

# Pattern of use of incretin-based drugs in clinical practice

**First published:** 13/11/2015

**Last updated:** 02/04/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS10902

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### Study ID

28087

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### DARWIN EU® study

No

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### Study countries

 Italy

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### Study description

Incretin based drugs represent a class of hypoglycemic agents including different molecules approved during the last decade for the treatment of type 2 diabetes (T2DM). The clinical efficacy of this class of drugs in the treatment of

T2DM relies on the potentiation of the activity of the glucagon-like peptide 1 (GLP-1), an endogenous hormone belonging to the family of incretins that exerts an important role in the glycaemic homeostasis. In particular, on the basis of the mechanism of action, incretin-based drugs can be distinguished in two groups: glucagon-like peptide-1 analogues and dipeptidylpeptidase-4 inhibitors (DPP4i). Different randomized clinical trials demonstrated a positive risk/benefit profile for these hypoglycaemic agents. However, given the relatively recent commercialization, evidence on the pattern of use of these medications in clinical practice is still scarce. Different incretin-based medicines are currently available in Italy. Although a trend of increase of their use has been reported in literature, specific information concerning GLP-1 analogues and DPP-4i or the individual molecules belonging to the two groups are still lacking. Moreover, since the effectiveness and safety profile of these drugs cannot be considered completely established yet, evidence on the exposure of the general population to these medications, as well as the characterization of treated patients, becomes of paramount importance for planning large-scale observational pharmacoepidemiological studies. Therefore, the aim of this study is to describe in greater detail the pattern of use of incretin-based drugs in a large sample of the Italian general population. For this purpose, electronic health records from three population-based administrative data bases collecting information on almost 6 million inhabitants from 2 Italian regions, Tuscany and Umbria, and one Local Health Authority, Caserta, will be analyzed.

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## **Study status**

Finalised

## **Research institutions and networks**

### **Institutions**

## Agenzia regionale di sanità della Toscana (ARS Toscana)

 Italy

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**Last updated:** 23/03/2026

**Institution**

EU Institution/Body/Agency

ENCePP partner

## Department of Biomedical and Dental Sciences and Morphofunctional Imaging, University of Messina

 Italy

**First published:** 29/11/2021

**Last updated:** 20/08/2024

**Institution**

Educational Institution

Hospital/Clinic/Other health care facility

## National Centre for Epidemiology, Italian National Institute of Health Rome, Italy

### Contact details

#### Study institution contact

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Study contact

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### Primary lead investigator

Roberto Giuseppe

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 07/09/2015

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### Study start date

Actual: 09/11/2015

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### Date of final study report

Planned: 31/01/2017

Actual: 31/01/2017

## Sources of funding

- Other

## More details on funding

This is an independent study based on a spontaneous initiative of the participating partners

# Study protocol

[Pattern of use of incretin based drugs in clinical practice.pdf](#) (52.3 KB)

[Pattern of use of incretin based drugs in clinical practice\\_version\\_1.1.pdf](#) (62.27 KB)

## Regulatory

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

No

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

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To describe in greater details the pattern of use of incretin-based drugs in large sample of the Italian general population.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Pharmacoepidemiological study

## Study drug and medical condition

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

SITAGLIPTIN

VILDAGLIPTIN

SAXAGLIPTIN

ALOGLIPTIN

LINAGLIPTIN

EXENATIDE

LIRAGLUTIDE

### **Medical condition to be studied**

Type 2 diabetes mellitus

## Population studied

### **Short description of the study population**

All subjects registered in the administrative databases of Tuscany, Umbria and Caserta between January 1, 2008 and December 31, 2014 who had  $\geq 18$  years of age and at least 365 days of look-back period.

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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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### **Estimated number of subjects**

6000000

## Study design details

### **Data analysis plan**

The annual incidence and prevalence of use of incretin-based therapies, in the general population will be calculated per each year of the period 2008-2014.

The annual percentages of incident and prevalent incretin users on total number of users of antidiabetics will be observed. Annual percentage of new

users of GLP-1 analogues, DPP-4 inhibitors and relevant active principles belonging to the two groups will be calculated on the total number of new users of incretin-based therapies. Incident incretin users will be described in terms of demographic characteristics, previous antidiabetics treatments and other drug therapies.

## Documents

### Study results

[poster\\_incretin\\_Glasgow.pdf](#) (461.18 KB)

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### Study publications

[Roberto G, Barone-Adesi F, Giorgianni F, Pizzimenti V, Ferrajolo C, Tari M, Bar...](#)

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## 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 source(s)

ARS Toscana

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**Data source(s), other**

Regional Health Authority of Umbria Italy, Local Health Authority of Caserta Italy

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**Data sources (types)**

[Administrative healthcare records \(e.g., claims\)](#)

## 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**

Unknown