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

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# Administrative details

#### **EU PAS number**

EUPAS31210

#### **Study ID**

46441

#### DARWIN EU® study

No

## **Study countries**

Brazil

## **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).

**Study status** 

Finalised

# Research institutions and networks

# Institutions

# Sanofi

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Institution

# Contact details

Study institution contact

# Trial Transparency Team Trial Transparency Team Contact-US@sanofi.com

Study contact

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

**Study start date** Planned: 22/01/2022 Actual: 11/03/2022

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

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

## 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

# Name of medicine DENGVAXIA

## 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)

#### Special population of interest

Pregnant women

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).

#### 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

## Data sources

#### Data sources (types)

Other

#### 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

## **Check completeness**

Unknown

## **Check stability**

Unknown

## **Check logical consistency**

Unknown

# Data characterisation

## Data characterisation conducted

No