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

Study ID

33764

DARWIN EU® study

No

Study countries

France

Germany

United Kingdom

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.

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

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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: 02/08/2019

Actual: 02/08/2019

Study start date

Planned: 02/08/2019

Actual: 02/08/2019

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

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Other

Study topic, other:

Disease/Epidemiology study

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

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

Age groups

- Adolescents (12 to < 18 years)
- Children (2 to < 12 years)
- Infants and toddlers (28 days – 23 months)
- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- 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)

Estimated number of subjects

819.175

Study design details

Outcomes

Number of prescriptions Number of patients exposed

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...

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 source(s)

THIN® (The Health Improvement Network®)

Clinical Practice Research Datalink

Data source(s), other

THIN, CPRD

Data sources (types)

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