

# Prescribing Patterns of Lipegfilgrastim (Lonquex®) in the European Union

**First published:** 01/09/2016

**Last updated:** 19/05/2021

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS12984

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### Study ID

28713

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### DARWIN EU® study

No

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### Study countries

-  Austria
  -  Belgium
  -  Croatia
  -  Germany
  -  Netherlands
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## Study description

This is a post-authorisation, multi-national, non-interventional, multicentre, retrospective DUS, to describe the pattern of lipegfilgrastim use, and specifically to quantify the extent of lipegfilgrastim off-label use in routine clinical practice. Data for approx. 500 patients of all ages who were treated with lipegfilgrastim as part of usual clinical practice will be collected at sites in several European countries. Data will be abstracted from medical charts. Data analysis in the study will be descriptive. Initially a pilot study will be conducted in order to assess the feasibility of the data collection, and to modify the protocol if needed.

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## Study status

Ongoing

# Research institutions and networks

## Institutions


### PRA Health Sciences


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

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

Institution

### Real World Solutions, PRA Real World Solutions

 France

 Germany

**First published:** 19/05/2021

**Last updated:** 06/03/2024

**Institution**

**Non-Pharmaceutical company**

**ENCePP partner**

## Contact details

### Study institution contact

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**Study contact**

[Nicole.Lang@ratiopharm.de](mailto:Nicole.Lang@ratiopharm.de)

### Primary lead investigator

Bettina Rillmann

**Primary lead investigator**

## Study timelines

### Date when funding contract was signed

Actual: 03/05/2016

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### Study start date

Planned: 10/06/2019

Actual: 16/12/2016

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### Data analysis start date

Planned: 15/04/2020

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## **Date of final study report**

Planned: 16/11/2020

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

TEVA

## 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:**

The primary objective is to quantify the extent of off-label Lipegfilgrastim use in routine clinical practice in several countries in the European Union (EU).

## Study drug and medical condition

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

LIPEGFILGRASTIM

## Population studied

**Age groups**

- 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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**Special population of interest**

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

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## Estimated number of subjects

500

## Study design details

### Outcomes

The primary endpoint of this study is off-label use of Lipegfilgrastim as documented in the most recent chemotherapy cycle with administration of Lipefilgrastim.

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### Data analysis plan

There will be descriptive data analysis. Off-label use will be described by type and frequency. Study results will be quantified in terms of incidence of off-label lipegfilgrastim use per 1,000 investigated population. The rates and 95% confidence intervals of off-label use stratified by sex, age-group, center clinical setting, country and possibly, depending on the numbers in the sub-category, type of off-label use will be reported per 1,000 investigated population. Similarly, rates per 1000 and 95% CI will be provided for the authorized lipegfilgrastim use by sex, age-group, center clinical setting, and country.

## 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)**

Drug dispensing/prescription data

Other

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## **Data sources (types), other**

Medical records

# 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