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

**First published:** 16/08/2016

**Last updated:** 18/08/2017

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

**First published:** 01/02/2024

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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

Primary lead investigator

## Study timelines

**Date when funding contract was signed**
Planned: 30/11/2014

Actual: 30/11/2014

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**Study start date**
Planned: 30/11/2015

Actual: 30/11/2015

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**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

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**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)

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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)

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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.

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**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