

# A description of oral and non-insulin injected hypoglycemic therapy utilization patterns including initiation, switching, and discontinuation (Non-insulin hypoglycemic therapy utilization)

**First published:** 22/05/2014

**Last updated:** 23/03/2015

Study

Finalised

## Administrative details

### EU PAS number

EUPAS4373

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### Study ID

9071

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### DARWIN EU® study

No

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### Study countries

 United States

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## Study description

This protocol is for a series of descriptive analyses conducted within a cohort of patients using linagliptin, other dipeptidyl peptidase-4 (DPP-4) inhibitors, and other oral and non-insulin injected hypoglycemic medications between May 2011 and June 2012. Understanding 1) the existing utilization patterns for linagliptin, sitagliptin, saxagliptin, and other oral and non-insulin injected hypoglycemic agents and (2) the differences in utilization patterns between these agents will help with the design, analysis and interpretation of comparative effectiveness and safety studies of linagliptin, other DPP-4 inhibitors, and other agents. The study will provide an overview of existing utilization patterns for linagliptin, other dipeptidyl peptidase-4 (DPP-4) inhibitors, other oral and non-insulin injected hypoglycemic agents, in order to detect potential selective prescribing patterns that might lead to channeling bias.

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## Study status

Finalised

## Research institutions and networks

### Institutions

#### Brigham and Women's Hospital

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Institution

### Contact details

**Study institution contact**

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Study contact

[cgopalakrishnan@partners.org](mailto:cgopalakrishnan@partners.org)

**Primary lead investigator**

Sebastian Schneeweiss

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 28/12/2012

Actual: 28/12/2012

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**Study start date**

Planned: 26/05/2014

Actual: 01/06/2014

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**Data analysis start date**

Planned: 01/07/2014

Actual: 01/07/2014

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**Date of interim report, if expected**

Planned: 31/07/2014

Actual: 01/08/2014

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**Date of final study report**

Planned: 30/09/2014

Actual: 04/12/2014

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Boehringer Ingelheim

## Regulatory

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

No

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

Disease /health condition

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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 understand (1) existing utilization patterns for linagliptin, other dipeptidyl peptidase-4 (DPP-4) inhibitors, other oral and non-insulin injected hypoglycemic agents, and (2) differences in utilization patterns between these agents to help with the design, analysis and interpretation of comparative effectiveness and safety studies of linagliptin, other DPP-4 inhibitors, and other agents.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(A10B) BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS

BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS

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**Medical condition to be studied**

Diabetes mellitus

## Population studied

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

Patients with Diabetes mellitus aged 18 years and over

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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

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### **Special population of interest, other**

Diabetes mellitus patients

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### **Estimated number of subjects**

200000

## **Study design details**

### **Outcomes**

Primary outcomes are:- Proportion of initiators - Treatment switching- Treatment augmentation- Subsequent Insulin initiation, Secondary outcomes are:- Persistence at 12 months - Persistence at 3 months- Persistence at 6 months- Proportion of days covered- Treatment discontinuation

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### **Data analysis plan**

Analyses are descriptive. Utilization patterns will be examined overall and in subgroups defined by patient characteristics, incident/former use, and over time. Adherence analyses will be conducted in propensity-score matched cohorts. The analyses will be based on May 2011 - June 2012 data.

## 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 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**

No