SURVEY TO EVALUATE THE KNOWLEDGE AND UNDERSTANDING OF THE KEY SAFETY MESSAGES IN THE HEALTHCARE PROFESSIONAL GUIDE AND THE PATIENT GUIDE FOR SULIQUA

First published: 09/05/2018

Last updated: 14/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS23920

Study ID

46147

DARWIN EU® study

No

Study countries

Belgium

Czechia

Hungary

Romania

Slovenia

United Kingdom

Study description

The objective is to assess the knowledge and understanding of the key safety messages in the health care professionals (HCP) and patient guides among HCPs who prescribed or dispensed SULIQUA and patients treated with SULIQUA, respectively. The study will be a cross-sectional survey conducted in 3 distinct waves in selected European countries, in which SULIQUA® will be marketed. Each wave will correspond to the sequential inclusion of the targeted countries according to the timing of SULIQUA launch and implementation of risk minimization measures in these countries. Each wave will last for approximately 7 months from HCP/patient enrolment to the submission of a report

Study status

Finalised

Research institutions and networks

Institutions

Sanofi

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Institution

Contact details

Study institution contact

Trial Transparency Team Trial Transparency Team contact-us@sanofi.com

Study contact

contact-us@sanofi.com

Primary lead investigator

Trial Transparency Team Trial Transparency Team

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/05/2018

Actual: 31/05/2018

Study start date

Planned: 01/01/2019

Actual: 01/09/2019

Date of final study report

Planned: 30/06/2022

Actual: 13/01/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi

Study protocol

rdct-INSLIC08571-protocol-PDFA.pdf (2.73 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)

Other study registration identification numbers and links

INSLIC08571 / OBS16114

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To assess the knowledge and understanding of the key safety messages in the health care professionals (HCP) and patient guides among HCPs who prescribed or dispensed SULIQUA and patients treated with SULIQUA, respectively.

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Post authorization safety study (PASS)

Study drug and medical condition

Medical condition to be studied

Type 2 diabetes mellitus

Population studied

Short description of the study population

HCPs as well as patients/caregivers in 3 waves.

Inclusion criteria

The HCP survey will be conducted among HCPs meeting the following inclusion criteria:

1. HCPs who prescribe/deliver SULIQUA

The patient survey will be conducted among patients (or their caregivers) meeting the following inclusion criteria:

1. Respondents (patients or caregivers of a patient) who receive SULIQUA

Exclusion criteria

HCP survey

The following exclusion criteria will be checked at the beginning of the web questionnaire:

1. HCPs who are not involved in patient treatment
2. HCPs who may have conflicts of interest with the survey (i.e. HCPs employed by regulatory bodies, pharmaceutical industries)
3. HCPs who have participated in the previous waves of the survey
4. HCPs who have already 2 or more colleagues participating in the survey from the same practice in the same wave

Patient survey

The following exclusion criteria will be checked at the beginning of the web questionnaire:

1. Patients (or caregivers) who may have conflicts of interest with the survey
2. Patients (or caregivers) who have participated in the previous waves of the survey

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Age groups

- 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

900

Study design details

Outcomes

Correct answers to questions related to key safety messages in the HCP and patient guides.

Data analysis plan

Descriptive analysis will be conducted to calculate the proportions of respondents who provide correct answers to safety related questions

Documents

Study results

rdct-INSLIC08571-study report abstract-PDFA.pdf (1.06 MB)

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

HCP 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