

# Database Study of Thalidomide (Thalidomide Celgene®) in Germany: Monitoring Off-Label Use

**First published:** 08/07/2014

**Last updated:** 02/07/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS7020

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### Study ID

16822

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### DARWIN EU® study

No

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### Study countries

Germany

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### Study description

The immunomodulator thalidomide, in combination with melphalan and prednisone is indicated for the first-line treatment of multiple myeloma in patients 65 years of age and patients for which a high-dose chemotherapy is not suitable. Aim of this project is to analyse the extent of the ambulatory off-label use (use of a drug outside the terms of its marketing authorisation) of thalidomide. The study is part of a risk management plan required by EMA (European Medicines Agency) and the German Federal Institute for Drugs and Medical Devices (BfArM) due to the teratogenic potential of the drug.

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## Study status

Finalised

## Research institutions and networks

### Institutions

#### Leibniz Institute for Prevention Research and Epidemiology - BIPS

Germany

**First published:** 29/03/2010

**Last updated:** 30/03/2026

Institution

Not-for-profit

ENCePP partner

## Contact details

### Study institution contact

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Study contact

[gepard@leibniz-bips.de](mailto:gepard@leibniz-bips.de)

### Primary lead investigator

Oliver Riedel

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 15/04/2008

Actual: 15/04/2008

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### Study start date

Planned: 03/12/2010

Actual: 03/12/2010

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### Data analysis start date

Planned: 13/04/2011

Actual: 12/04/2011

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### Date of interim report, if expected

Planned: 10/06/2014

Actual: 10/06/2014

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### Date of final study report

Planned: 31/12/2014

Actual: 31/12/2014

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Celgene GmbH

## Regulatory

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

Yes

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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

Human medicinal product

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#### **Study type:**

Non-interventional study

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

Drug utilisation

**Data collection methods:**

Secondary use of data

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**Main study objective:**

The objectives of this study were to determine off-label use of thalidomide by indication in the years 2009 (subproject 1) and 2010 (subproject 2) and to investigate probable indications for thalidomide use in off-label users. On-label and off-label users of thalidomide were characterised. Furthermore, the incidence rates of thalidomide use were investigated.

## Study Design

**Non-interventional study design**

Cross-sectional

## Study drug and medical condition

**Medicinal product name, other**

Thalidomide Celgene

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**Medical condition to be studied**

Plasma cell myeloma

## Population studied

**Short description of the study population**

Myeloma patients with off-label use of thalidomide in 2009 and 2010.

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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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### **Special population of interest**

Other

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

Plasma cell myeloma patients

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### **Estimated number of subjects**

200

## Study design details

### **Outcomes**

frequency of off-label use

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### **Data analysis plan**

Descriptive analyses were conducted for all users of thalidomide with respect to demographic characteristics, i.e. sex, age and federal state of residence, death and frequency of dispensations. Incidence rates of thalidomide use by sex, age and federal state of residence were determined. Prevalence and incidence rates of thalidomide use were calculated with 95% confidence intervals.

Demographics and comorbidities are determined for patient with off-label use.

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)

German Pharmacoepidemiological Research Database

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### 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