

# Ability of primary care health databases to assess medicinal products discussed by the European Union Pharmacovigilance Risk Assessment Committee (CAPs and NAPs in primary EHDs)

**First published:** 21/10/2019

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

Study

Finalised

## Administrative details

### EU PAS number

EUPAS31879

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### Study ID

33764

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### DARWIN EU® study

No

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### Study countries

☐ France

☐ Germany

☐ United Kingdom

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### Study description

Electronic primary care health databases are used by to assess the need for and the impact of post-licensing regulatory interventions. This study aims to measure the extent to which exposure to different categories of medicines, including centrally authorised products (CAPs) and nationally authorised products (NAPs), discussed by the Pharmacovigilance Risk Assessment Committee (PRAC) in a 3-month period (September-November 2019) was adequately covered in four electronic primary care health databases in their entire lifespan until 31 August 2018.

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### Study status

Finalised

## Research institutions and networks

### Institutions

#### European Medicines Agency (EMA)

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

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

Institution

#### Clinical Practice Research Datalink (CPRD)

☐ United Kingdom

**First published:** 15/03/2010

**Last updated:** 17/01/2025

**Institution**

**Laboratory/Research/Testing facility**

**ENCePP partner**

European Medicines Agency Amsterdam

## Contact details

### Study institution contact

Robert Flynn robert.flynn@ema.europa.eu

**Study contact**

[robert.flynn@ema.europa.eu](mailto:robert.flynn@ema.europa.eu)

### Primary lead investigator

Robert Flynn

**Primary lead investigator**

## Study timelines

### Date when funding contract was signed

Planned: 02/08/2019

Actual: 02/08/2019

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### Study start date

Planned: 02/08/2019

Actual: 02/08/2019

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

Planned: 17/10/2019

Actual: 17/10/2019

## Sources of funding

- EMA
- Other

## More details on funding

CPRD

## 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

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Other

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**Study topic, other:**

Disease/Epidemiology study

**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:**

To measure the extent to which exposure to different categories of medicines, including centrally authorised products (CAPs) and nationally authorised products (NAPs), discussed by the Pharmacovigilance Risk Assessment Committee (PRAC) in a 3-month period (September-November 2019) was adequately covered in four electronic primary care health databases in their entire lifespan until 31 August 2018

## Study Design

**Non-interventional study design**

Cross-sectional

## Population studied

## Short description of the study population

Patients receiving at least one prescription for each substance (or class of substances) during the entire lifespan of each database until August 31, 2018

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### Age groups

Preterm newborn infants (0 – 27 days)

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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### Estimated number of subjects

819175

## Study design details

### Outcomes

Number of prescriptions Number of patients exposed

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### Data analysis plan

Descriptive analyses include the number of substances without any prescription per database, authorisation type and duration of authorisation in 3 categories (<2 years, 2-5 years, >5 years), and the median (with range) number of prescriptions and patients available per database, authorisation type and duration of authorisation. To estimate the number of substances for which each

database could meaningfully assess adverse events, we calculated the numbers of patient exposures required to detect a statistically significant adverse event associated with a range of theoretical relative risks (RR) for CAPs and NAPs in different frequency categories. This was based on a hypothetical comparison of two proportions using a 2-sided Fisher exact test with  $\alpha = 0.05$ , power = 0.90 and equal numbers of patients exposed to the drug of interest and a comparator. Effect sizes of a doubling and a four-times increase in events rate against a hypothetical comparator were used

## Documents

### Study publications

[Flynn R, Hedenmalm K, Murray-Thomas T, Pacurariu A, Arlett P, Shepherd H, Myles...](#)

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## Data management

### Data sources

#### Data source(s)

THIN® (The Health Improvement Network®)  
Clinical Practice Research Datalink

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#### Data source(s), other

THIN, CPRD

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#### Data sources (types)

[Electronic healthcare records \(EHR\)](#)

## 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