TDV exposure (dates doses administered, number of doses, dose intervals, and timing of pregnancy exposure), offspring data (sex, length, weight, and breastfeeding history).

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### **Data analysis plan**

To assess the safety of CYD-TDV exposure during pregnancy, descriptive analyses will be undertaken to summarize the maternal, pregnancy, birth, neonatal and infant outcome data using frequencies expressed as absolute risk estimates with corresponding 95% CIs, and these data will be compared background incidence rates for the age-matched population in Paraná prior to the availability of CYD-TDV (i.e. unvaccinated comparator population). In

addition, analyses will be stratified by reporting status (prospective vs. retrospective), as well as by trimester of exposure, with an additional stratum for periconceptional exposure. Reports of multiple CYD-TDV exposures during a pregnancy will be classified according to the earliest pregnancy exposure. Descriptive analyses will also be undertaken to characterize pregnancy exposure with regards to number of doses received, dose intervals and trimester of exposure, as well as the population of pregnant women inadvertently exposed to CYD-TDV.

## Documents

### Study report

[rdct-dng16-csr-synopsis.pdf](#) (232.7 KB)

## Data management

### ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

### Data sources (types)

[Other](#)

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### Data sources (types), other

Spontaneous reporting system, Prospective patient-based data collection,  
Exposure registry, Mortality database

## Use of a Common Data Model (CDM)

### **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No