# NN8022-4241 In-market utilisation of liraglutide used for weight management in Europe: a retrospective medical record review study

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# Administrative details

EU PAS number
EUPAS16225
Study ID
35489
DARWIN EU® study
No
Study countries
Germany
Italy

#### **Study description**

The aim of this study is to investigate usage of liraglutide for weight management in clinical practice.

#### **Study status**

Finalised

# Research institutions and networks

#### **Institutions**

# **Novo Nordisk**

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Institution

Multiple centres: 50 centres are involved in the study

# Contact details

#### Study institution contact

Clinical Reporting Anchor and Disclosure (1452) Novo Nordisk A/S pactadmin@novonordisk.com

Study contact

pactadmin@novonordisk.com

#### **Primary lead investigator**

Clinical Reporting Anchor and Disclosure (1452) Novo Nordisk A/S

**Primary lead investigator** 

# Study timelines

#### Date when funding contract was signed

Planned: 25/02/2016 Actual: 25/02/2016

#### Study start date

Planned: 16/11/2016 Actual: 22/12/2016

#### Date of final study report

Planned: 31/05/2020 Actual: 04/10/2019

# Sources of funding

• Pharmaceutical company and other private sector

# More details on funding

Novo Nordisk

# Study protocol

4241-protocol-redacted.pdf (526.16 KB)

4241-protocol-version-8.0-eu-pas-reg-redacted.pdf (476.15 KB)

# Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

# Other study registration identification numbers and links

U1111-1185-3661 (WHO)

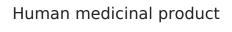
# Methodological aspects

Study type

Study type list

**Study topic:** 

Disease /health condition



#### **Study type:**

Non-interventional study

#### Scope of the study:

Drug utilisation

Safety study (incl. comparative)

#### **Data collection methods:**

Secondary use of data

#### Main study objective:

To assess the use of Saxenda® according to the approved indication

# Study Design

#### Non-interventional study design

Cohort

Other

#### Non-interventional study design, other

Post Authorisation Safety Study (PASS)

# Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

LIRAGLUTIDE

# Population studied

#### Short description of the study population

To be eligible for this full study, patients were required to meet both of the following inclusion criteria:

- 1. Initiation of Saxenda® or Victoza® (initiation is defined as no prescription of the same brand within the previous 12 months).
- 2. Informed consent obtained before any study-related activities. Study-related activities (e.g. data collection) are any procedures that are carried out as part of the study, including activities to determine suitability of the study.

Exclusion criteria:

- 1. Patients or physicians who previously participated in interventional programs for Saxenda® or Victoza® will not be eligible to participate in the study.
- 2. For the full study, sites and patients included in the pilot will be excluded.

#### 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**

316

# Study design details

#### **Outcomes**

Number of p with BMI above or equal to 30 kg/m^2Number of patients with BMI above or equal to 27kg/m^2 and below 30 kg/m^2 and 1 or more comorbidityNumber of patients with above or equal to 27 kg/m^2 and below 30 kg/m^2 and no comorbiditiesNumber of patients with BMI below 27 kg/m^2Number of patients with BMI not measured, See attached protocol

#### Data analysis plan

As this is a descriptive study that will investigate in-market utilisation of liraglutide, no formal statistical testing will be conducted.

#### **Documents**

#### **Study results**

4241-nsr-nn-trials-redacted.pdf (1.13 MB)

# 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

Other	
Data sources (types), other	
Retrospective abstraction of data from patient medical re	ecords
Use of a Common Data Model (CDN	4)
CDM mapping	
No	
Data quality specifications	
Check conformance	
Unknown	
Unknown	
Unknown  Check completeness	
Unknown  Check completeness  Unknown	
Unknown  Check completeness Unknown  Check stability	

# Data characterisation

#### **Data characterisation conducted**

No