Post-Authorization Safety Study Cohort Event Monitoring for Dengvaxia®, CYD-TDV Dengue Vaccine (DNG15-Post Authorisation safety Surveillance study)

First published: 06/08/2019

Last updated: 04/10/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS28947

Study ID

48340

DARWIN EU® study

No

Study countries

Brazil

Mexico

Philippines

Study description

DNG15 is a prospective multi-national non-interventional study that includes two components of Cohort Event Monitoring (CEM):

1. Short-term safety surveillance with a follow-up of 6 months after each Dengvaxia® dose administration followed by,

2. Long-term safety surveillance with a follow-up of five years after the first dose.

Study status

Finalised

Research institutions and networks

Institutions

Sanofi

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Study Transparency team Study Transparency team
contact-US@sanofi.com

Study contact

contact-US@sanofi.com

Primary lead investigator

Study Transparency team Study Transparency team

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 24/11/2016

Study start date

Actual: 13/12/2016

Date of final study report

Planned: 05/09/2023

Actual: 05/09/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

sanofi pasteur

Study protocol

rdct-dng15-amended-protocol10.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

DNG15 - NCT02948933

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Main study objective:

To evaluate the safety profile of Dengvaxia® when used in the real-world immunization setting.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

DENGVAXIA

Anatomical Therapeutic Chemical (ATC) code

(J07BX04) dengue virus vaccines

dengue virus vaccines

Population studied

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)

Estimated number of subjects

30000

Study design details

Outcomes

Selected AEs (allergic reactions including anaphylactic, multi-organ failure, aseptic meningitis, Guillain-Barré syndrome, Fisher syndrome, acute disseminated encephalomyelitis, epilepsy, convulsions), during short-term period,6 months after each dose.Hospitalized dengue disease.Other SAEs during the short term surveillance, SAEs leading to hospitalization or death during the long term. Misuse of Dengvaxia® i.e. not in accordance with the authorized product information.

Data analysis plan

To quantify the incidence of the selected AEs, simple frequencies, incidence rates (with 95% confidence intervals), and time of occurrence will be obtainedIn order to assess the association between Dengvaxia® and each of the selected AEs for which a risk window can be defined after vaccination (primary objective for the short-term surveillance period), occurrence of three (3) cases or more will trigger a SCCS (Self-controlled case series) analysis using CEM data collected over the four and half (4.5) months following each vaccine dose/A sensitivity analysis will be conducted using all 6 months follow-up period for the SCCS instead of 4.5Lifetable analyses of time to event onset will be obtained in order to identify safety signals For hospitalized dengue, occurrence of three (3) or more confirmed cases will trigger a nested case-control analysis

Documents

Study report

rdct-dng15-csr-synopsis.pdf (187.65 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

Data sources (types), other

Prospective patient-based data collection

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