# Healthcare Professional and Patient Surveys to Assess the Effectiveness of Risk Minimization Measures for Concentrated Insulin Lispro (Humalog 200 units/mL KwikPen) (F3Z-MC-B020)

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## Administrative details

#### **PURI**

https://redirect.ema.europa.eu/resource/20643

#### **EU PAS number**

**EUPAS14789** 

#### Study ID

20643

#### **DARWIN EU® study**

No

#### **Study countries**

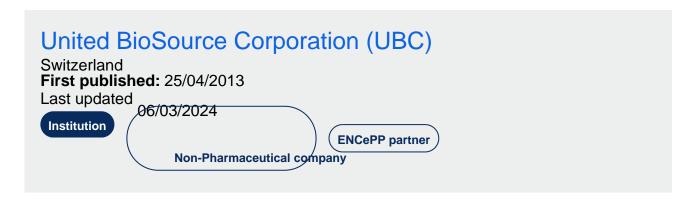
**United States** 

#### Study description

This study aims to evaluate the impact of the additional risk minimization measures on healthcare professional and patient understanding and behavior regarding the risk of hypoglycemia and/or hyperglycemia due to medication errors associated with administration of Humalog KwikPen 200 units/ml. The study will be conducted in the United States within 18 months of product launch.

## Research institution and networks

## Institutions



## Contact details

Study institution contact

Ayad Ali

Study contact

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**Primary lead investigator** 

Ayad Ali

Primary lead investigator

## Study timelines

Date when funding contract was signed

Planned:

31/10/2014

Study start date

Planned:

30/08/2016

Actual:

15/08/2016

Date of final study report

Planned: 30/01/2017

# Sources of funding

Pharmaceutical company and other private sector

## More details on funding

Eli Lilly and Company

## Study protocol

F3Z-MC-B020\_EU-PAS-Registered.pdf(303.88 KB)

## Regulatory

Was the study required by a regulatory body? No

Is the study required by a Risk Management Plan (RMP)? Non-EU RMP only

# Methodological aspects

# Study type list

#### Study type:

Non-interventional study

#### Scope of the study:

Other

#### If 'other', further details on the scope of the study

Evaluation of the Effectiveness of a Risk Minimization Plan

#### Main study objective:

This primary study objective is to evaluate the impact of the risk minimization measures on HCP and patient understanding regarding the risk of hypoglycemia and/or hyperglycemia due to medication errors associated with administration of Humalog KwikPen 200 units/ml as communicated through the risk minimization measures.

## 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 INSULIN LISPRO

## 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**

560

## 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.

#### 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

### 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