

# Study of the impact of non-compliance with GINA recommendations on the care consumption of adult asthmatic patient

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Study

Finalised

## Administrative details

### **PURI**

<https://redirect.ema.europa.eu/resource/15436>

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### **EU PAS number**

EUPAS5309

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### **Study ID**

15436

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### **DARWIN EU® study**

No

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### **Study countries**

France

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## Study description

Asthma is a chronic disease that has major implications not only in terms of morbidity and mortality or of deterioration in the quality of life for patients, but also in terms of costs associated with the disease. The management of persistent asthma (GINA 2, 3 and 4) is mainly based on the trigger eviction and on drug therapy. In current medical practice, asthma remains generally under-diagnosed, under-treated and poorly controlled yet. Based on the French national health insurance database (EGB), which contains healthcare reimbursement data of 1/97 of the French population, this study aims to better understand the impact of non-compliance with GINA therapeutic recommendations on healthcare use and on absenteeism of persistent asthmatic patients. It also identifies the characteristics of patients whose care is not in accordance with these recommendations and tests the economic impact of medical nomadism on the management of asthma in 2007 and 2008.

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## Study status

Finalised

## Research institution and networks

### Institutions

[Université Claude Bernard Lyon 1](#)

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**Institution**

## Contact details

### **Study institution contact**

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Study contact

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### **Primary lead investigator**

Eric VAN GANSE

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Actual: 30/06/2009

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### **Study start date**

Actual: 30/10/2009

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

Actual: 31/03/2011

## Sources of funding

- Other

## More details on funding

CNAMTS

## Regulatory

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

No

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

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

Healthcare resource utilisation

**Data collection methods:**

Secondary use of data

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**Main study objective:**

This study aims to better understand the impact of non-compliance with GINA therapeutic recommendations on healthcare use and on absenteeism of persistent asthmatic patients. It also identifies the characteristics of patients

whose care is not in accordance with these recommendations and tests the economic impact of medical nomadism on the management of asthma in 2007 and 2008.

## Study Design

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

Cohort

## Study drug and medical condition

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

Asthma

## Population studied

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

Persistent asthmatic patients.

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### **Age groups**

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

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### **Special population of interest**

Other

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

Asthma patients

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### **Estimated number of subjects**

2000

## Study design details

## Outcomes

To study the frequency of non-compliance with GINA recommendations and its potential impact on health care consumption and absenteeism in asthmatic patients. To study and compare the characteristics of patients, their health care consumption and nomadism in 2007 and 2008.

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## Data analysis plan

A / Description of the general characteristics of the study population on 01/01/2007. B / Description of the components of the healthcare consumption and absenteeism in 2007 and 2008 for the entire population included. C / Study of the characteristics of the healthcare consumption and absenteeism of patients in 2007 and 2008 depending on the frequency of rescues CI in 2007. D / Study of the characteristics of the healthcare consumption and absenteeism in 2007 and 2008 patients who received BAILDA without CI in 2007. E / Study of the characteristics of the healthcare consumption and absenteeism in 2007 and in 2008 patients with high BAICDA rescues in 2007.

## Data management

### Data sources

#### Data source(s), other

EGB France

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#### Data sources (types)

[Administrative data \(e.g. claims\)](#)

### 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