# Population incidence rates of pemphigoid in six European countries

**First published:** 22/05/2023

**Last updated:** 23/04/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS104284

**Study ID**

104285

**DARWIN EU® study**

No

**Study countries**

- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] Romania
- [ ] United Kingdom

**Study description**

A cohort study describing incidence rates of pemphigoid across six European databases, stratified by age, sex and year of diagnosis as well as by season of diagnosis (Autumn, Winter, Spring, Summer)

**Study status**

Finalised

# Research institutions and networks

## Institutions

### European Medicines Agency (EMA)

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

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

Institution

# Contact details


**Study institution contact**

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Study contact

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**Primary lead investigator**

Robert Flynn

Primary lead investigator

# Study timelines

**Date when funding contract was signed**
Planned: 10/05/2022

Actual: 10/05/2022

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**Study start date**
Planned: 10/05/2022

Actual: 10/05/2022

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**Date of final study report**
Planned: 08/07/2022

Actual: 08/07/2022

# Sources of funding

- EMA

# Study protocol

Analysis Plan_Pemphigoid_20220510.pdf(995.61 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)?**

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:**

Disease epidemiology

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To describe the background incidence rate of pemphigoid stratified by age, sex, year of diagnosis and season of diagnosis

## Study Design

**Non-interventional study design**

Cohort

# Study drug and medical condition

**Medical condition to be studied**

Pemphigoid

Mucous membrane pemphigoid

# Population studied

**Short description of the study population**

Pemphigoid patients identified from the European database which cover primary health care users from France, Germany, UK, Spain, Italy and Romania.

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**Age groups**

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

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**

Other

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**Special population of interest, other**

Pemphigoid patients

**Estimated number of subjects**

1856

## Study design details

**Outcomes**

new onset of pemphigoid

**Data analysis plan**

Patients were required to have a minimum observation time of 365 days prior to entering into each period in order to establish whether events observed during the period are incident (first-ever) cases. The study period was from 2015 to 2019. The numerator consisted of the number of patients who experienced new onset of pemphigoid diagnosis during the yearly or quarterly time period. Patients with any recorded baseline history of pemphigoid were excluded and patients were only able to contribute one event each. For the denominator, as with the numerator, patients with a baseline history of pemphigoid at the start of each quarter or year were excluded. Patient follow-up time was truncated at the occurrence of the first event after which they did not contribute to the analysis. Incidence rate = (number of new onset events) / (total follow up time (years)), was calculated for the entire population and stratified by year, season, gender and age.

## Documents

**Study results**

FINAL_Report_Pemphigoid_20220708.pdf(1.3 MB)

## Data management

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)**

IQVIA Disease Analyzer Germany

THIN® (The Health Improvement Network®)

Disease Analyzer - OMOP

**Data sources (types)**

Drug dispensing/prescription data

Electronic healthcare records (EHR)

# Use of a Common Data Model (CDM)

**CDM mapping**

No

# Data quality specifications

**Check conformance**

Unknown

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

# Data characterisation

**Data characterisation conducted**

No