Healthcare Professional Survey to Assess the Effectiveness of Risk Evaluation and Mitigation Strategy for Dulaglutide (36 Month) (H9X-MC-B003)

First published: 01/08/2017

Last updated: 18/08/2017

Study Ongoing

Administrative details

EU PAS number

EUPAS20159

Study ID

20646

DARWIN EU® study

No

Study countries

United States

Study description

This study aims to assess the impact of Risk Evaluation and Mitigation Strategy (REMS) for dulaglutide on healthcare professional knowledge regarding the risk of pancreatitis and the potential risk of medullary thyroid carcinoma associated with dulaglutide therapy. The study will be conducted in the United States at 36 months after initial approval of the REMS.

Study status

Ongoing

Research institutions and networks

Institutions

Nielsen

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Ayad Ali ali_ayad@lilly.com

Study contact

ali_ayad@lilly.com

Primary lead investigator

Ayad Ali

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 30/04/2017

Study start date
Planned: 15/05/2017

Actual: 15/05/2017

Date of final study report
Planned: 15/08/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

H9X-MC-B003_Registered.pdf (242.43 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

This study aims to assess the impact of a Risk Evaluation and Mitigation Strategy (REMS) for dulaglutide on healthcare provider knowledge regarding the risk of pancreatitis and the potential risk of medullary thyroid carcinoma associated with dulaglutide therapy. A threshold of at least 80% will be used to assess healthcare provider understanding of the key risk messages.

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Survey Design

Study drug and medical condition

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

DULAGLUTIDE

Population studied

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

200

Study design details

Outcomes

The target for the assessment of the effectiveness of the 36 month REMS effectiveness assessment survey is that at least 80% of participating HCPs

demonstrate awareness of the key risk messages in the REMS program.

Data analysis plan

Data collected from the survey will be reported as descriptive statistics. Frequency distributions with 95% CIs will be calculated for respondent responses to all questions that address the survey objectives

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

Cross-Sectional Survey, involving primary data collection.

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