

# 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

**Last updated:** 23/07/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS50782

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### Study ID

105873

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### DARWIN EU® study

No

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### Study countries

United Kingdom

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## 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).

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## Study status

Finalised

# Research institutions and networks

## Institutions

Sanofi

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Institution

## Contact details

### Study institution contact

Trial Transparency Team [contact-us@sanofi.com](mailto:contact-us@sanofi.com)

Study contact

[contact-us@sanofi.com](mailto: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

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**Study start date**

Planned: 01/03/2023

Actual: 01/03/2023

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**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

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### **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

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##### **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

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### **Non-interventional study design, other**

Survey

## Study drug and medical condition

### **Medicinal product name, other**

STAMARIL

Stamaril Pasteur

Live attenuated yellow fever virus

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### **Anatomical Therapeutic Chemical (ATC) code**

(J07BL) Yellow fever vaccines

Yellow fever vaccines

(J07BL01) yellow fever, live attenuated

yellow fever, live attenuated

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### **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)
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## **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.

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### **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

### 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

Survey

## 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