

# 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

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### Study ID

20646

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### DARWIN EU® study

No

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### Study countries

United States

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### 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.

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### **Study status**

Ongoing

## 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**

[ali\\_ayad@lilly.com](mailto:ali_ayad@lilly.com)

### **Primary lead investigator**

Ayad Ali

## Study timelines

### **Date when funding contract was signed**

Planned: 30/04/2017

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### **Study start date**

Planned: 15/05/2017

Actual: 15/05/2017

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### **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

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### **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

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##### **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

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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

### **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**

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.

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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](#)

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### **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

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No