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: 14/03/2024

Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/48340

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
Ongoing

Research institution 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
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

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

sanofi pasteur

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 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

Anatomical Therapeutic Chemical (ATC) code
(J07BX) Other viral 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

Data management

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