Effectiveness evaluation of the local additional risk minimisation measures for STAMARIL® in the United Kingdom: a survey for healthcare professionals and vaccinees

First published: 22/02/2023

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/105873

EU PAS number

EUPAS50782

Study ID

105873

DARWIN EU® study

No

Study countries

United Kingdom

Study description

This will be a national, multicentre, prospective, cross-sectional, and multi-channel survey based on primary data collection conducted separately among qualified HCPs (physicians, nurses and pharmacists) and STAMARIL® vaccinees (or their parents/guardians if vaccinees are younger than 18 years old) in the UK (England, Wales, Northern Ireland and Scotland). The survey will be conducted primarily through a web (and/or paper for vaccinees) questionnaire. The survey will be conducted within 12 to 18 months following the implementation of the local aRMM in the UK as per the European guideline on good pharmacovigilance practices (GVP) – Module XVI (Rev 3).

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

Study contact

contact-us@sanofi.com

Primary lead investigator

Trial Transparency Team

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 02/12/2021

Actual: 02/12/2021

Study start date

Planned: 01/03/2023

Actual: 01/03/2023

Date of final study report

Planned: 29/02/2024

Actual: 25/06/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi

Study protocol

rdct-sta00059-protocol-amendment.pdf(2.68 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

To measure awareness and utilisation of any standardized UK yellow fever pre-vaccination checklist(s), evaluate knowledge and understanding of the key safety messages in checklist(s), among qualified HCPs of designated authorised YFVCs in UK.
To measure distribution of the STAMARIL® PIL by qualified HCPs of designated authorised YFVCs and verify the receipt of the PIL by yellow fever vaccinees.

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Survey

Study drug and medical condition

Name of medicine, other

STAMARIL

Stamaril Pasteur

Live attenuated yellow fever virus

Anatomical Therapeutic Chemical (ATC) code

(J07BL) Yellow fever vaccines

Yellow fever vaccines

(J07BL01) yellow fever, live attenuated

yellow fever, live attenuated

Medical condition to be studied

Yellow fever

Population studied

Age groups

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

600

Study design details

Outcomes

Awareness of the UK (STAMARIL®) yellow fever pre-vaccination checklist Utilisation of any standardised yellow fever pre-vaccination checklist(s) Distribution of the STAMARIL® PIL by qualified HCPs to vaccinees Knowledge and understanding of the key safety messages Receipt of the STAMARIL® PIL.

Data analysis plan

The statistical analysis will be conducted using the SAS® software V9.4 (SAS Institute North Carolina, USA), or R version 3.6 or higher on Windows™. All the analyses will be descriptive. Continuous variables will be described by their

number (of valid cases, of missing values), mean, standard deviation, and median, Q1, Q3, minimum and maximum. Categorical variables will be described as the total number and relative percentage per category. The proportions of respondents who provide correct answers to each question will be calculated. Confidence intervals of 95% will be calculated when relevant.

Documents

Study report

rdct-sta00059-csr-abstract.pdf(156.54 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Survey

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