

# Drug utilisation study (DUS) on the use of Cholib® (fenofibrate and simvastatin fixed combination): a European multinational study using secondary health records databases

**First published:** 28/05/2015

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

Study

Planned

## Administrative details

### EU PAS number

EUPAS9827

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### Study ID

15808

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### DARWIN EU® study

No

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### Study countries

 France

 Hungary

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## Study description

Statins have been shown to reduce total cholesterol and LDL-C levels. They are commonly used and recommended in patients with dyslipidaemia (Catapano et al. 2011).<sup>3</sup> Fibrates are also used to lower total cholesterol and triglycerides (TG) levels. They are prescribed to patients intolerant to statins alone, or as second line of treatment in combination with statins. Combination of simvastatin and fenofibrate leads to additional improvement of lipid parameters compared with simvastatin monotherapy in patients with mixed dyslipidaemia who required a treatment targeting a broader lipoprotein spectrum (Grundy et al. 2005).<sup>11</sup> Cholib® is a fixed combination tablet, composed of fenofibrate (145 mg) and simvastatin (20mg or 40mg). It will be the first available registered drug combining both substances in one tablet. Cholib® is indicated as adjunctive therapy to diet and exercise in high cardiovascular risk adult patients with mixed dyslipidaemia to reduce triglycerides and increase HDL- C levels when LDL-C levels are adequately controlled with the corresponding dose of simvastatin monotherapy. Initiation of Cholib® treatment requires an adequate pre-treatment with simvastatin (at 20 or 40 mg) otherwise it is considered off-label use. This potential risk is part of the Risk Management Plan (RMP) and will be further investigated in this study conducted to estimate the proportion of patients who initiated Cholib® without prior simvastatin therapy.

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## Study status

Planned

## Research institutions and networks

### Institutions

IMS Health

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

**Last updated:** 01/02/2024

**Institution**

## Contact details

### Study institution contact

Toussi Massoud [mtoussi@fr.imshealth.com](mailto:mtoussi@fr.imshealth.com)

**Study contact**

[mtoussi@fr.imshealth.com](mailto:mtoussi@fr.imshealth.com)

### Primary lead investigator

Toussi Massoud

**Primary lead investigator**

## Study timelines

### Date when funding contract was signed

Planned: 06/01/2015

Actual: 06/01/2015

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### Study start date

Planned: 01/06/2015

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### Date of final study report

Planned: 31/12/2017

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Mylan

## Regulatory

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

Yes

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

EU RMP category 3 (required)

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Drug utilisation

#### **Main study objective:**

to estimate the proportion of patients with mixed dyslipidaemia, initiating Cholib® without prior prescription of simvastatin of the corresponding daily

dose (“off-label use”)

## Study Design

### **Non-interventional study design**

Cross-sectional

## Study drug and medical condition

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

FENOFIBRATE

SIMVASTATIN

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

Dyslipidaemia

## Population studied

### **Age groups**

- Infants and toddlers (28 days - 23 months)
  - Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
  - 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

323

## Study design details

### Data analysis plan

The statistical analysis will be conducted using SAS® software Version 9.3 for Windows™ (SAS Institute, North Carolina, USA) and Excel. The statistical unit is the patient. Calculations will be performed on raw data without extrapolation. Continuous variables will be described by the number of valid cases, the number of missing values, mean, standard deviation, median, quartiles (Q1, Q3) and range. Categorical variables will be described as the total number and relative percentage per category. The number of missing data will be indicated, they will not be replaced and not be taken into account for the calculation of the percentages. Confidence intervals of 95% will be calculated for each item, when relevant. Prescribers' profile will be described per country: age, gender, specialty and region through LTD database. Summaries will be reported at country level. For each analysis period (pre- and post- launch periods) they will be categorized according to the speciality.

## 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), other**

IMS Lifelink Longitudinal Prescription Database Hungary, IMS LifeLink EMR  
France

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**Data sources (types)**

[Drug dispensing/prescription data](#)

[Electronic healthcare records \(EHR\)](#)

## 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