

# An Evaluation of the Misuse and Abuse of Pregabalin using RADARS® System Programs in the United States and the European Union

**First published:** 10/07/2018

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

Study

Finalised

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/29172>

### EU PAS number

EUPAS24790

### Study ID

29172

### DARWIN EU® study

No

## Study countries

- ☐ France
  - ☐ Germany
  - ☐ Italy
  - ☐ United States
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## Study description

The primary objectives of this evaluation:1) Summarize misuse and abuse data for pregabalin and each comparator within each country for each data source2) Perform a statistical analysis of trends over time for pregabalin and each comparator to assess changes in misuse and abuse within each country and data source

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## Study status

Finalised

# Research institutions and networks

## Institutions

**RADARS® System**

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

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Institution

**Cystic Fibrosis Trust**

## Contact details

### Study institution contact

Kofi Asomaning

Study contact

[kofi.asomaning@pfizer.com](mailto:kofi.asomaning@pfizer.com)

### Primary lead investigator

Kofi Asomaning

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 06/06/2018

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### Study start date

Planned: 15/06/2018

Actual: 15/06/2018

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### Data analysis start date

Planned: 30/06/2018

Actual: 30/06/2018

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### Date of final study report

Planned: 30/10/2018

Actual: 17/10/2018

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer

## Study protocol

[RADARS System Pregabalin Study Protocol 06June2018 FINAL.pdf](#)(979.58 KB)

## 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

## Other study registration identification numbers and links

A0081363

## 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:**

Disease epidemiology

**Data collection methods:**

Secondary use of data

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**Main study objective:**

The primary objectives of this evaluation:1) Summarize misuse and abuse data for pregabalin and each comparator within each country for each data source2) Perform a statistical analysis of trends over time for pregabalin and each comparator to assess changes in misuse and abuse within each country and data source

## Study Design

**Non-interventional study design**

Cross-sectional

## Study drug and medical condition

**Name of medicine**

LYRICA

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**Medical condition to be studied**

Drug abuse

## Population studied

**Short description of the study population**

Entire population enrolled by each data source

EUROPAD Program:

The surveillance population consists of individuals seeking treatment for substance use disorders (other than alcohol) at sites that offer treatment for opioid use disorders in France, Germany, and Italy.

Treatment Center Programs Combined:

The surveillance population consists of patients entering treatment for opioid dependence in the United States.

GTNet Program:

The surveillance population consists of exposure cases recorded by participating poison centres in France, Germany, and Italy.

National Poison Data System:

The surveillance population consists of exposure cases recorded by 55 regional poison control centers in all 50 states covering 100% of the total United States population.

Survey of Non-Medical Use of Prescription Drugs Program:

The surveillance population consists of the adult general population via an online survey panel company. The sample is stratified by United States Census region and gender, mirroring the distribution of the population in both

percentage and gender representation (approximately 50% female, 50% male within each region). The samples from France, Germany and Italy are stratified by gender and Nomenclature des unités territoriales statistiques (NUTS) 1 level regions.

#### Web Monitoring Program:

The Web Monitoring Program surveillance population consists of individuals within the United States who post statements related to misuse and abuse on public social media accounts, online blogs, web forums and other internet sites.

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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**

100

## Study design details

#### **Outcomes**

Non medical useAbuse

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#### **Data analysis plan**

The primary objective will be to estimate rates or prevalence estimates for each of the outcomes (non-medical use, misuse, abuse, intentional exposures) by program for pregabalin and comparators within each country using descriptive statistics.

## Documents

## Study results

[RADARS summary.pdf](#)(116.53 KB)

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## Data management

### Data sources

#### Data sources (types)

[Disease registry](#)

### 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