

# Drug Utilization Study of eliglustat in the US population using MarketScan® Database (ELIGLC06912)

**First published:** 21/09/2017

**Last updated:** 25/06/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS21025

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### Study ID

29327

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### DARWIN EU® study

No

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### Study countries

 United States

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### Study description

Retrospective cohort study to estimate the proportion of patients taking concomitant medications of interest including strong CYP3A inducers, strong and moderate CYP2D6 inhibitors and CYP3A inhibitors, and P-gp or CYP2D6 substrate medications prior to starting eliglustat and those who continue or start these medications concurrently while on eliglustat treatment in the US.

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## Study status

Finalised

## Research institutions and networks

### Institutions

Sanofi

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

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Institution

## Contact details

### Study institution contact

Trial transparency team [Contact-Us@sanofi.com](mailto:Contact-Us@sanofi.com)

Study contact

[Contact-Us@sanofi.com](mailto:Contact-Us@sanofi.com)

### Primary lead investigator

Trial transparency team

## Study timelines

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

Planned: 30/06/2016

Actual: 30/06/2016

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### **Study start date**

Planned: 30/06/2016

Actual: 30/06/2016

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### **Data analysis start date**

Planned: 30/06/2016

Actual: 30/06/2016

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### **Date of interim report, if expected**

Planned: 30/09/2016

Actual: 25/09/2016

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

Planned: 30/09/2018

Actual: 05/11/2018

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Sanofi Genzyme

## Study protocol

[CLB-DOC-72938 on 01Aug2018.pdf](#) (554.75 KB)

## 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 topic:**

Human medicinal product

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#### **Study type:**

Non-interventional study

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

Drug utilisation

Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Main study objective:**

Objectives:

- 1) To estimate the proportion of patients in the U.S. who have been genotyped for CYP2D6 prior to the initiation of eliglustat therapy,
- 2) To estimate the dose and duration of eliglustat therapy, as well as the prevalence, duration and type of past and concomitant medication use of strong and moderate inhibitors of CYP2D6 and CYP3A, strong CYP3A inducers, P-gp and CYP2D6 substrates, in patients treated with eliglustat in the U.S.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

CERDELGA

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

ELIGLUSTAT

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**Anatomical Therapeutic Chemical (ATC) code**

(A16AX10) eliglustat

## Population studied

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

Patients with at least one prescription of eliglustat in the MarketScan™ database from September 18, 2014 (date of market availability) until September 30, 2017.

Also, to assess the proportion of patients who were genotyped for CYP2D6, US patients from the ICGG Gaucher Registry database will be used as an alternative data source for estimating the proportion of eliglustat treated patients who were genotyped for CYP2D6.

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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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### **Estimated number of subjects**

50

## Study design details

### **Data analysis plan**

The following data analyses were performed:

- Descriptive analysis of patients who have a genotyping procedure for CYP2D6 prior to treatment initiation of eliglustat (i.e. N, proportion) in the claims

records.

- Descriptive analysis of patient's dose and duration on eliglustat therapy within the study period from index date until the end of continuous treatment (i.e. N, mean, standard deviation, median, min, max).
- Descriptive analyses of the prior medication use of concomitant medication of interest (proportion, type, and duration) in the year prior to treatment initiation of eliglustat therapy.
- Descriptive analyses of the concomitant medication use of concomitant medication of interest (proportion, type, and duration) in patients while receiving eliglustat therapy.

## Documents

### Study results

[study-report-eligl06912.pdf](#) (911.36 KB)

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## 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**

Unknown