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

PURI
https://redirect.ema.europa.eu/resource/46147

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 institution and networks

Institutions

Sanofi
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Institution

Contact details

Study institution contact
Trial Transparency Team Trial Transparency Team
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

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

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