

# Healthcare Professional Survey to Assess the Effectiveness of Additional Risk Minimization Measures for Prescribing and Administration of Concentrated Insulin Human (Humulin R U-500 KwikPen) (B5K-MC-B012)

**First published:** 06/11/2017

**Last updated:** 08/11/2017

Study

Planned

## Administrative details

### EU PAS number

EUPAS21539

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### Study ID

21607

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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 evaluate the impact of the Dear Health Care Provider Letter on prescriber understanding about the risk of hypoglycemia associated with Humulin R U-500 KwikPen and educational points to be emphasized in discussion with patients.

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### Study status

Planned

## Research institutions and networks

### Institutions

#### Covance

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

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Institution

## Contact details

### Study institution contact

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

Study contact

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

## Primary lead investigator

Ayad Ali

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 30/11/2016

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### Study start date

Planned: 31/07/2017

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### Date of final study report

Planned: 31/10/2017

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Eli Lilly and Company

## Study protocol

[B5K-MC-B012\\_EU\\_PAS\\_Registered.pdf](#) (1.06 MB)

## Regulatory

## **Was the study required by a regulatory body?**

No

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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:**

The primary study objective is to evaluate the impact of the Dear Healthcare Professional letter on prescriber understanding about the risk of hypoglycemia associated with Humulin R U-500 KwikPen and educational points to be emphasized in discussion with patients.

## 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**

INSULIN HUMAN

## 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 risk minimization tools 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. In addition to the overall analysis, survey data will be analyzed to determine if there are any differences for HCPs and medical specialty.

## 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