

Healthcare Professional Survey to Assess the Effectiveness of Risk Evaluation and Mitigation Strategy for Dulaglutide (H9X-MC-B002)

First published: 16/08/2016

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Study

Finalised

Administrative details

EU PAS number

EUPAS14792

Study ID

20649

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 18 months after initial approval of the REMS.

Study status

Finalised

Research institutions and networks

Institutions

Nielsen

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Ayad Ali

Study timelines

Date when funding contract was signed

Planned: 30/11/2014

Actual: 30/11/2014

Study start date

Planned: 30/11/2015

Actual: 30/11/2015

Date of final study report

Planned: 25/02/2016

Actual: 25/02/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

[H9X-MC-B002_Registered.pdf](#) (241.41 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 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

Main study objective:

This primary study objective is to evaluate the impact of the risk evaluation and mitigation strategy on HCP and understanding regarding the risk of pancreatitis and the potential risk of medullary thyroid carcinoma associated with

dulaglutide therapy as communicated through the risk evaluation and mitigation strategy

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

Short description of the study population

Certain health care professionals (HCPs) who have prescribed TRULICITY to at least 1 patient.

The participant must: live in the US, be a current or past prescriber of TRULICITY, and be an HCP (including physicians [family practice, internal medicine, and endocrinologists], nurse practitioners, physician assistants)

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)
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Estimated number of subjects

201

Study design details

Outcomes

The risk evaluation and mitigation strategy will be considered effective if the majority of respondents demonstrate they are aware of the key risks communicated.

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