A Survey of Healthcare Professionals in Europe to Evaluate the Effectiveness of the ENJAYMO™ Physician's Guide

First published: 18/06/2024

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000209

EU PAS number

EUPAS1000000209

Study ID

1000000209

DARWIN EU® study

No

Study countries

☐ Austria

- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] Netherlands

Study description

This is a multinational, non-interventional, cross sectional survey study to evaluate the effectiveness of the ENJAYMO™ Physician’s Guide among EEA-based HCPs.

The current study is planned to be conducted among HCPs in countries in the EEA where the product is expected to be commercially available for at least 6 months. The survey will be launched no sooner than 6 months, and no longer than 18 months, after the ENJAYMO™ Physician’s Guide has been disseminated in each participating country. The survey may be conducted in up to 2 waves with the second wave of the same survey opening 6 to 12 months after the first wave is closed.

The survey is anticipated to be open between 3 to 6 months per country per wave. Depending on response rates, follow-up reminders will be sent to non-respondents to endeavor to achieve the target sample size, and the medical scientific liaison team of Sanofi could also be involved in some countries to advocate via their personal contacts the participation to the survey for HCPs already contacted via e-mail. In the event that less than 30 completed surveys are achieved in the first wave of the study, a second wave of the same survey will be triggered.

Data will be collected by web-based electronic data capture. Information collected will include the receipt and reading of the ENJAYMO™ Physician’s Guide, knowledge of the key information included in the ENJAYMO™ Physician’s

Guide, the impact of the ENJAYMO™ Physician's Guide on clinical action, and HCP characteristics.

Study status

Ongoing

Research institutions and networks

Institutions

Sanofi

First published: 01/02/2024

Last updated: 01/02/2024

Institution

ICON Commercialisation & Outcomes

☐ Germany

☐ Ireland

First published: 19/03/2010

Last updated: 05/07/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

William Blumentals

Study contact

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Primary lead investigator

Samantha Kimball

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 28/06/2021

Actual: 28/06/2021

Study start date

Planned: 07/03/2022

Actual: 07/03/2022

Data analysis start date

Planned: 31/10/2025

Date of final study report

Planned: 03/02/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Genzyme Europe BV

Study protocol

0085-0644 Sanofi ENJAYMO Survey Protocol__v2.0_05Jun2024_redactedd.pdf
(566.02 KB)

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)

Other study registration identification numbers and links

Protocol number: CEF-0205

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Study design:

This is a multinational, non-interventional, cross sectional survey study to evaluate the effectiveness of the ENJAYMO™ Physician’s Guide among EEA-based HCPs.

Main study objective:

To assess HCPs’ knowledge levels of key information included in the ENJAYMO™ Physician’s Guide across these 4 domains:

- Indication for cold agglutinin disease (CAD) patients only
- Important potential risks of serious infections including meningococcal infections
- Recommendations for vaccination of patients as per local regulations
- Recommendations for monitoring and counseling patients to promote real-world safe-use conditions

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Name of medicine

ENJAYMO

Study drug International non-proprietary name (INN) or common name

SUTIMLIMAB

Anatomical Therapeutic Chemical (ATC) code

(L04AA55) sutimlimab

sutimlimab

Medical condition to be studied

Cold agglutinins

Additional medical condition(s)

Cold agglutinin disease

Population studied

Short description of the study population

The current study is planned to be conducted among HCPs in countries in the EEA where the product is expected to be commercially available for at least 6 months.

Age groups

Adult and elderly population (≥18 years)

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

50

Study design details

Outcomes

HCPs’ knowledge levels of key information included in the ENJAYMO™ Physician’s Guide

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Data analysis plan

Descriptive data analyses will be conducted for all primary and secondary objectives. Descriptive statistics for continuous data will include N, means, and standard deviations. Results for some continuous variables may include ranges (minimums and maximums) and medians as well. Categorical data will be summarized using frequency counts and percentages. Knowledge levels will be calculated with 95% 2-sided CI. Knowledge levels will also be stratified by items with potential to confound the knowledge level (e.g., country, specialty, reads/uses vs. did not read/does not use the ENJAYMO™ Physician’s Guide, prescribing status). Missing data will be reported, but no replacement or

imputation will be performed.

Summary results

Not applicable

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

HCPs 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