Evolution of Prescribing Patterns of Antidiabetic and Anti-Obesity Drugs in the Tuscany Region: An Integrated of Utilization and Safety Analysis, and the Role of AIFA Note 100 (PATTERN-100 Prescribing PATTERNs of Antidiabetic and Anti-obesity Drugs: Utilization, Safety and the Role of AIFA Note 100)

First published: 06/07/2026

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Study Finalised

Administrative details

EU PAS number

EUPAS1000001050

Study ID

1000001050

DARWIN EU® study

No

Study countries

Italy

Study description

Rationale. New-generation antidiabetic drugs (SGLT2 inhibitors, GLP-1 receptor agonists, DPP-4 inhibitors, and dual GIP/GLP-1 receptor agonists) have transformed type 2 diabetes management, extending benefits beyond glycaemic control to cardiovascular and renal protection and weight management. In Italy, AIFA Note 100 redefined prescribing and reimbursement criteria for these classes, extending prescribing rights to GPs. This study describes the evolution of antidiabetic drug prescribing patterns in Tuscany (2016-2025), focusing on changes before and after Note 100's introduction and update, and integrates drug utilization data with adverse drug reaction (ADR) reports from the Italian National Pharmacovigilance Network (RNF).
Methods. The study has two phases: (1) a retrospective cohort analysis of drug utilization using Tuscany Region healthcare administrative data (ARS Toscana); (2) a pharmacovigilance analysis based on ADR reports from Tuscany within the RNF. The study population includes all individuals in the inhabitant registry with at least one dispensing of antidiabetic drugs of interest (DPP-4 inhibitors, SGLT2 inhibitors, GLP-1 receptor agonists, tirzepatide, and combinations) during 2016-2025, with at least 2 years of observation before the index date. For each Regional Health Areas (Central, North-West, South-East Tuscany), annual incident and prevalent users will be described, with demographic and clinical characteristics of new users, including comorbidities per Note 100, across three periods (pre-, during, and post-update Note 100). For pharmacovigilance, annual reporting rates and patient characteristics will be described, and adverse events classified.
Relevance. Findings will provide descriptive evidence on dispensing patterns of

antidiabetic drugs in Tuscany following regulatory changes, highlight geographical differences among the three Health Areas, and identify potential safety signals related to utilization trends.

Study status

Finalised

Research institutions and networks

Institutions

Pharmacovigilance and Pharmacoepidemiology Research Unit, Department Neurofarba, University of Florence

Italy

First published: 05/11/2020

Last updated: 08/07/2026

Institution | Educational Institution | ENCePP partner

Agenzia regionale di sanità della Toscana (ARS Toscana)

Italy

First published: 01/02/2024

Last updated: 23/03/2026

Institution | EU Institution/Body/Agency | ENCePP partner

Department of Statistics, Informatics and Applications 'Giuseppe Parenti', University of Florence.

Italy

First published: 03/07/2026

Last updated: 22/07/2026

Institution | Educational Institution

Networks

Centro Regionale di Farmacovigilanza della Toscana (CRFVT)

Italy

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Network | ENCePP partner

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Study timelines

Date when funding contract was signed

Planned: 02/03/2026

Actual: 02/03/2026

Study start date

Planned: 06/07/2026

Actual: 02/03/2026

Data analysis start date

Planned: 06/07/2026

Actual: 30/06/2026

Date of final study report

Planned: 18/09/2026

Actual: 30/06/2026

Sources of funding

- No external funding

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Other

Study topic, other:

Antidiabetics and anti-obesity drugs use

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

1) A retrospective observational cohort study on healthcare administrative data
2) A pharmacovigilance study of reports of suspected adverse drug reactions to antidiabetic medications
Study period: Jan 2016 - Dec 2025
Country: Italy, Tuscany Region

Main study objective:

This study aims to describe the evolution of utilization patterns of medications used for the treatment of diabetes and obesity in the Tuscany Region, and specifically within its three Regional Health Areas, during the period 2016–2025. In addition, safety data will be analysed to support the interpretation of utilization findings.

Objectives
-To assess trends in the number of incident and prevalent users of antidiabetic drugs of interest within each Regional Health Area during the study period (2016–2025), before and after the introduction of AIFA Note 100 in January 2022 and its subsequent update in July 2025.
-To describe the characteristics of new users of specific antidiabetic drug classes of interest in terms of demographic characteristics, comorbidities, and prior antidiabetic treatments from 2016 to 2025, with particular emphasis on the periods before and after the introduction of AIFA Note 100 and its subsequent update.
-To evaluate trends in reports of suspected adverse reactions to antidiabetic

drugs originating from the regional territory during the study period and compare them with trends in drug utilization.

The description of utilization patterns observed before and after the implementation and modification of AIFA Note 100 is intended solely to characterize potential changes in the use of antidiabetic medications within the evolving regulatory context. The findings of this study are expected to generate hypotheses that may be explored in future dedicated investigations. Therefore, the present study is not intended to assess causal relationships, nor to identify determinants or predictors of prescribing patterns.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A10) DRUGS USED IN DIABETES

DRUGS USED IN DIABETES

Medical condition to be studied

Diabetes mellitus

Obesity

Population studied

Short description of the study population

Drug Utilization Analysis

The study population will be identified from all individuals registered in the regional healthcare registry during the study period (1 January 2016 to 31 December 2025). Among these individuals, all subjects with at least one dispensing of an antidiabetic drug of interest during the study period will be identified. The date corresponding to the first dispensing of any antidiabetic drug of interest during the study period will be defined as the index date. Subjects with less than two years of observation before the index date will be excluded from the study population.

Pharmacovigilance Analysis

All reports recorded in the italian national pharmacovigilance network (Rete Nazionale di Farmacovigilanza RNF for the Tuscany Region will be included if they concern adverse events occurring during the study period and list, as suspected or interacting drugs, molecules belonging to the ATC classes of interest (antidiabetics).

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Study design details

Setting

Drug Utilization Analysis

The study population will be identified from all individuals registered in the regional healthcare registry during the study period (1 January 2016 to 31 December 2025). Among these individuals, all subjects with at least one dispensing of an antidiabetic drug of interest during the study period will be identified. The date corresponding to the first dispensing of any antidiabetic drug of interest during the study period will be defined as the index date. Subjects with less than two years of observation before the index date will be excluded from the study population.

Pharmacovigilance Analysis

All reports recorded in the italian national pharmacovigilance network (Rete Nazionale di Farmacovigilanza RNF for the Tuscany Region will be included if they concern adverse events occurring during the study period and list, as suspected or interacting drugs, molecules belonging to the ATC classes of interest (antidiabetics).

Comparators

Not applicable

Outcomes

-Trends in the number of incident and prevalent users of antidiabetic drugs of interest within each Regional Health Area during the study period (2016–2025), before and after the introduction of AIFA Note 100 in January 2022 and its subsequent update in July 2025.

-Characteristics of new users of specific antidiabetic drug classes of interest in terms of demographic characteristics, comorbidities, and prior antidiabetic treatments from 2016 to 2025, with particular emphasis on the periods before and after the introduction of AIFA Note 100 and its subsequent update.

-Trends in reports of suspected adverse reactions to antidiabetic drugs originating from the regional territory during the study period and compare them with trends in drug utilization.

Data analysis plan

Drug Utilization Analysis

All analyses will be descriptive. Continuous variables will be summarized as median and interquartile range (IQR); categorical variables as absolute frequencies and percentages.

For each calendar year (2016-2025), users will be classified as prevalent users (at least one dispensing in the year) or incident/new users (no dispensing of the same drug in the preceding two years). Annual trends in incident and prevalent users of each antidiabetic drug class (DPP-4 inhibitors, SGLT2 inhibitors, GLP-1 receptor agonists, tirzepatide, and combinations) will be described for each Regional Health Area throughout 2016-2025. New users will be characterized by age, sex, prior metformin use, prior use of other antidiabetics, and comorbidities, stratified by Regional Health Area and period (pre-, during, and post-update of Note 100).

An additional analysis will explore the impact of body mass index (BMI) on antidiabetic drug utilization among users who delivered a child in the year preceding the index dispensing, identified via linkage with the Birth Registry (CAP) database, recording maternal weight, height, and gestational/pre-existing diabetes. Pre-pregnancy BMI (kg/height² in m²) will be categorized as underweight (<18.5), normal weight (18.5-24.9), or overweight/obesity (>24.9).

Pharmacovigilance

Analyses will be descriptive, characterizing clinical and demographic features of patients reporting adverse drug reactions (ADRs) to antidiabetic drugs, and reported events (MedDRA classification, seriousness, outcome), from the National Pharmacovigilance Network (RNF). Categorical variables as

frequencies/percentages; continuous variables by mean and median, per distribution.
Annual reporting rates = number of reports / number of antidiabetic drug users × 1,000. Administrative databases will estimate annual users, i.e. all individuals with at least one dispensing of a drug of interest per study year.

Summary results

As of the current registration date, data extraction and statistical analyses have not yet been finalized.

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

Data source(s), other

Italian National Pharmacovigilance Network (Rete Nazionale di Farmacovigilanza, RNF)

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No