# Healthcare Professional and Patient Surveys to Assess the Effectiveness of Risk Minimisation Measures for Concentrated Insulin Lispro (Humalog 200 units/ml KwikPen; Liprolog 200 units/ml KwikPen) (F3Z-MC-B019)

**First published:** 10/05/2016

**Last updated:** 26/09/2017

Study Finalised

## Administrative details

**PURI**

https://redirect.ema.europa.eu/resource/21063

**EU PAS number**

EUPAS13422

**Study ID**

21063

**DARWIN EU® study**

No

**Study countries**

- ☐ France
- ☐ Germany
- ☐ Sweden

**Study description**

This study aims to evaluate the impact of the additional risk minimisation measures on healthcare professional and patient understanding and behaviour regarding the risk of hypoglycaemia and/or hyperglycaemia due to medication errors associated with administration of Humalog KwikPen 200 units/ml. The study will be conducted in France, Germany, and Sweden within 12-18 months of product launch.

**Study status**

Finalised

# Research institutions and networks

## Institutions

### United BioSource Corporation (UBC)

☐ Switzerland

**First published:** 25/04/2013

**Last updated:** 06/03/2024

Institution | Non-Pharmaceutical company | ENCePP partner

# 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: 31/10/2014

Actual: 31/10/2014

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**Study start date**

Planned: 30/06/2016

Actual: 16/05/2016

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**Date of final study report**

Planned: 30/06/2017

Actual: 29/03/2017

# Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Eli Lilly and Company

## Study protocol

F3Z-MC-B019_EU-PAS-Registered.pdf(494.57 KB)

## Regulatory

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

No

**Is the study required by a Risk Management Plan (RMP)?**

EU RMP category 3 (required)

# 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

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**Main study objective:**

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

## 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 LISPRO

## Population studied

**Short description of the study population**

HCPs involved in the treatment and management of patients with diabetes who are aware of the insulin product Humalog 200 units/ml KwikPen were eligible. Patients who are 18 years or older, have diabetes and have been prescribed Humalog 200 units/ml KwikPen were eligible.
HCPs and patients in the United Kingdom (UK, if product uptake does not allow for participation, another comparable EU country will be selected), Germany, and one additional EU country, to be determined based on product launch and market uptake.

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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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**Special population of interest**

Other

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**Special population of interest, other**

Diabetes mellitus patients

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**Estimated number of subjects**

560

# Study design details

**Outcomes**

The risk minimisation 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 analysed to determine if there are any differences by country and, for HCPs, medical specialty.

## Documents

**Study results**

F3Z-MC-B019_Final_Report_EUPAS_Registered.pdf(1020.41 KB)

# 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