

# Comparison of care use between cohorts differentiated by the patients adherence to statins in France between 2005 and 2008 (C2STAT)

**First published:** 02/12/2013

**Last updated:** 29/03/2024

Study

Finalised

## Administrative details

### **PURI**

<https://redirect.ema.europa.eu/resource/15439>

---

### **EU PAS number**

EUPAS5275

---

### **Study ID**

15439

---

### **DARWIN EU® study**

No

---

## Study countries

France

---

## Study description

Cardiovascular disease is the leading cause of death worldwide, with about 30 % of deaths. Statins (or HMG -CoA reductase inhibitors) form a class of lipid-lowering drugs, drugs used to lower cholesterol levels in people at risk for cardiovascular disease. Statins are now considered as the most effective therapeutic class for the treatment of hypercholesterolemia. They also demonstrated their beneficial effect on all-cause mortality decrease and on the occurrence of cardiovascular events. Statins are one of the main expenditure for the French health insurance since the early 2000s (1.28 billion euros in 2008). The financial burden associated with statins should remain a major concern in the coming years, particularly because of the aging population and the increased prevalence of risk factors such as diabetes or obesity, often associated with abnormal lipids. The objective of this study is to compare the use of health care, and the costs associated, with each patient cohorts differentiated by adherence to statin therapy, between 2005 and 2008, based on the French health national insurance database (EGB) which contains healthcare reimbursement data of 1/97 of the French population. The study mainly describes the annualized costs of care use in patients who have had an introduction to statin therapy and compares these costs between three cohorts defined by the level of adherence to statin therapy. It also describes the study population (socio-demographic characteristics, therapeutic profile of patients, characteristics associated with the initiation of statin therapy, level of adherence), identifies factors associated with annualized costs and poor adherence to statins and compare cardiovascular events between the three cohorts defined by level of adherence to statins.

---

## Study status

Finalised

## Research institutions and networks

# Institutions

## Université Claude Bernard Lyon 1

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

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

Institution

## Contact details

### Study institution contact

Eric VAN GANSE

Study contact

[eric.van-ganse@univ-lyon1.fr](mailto:eric.van-ganse@univ-lyon1.fr)

### Primary lead investigator

Eric VAN GANSE

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 01/07/2009

Actual: 01/07/2009

---

### Study start date

Planned: 15/07/2009

Actual: 15/07/2009

---

### **Data analysis start date**

Planned: 15/07/2010

Actual: 02/08/2010

---

### **Date of final study report**

Planned: 16/09/2011

Actual: 16/09/2011

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer

## 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

---

**Study type:**

Non-interventional study

---

**Scope of the study:**

Drug utilisation

Healthcare resource utilisation

**Data collection methods:**

Secondary use of data

---

**Main study objective:**

The study describes the annualized costs of care use in patients who have had an introduction to statin therapy and compares these costs between three cohorts defined by the level of adherence to statin therapy.

## Study Design

**Non-interventional study design**

Cohort

Other

---

**Non-interventional study design, other**

Healthcare cost

## Study drug and medical condition

## **Anatomical Therapeutic Chemical (ATC) code**

(B01) ANTITHROMBOTIC AGENTS

ANTITHROMBOTIC AGENTS

(C01D) VASODILATORS USED IN CARDIAC DISEASES

VASODILATORS USED IN CARDIAC DISEASES

(C02) ANTIHYPERTENSIVES

ANTIHYPERTENSIVES

(C10) LIPID MODIFYING AGENTS

LIPID MODIFYING AGENTS

## Population studied

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

Patients who have had an introduction to statin therapy.

---

### **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)

---

### **Estimated number of subjects**

5000

## Study design details

## Outcomes

To describe annualized costs of care use in patients who have had an introduction to statin therapy and to compare these costs between three cohorts defined by the level of adherence to statin therapy. To identify the study population, factors associated with annualized costs and poor adherence to statins and compare cardiovascular events between the three cohorts.

---

## Data analysis plan

A / General description of the study population  
B / Description of the level of adherence to statins  
C / Description and comparison of annualized costs generated by patients  
D / Identification of factors associated with annualized costs  
E / Identification of factors associated with poor adherence to statin therapy  
F / Comparison of cardiovascular events between the three cohorts defined according to their level of adherence to statins

## Data management

### Data sources

#### Data source(s), other

EGB France

---

#### 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**

Unknown