# Intensive Monitoring in Portugal: a Model to Assess Medicines in Real-Life Conditions. Antidiabetics as example. (MOMI)

**First published:** 25/01/2015

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

Study Ongoing

## Administrative details

**EU PAS number**

EUPAS8433

**Study ID**

8434

**DARWIN EU® study**

No

**Study countries**

Portugal

**Study description**

Aiming to fill the gap between clinical trials, database studies and spontaneous reporting data, an intensive monitoring model – that can monitor selected drugs over time - is proposed to be implemented in Portugal. By pharmacy based tracking of patients and drug usage in a life-cycle based fashion, this model is actively focused on gathering post-authorization data, mainly safety, since the first day of drug use. In what concerns to methods, a database comprising 3 different sources: 1) baseline subject-reported demographics and health characteristics to be administered by the community pharmacy, 2) telephone follow-up questionnaires on subject-reported risk (adverse events), (proxy of)benefit (e.g. EQ5D) and pattern of use data to be administered by the research team of the project (pharmacists) and, 3) pharmacy records was developed. All treatment naïve patients initiating treatment (inception cohort) with DPP-4, GLP-1 and SGLT2 visiting one of the participant pharmacies will be invited and to give consent to participate in the study. This is an academic project (Carla Torre’s PhD project) from the Faculty of Pharmacy of the University of Lisbon under the supervision of Prof. dr. Ana Paula Martins (Faculty of Pharmacy of the University of Lisbon) and of Prof. dr. Hubert G. Leufkens (Utrecht Institute for Pharmaceutical Sciences, Division of Pharmacoepidemiology and Clinical Pharmacology, Faculty of Science, Utrecht University). This study is being conducted at the Centre for Health and Research (CEFAR), an ENCePP centre - that belongs to the Portuguese National Association of Pharmacies.According to the Portuguese legislation (Law no. 67/98, 26th October), this study was submitted and approved by the Portuguese Data Protection Authority (CNPD). The study was approved by the ethics committee of the Institute of Public Health of the University of Porto.

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**Study status**

Ongoing

## Research institutions and networks

# Institutions

## National Association of Pharmacies Portugal (ANF)

Portugal

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Institution | Pharmaceutical association/federation

# Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

Carla TORRE

Primary lead investigator

# Study timelines

**Date when funding contract was signed**

Planned: 30/01/2012

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**Study start date**

Planned: 10/11/2014

Actual: 10/11/2014

**Data analysis start date**
Planned: 15/04/2015

**Date of interim report, if expected**
Planned: 01/06/2015

**Date of final study report**
Planned: 31/12/2016

## Sources of funding

- Other

## More details on funding

CEFAR (CEFAR (Centre for Health Research & Evaluation) - National association of Pharmacies

## Regulatory

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

No

# Methodological aspects

## Study type

## Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

Other

**If ‘other’, further details on the scope of the study**

Active Surveillance (Intensive Monitoring)

**Main study objective:**

By pharmacy based tracking of patients and drug usage in a life-cycle based fashion, this model is actively focused on gathering post-authorization data, mainly safety, since the first day of drug use.

## Study Design

**Non-interventional study design**

Cohort

Other

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**Non-interventional study design, other**

intensive monitoring schemes

## Study drug and medical condition

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

SITAGLIPTIN

VILDAGLIPTIN

SAXAGLIPTIN

LINAGLIPTIN

LIRAGLUTIDE

EXENATIDE

DAPAGLIFLOZIN

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**Medical condition to be studied**

Type 2 diabetes mellitus

# 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**

1200

# Study design details

**Outcomes**

- Adverse drug events (ADE) self-reported by patients - (real-world) drug utilization pattern, - Self reported hypoglycemia- Health-related quality of life (EQ-5D)- RCT external validity (Portuguese population)

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**Data analysis plan**

The nr of patients reporting an ADE, the proportion of serious ADE defined according to the CIOMS criteria, and the incidence densities for all ADE during treatment will be calculated. The ADE will be divided into labelled or not labelled according to the European Public Assessment Report (EPAR) of the monitored drug. Generalized Linear Models will be conducted to explore and to identify factors associated with the ADE. Longitudinal models will be used to explore the association of each covariate with time to ADE (time-to-event analysis).Through the patient therapeutic profile, the existence of drug-drug interactions will be identified as well as the eventual existence of drug-disease interactions associated with the monitored drug. The reported monitored drug pattern of use will be described and compared with the one defined in the EPAR. The statistical significance level adopted will be 5% and statistical analysis will be done using the SAS Enterprise Guide v4.1.

# 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.

**Conflicts of interest of investigators**

Declaração de Honra.pdf (132.63 KB)

## Data sources

**Data sources (types)**

Drug dispensing/prescription data

Other

**Data sources (types), other**

Prospective patient-based 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