# A Study on the Utilization of Pioglitazone in Clinical Practice With Regard to Diabetic Treatment Regimen and Comorbidities

**First published:** 21/07/2015

**Last updated:** 16/08/2016

Study Finalised

## Administrative details

**EU PAS number**

EUPAS9998

**Study ID**

14800

**DARWIN EU® study**

No

**Study countries**

United Kingdom

**Study description**

The goal of this study is to describe the prescription of pioglitazone in diabetic patients according to Summary of Product Characteristics, and to evaluate the implementation of the risk minimisation measures introduced in July 2011 regarding bladder cancer, heart failure, and the need for regular review of the benefits of therapy. This drug utilization study will describe the pioglitazone users with regard to age, sex, concomitant drug use and prevalent comorbidities at the time of their first pioglitazone prescription, specifically hypertension and ischaemic heart disease.

**Study status**

Finalised

# Research institutions and networks

## Institutions

### University Hospital of Basel

**First published:** 01/02/2024

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**Institution**

# Contact details

**Study institution contact**

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**Study contact**

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**Primary lead investigator**

Christoph Meier

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**
Actual: 15/06/2012

**Study start date**
Actual: 01/07/2012

**Data analysis start date**
Actual: 01/08/2012

**Date of final study report**
Actual: 30/04/2013

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

TDC Europe

## 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)

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Human medicinal product

Disease /health condition

**Study type:**

Non-interventional study

**Scope of the study:**

Drug utilisation

**Data collection methods:**

Secondary use of data

**Main study objective:**

The goal of this study is to describe the prescription of pioglitazone in diabetic patients according to Summary of Product Characteristics, and to evaluate the

implementation of the risk minimisation measures introduced in July 2011 regarding bladder cancer, heart failure, and the need for regular review of the benefits of therapy.

## Study drug and medical condition

**Medicinal product name**

ACTOS

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**Medical condition to be studied**

Type 2 diabetes mellitus

## Population studied

**Short description of the study population**

Patients with pioglitazone use where most patients were between 50 and 79 years of age having type 2 diabetes mellitus along with comorbidities like hypertension and ischaemic heart disease.

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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

**Special population of interest, other**

Diabetes mellitus patients

**Estimated number of subjects**

32947

## Study design details

**Outcomes**

To describe trends in pioglitazone prescription patterns over time, before and after the key risk minimization milestones, To estimate the prevalence and incidence of HF in diabetic patients using pioglitazone, overall and stratified by insulin co-medication.

**Data analysis plan**

For all patients who ever received >= 1 prescription for pioglitazone, we will assess their age at first use, gender, body mass index, smoking status and the year in which the pioglitazone treatment was started, as well as concomitant drug use in the 12 months prior to starting pioglitazone, concomitant drug use after starting pioglitazone, and comorbidities at treatment initiation based on the entire available recorded patient history prior to starting pioglitazone.

## Documents

**Study results**

AD-4833-409A-RDS-2013-04-02.pdf (75.55 KB)

# 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)**

Clinical Practice Research Datalink

**Data sources (types)**

Electronic healthcare records (EHR)

Other

**Data sources (types), other**

Clinical Practice Research Datalink (CPRD) GOLD is the UK primary care database.

# 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