EURAP International Registry of Antiepileptic Drugs and Pregnancy

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Data source | Human | Other

Administrative details

Administrative details

Data source ID

20789

Data source acronym

EURAP

Data holder

International Registry of Antiepileptic Drugs and Pregnancy (EURAP)

Data source type

Other

Data source type, other

exposure registry, prospective studies database

Main financial support

Funding from industry or contract research

Care setting

Secondary care – specialist level (ambulatory)

Hospital outpatient care

Data source qualification

If the data source has successfully undergone a formal qualification process (e.g., from the EMA, ISO or other certifications), this should be described.

No

Data source website

http://www.eurapinternational.org/

Contact details

General Email eurap@eurapregistry.org

Main

eurap@eurapregistry.org

Data source regions and languages

Data source countries

Algeria

Argentina

Australia

Austria

Belarus

Belgium

Chile

Czechia

Denmark

El Salvador

Estonia

Finland

France

Georgia

Germany

India

Iran, Islamic Republic of

Israel

Italy

Japan

Lebanon

Netherlands

North Macedonia

Norway

Portugal

Serbia

Slovakia

Spain

Sweden

Taiwan

Türkiye

Data source languages

English

Data source establishment

Data source established

15/06/1999

Data source time span

First collection: 15/09/1999

The date when data started to be collected or extracted.

Publications

Data source publications

Several papers are available on the publication section. Please, refer to the link.

Studies

List of studies that have been conducted using the data source

Survey on the collection of data on adverse events related to medicinal products through registries

Data elements collected

The data source contains the following information

Disease information

Does the data source collect information with a focus on a specific disease? This might be a patient registry or other similar initiatives.

Yes

Disease details (other)

Maternal epilepsy and congenital malformation in offspring.

Rare diseases

Are rare diseases captured? In the European Union a rare disease is one that affects no more than 5 people in 10,000.

No

Pregnancy and/or neonates

Does the data source collect information on pregnant women and/or neonatal subpopulation (under 28 days of age)?

Yes

Hospital admission and/or discharge

No

ICU admission

Is information on intensive care unit admission available?

No

Cause of death

Captured

Cause of death vocabulary

Not coded (Free text)

Prescriptions of medicines

Captured

Dispensing of medicines

Not Captured

Advanced therapy medicinal products (ATMP)

Is information on advanced therapy medicinal products included? A medicinal product for human use that is either a gene therapy medicinal product, a somatic cell therapy product or a tissue engineered products as defined in Regulation (EC) No 1394/2007 [Reg (EC) No 1394/2007 Art 1(1)].

No

Contraception

Is information on the use of any type of contraception (oral, injectable, devices etc.) available?

Yes

Indication for use

Does the data source capture information on the therapeutic indication for the use of medicinal products?

Captured

Indication vocabulary

Not coded (Free text)

Medical devices

Is information on medicinal devices (e.g., pens, syringes, inhalers) available?

No

Administration of vaccines

No

Procedures

Does the data source capture information on procedures (e.g., diagnostic tests, therapeutic, surgical interventions)?

Captured

Procedures vocabulary

Not coded (Free text)

Healthcare provider

Is information on the person providing healthcare (e.g., physician, pharmacist, specialist) available? The healthcare provider refers to individual health professionals or a health facility organisation licensed to provide health care diagnosis and treatment services including medication, surgery and medical devices.

Yes

Clinical measurements

Is information on clinical measurements (e.g., BMI, blood pressure, height) available?

Yes

Genetic data

Are data related to genotyping, genome sequencing available?

Not Captured

Biomarker data

Does the data source capture biomarker information? The term “biomarker” refers to a broad subcategory of medical signs (objective indications of medical state observed from outside the patient), which can be measured accurately and reproducibly. For example, haematological assays, infectious disease markers or metabolomic biomarkers.

Not Captured

Patient-reported outcomes

Is information on patient-reported outcomes (e.g., quality of life) available?

No

Patient-generated data

Is patient-generated information (e.g., from wearable devices) available?

Yes

Units of healthcare utilisation

Are units of healthcare utilisation (e.g., number of visits to GP per year, number of hospital days) available or can they be derived? Units of healthcare utilisation refer to the quantification of the use of services for the purpose of preventing or curing health problems.

No

Unique identifier for persons

Are patients uniquely identified in the data source?

No

Diagnostic codes

Captured

Diagnosis / medical event vocabulary

Not coded (Free text)

Medicinal product information

Captured

Medicinal product information collected

Dose

Dosage regime

Active ingredient(s)

Medicinal product vocabulary

Other

If 'other,' what vocabulary is used?

generic drug names

Quality of life measurements

Captured

Quality of life measurements vocabulary

Not coded (Free text)

Lifestyle factors

Captured

Lifestyle factors

Tobacco use

Alcohol use

Sociodemographic information

Captured

Sociodemographic information collected

Age

Ethnicity

Country of origin

Education level

Gender

Quantitative descriptors

Population Qualitative Data

Population age groups

Paediatric Population (< 18 years)

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Estimated percentage of the population covered by the data source in the catchment area

This varies between countries ranging from a few up to approximately 25%. Regarding the quantitative descriptors by age, the primary objective of the EURAP study is to assess the prevalence of major congenital malformations in offspring exposed to antiseizure medication, with a follow-up until one year after birth.

Description of the population covered by the data source in the catchment area whose data are not collected (e.g., people who are registered only for private care)

Regional sub-set - Those under treatment by physicians that are not participating in the EURAP network

Family linkage

Family linkage available in the data source permanently or can be created on an ad hoc basis

Permanently

Family linkage available between the following persons

Mother-child

Sibling

Population

Population size

23400

Active population size

1585

Median observation time

Median time (years) between first and last available records for unique individuals captured in the data source

2.00

Median time (years) between first and last available records for unique active individuals (alive and currently registered) capt

1.00

Data flows and management

Access and validation

Governance details

Documents or webpages that describe the overall governance of the data source and processes and procedures for data capture and management, data quality check and validation results (governing data access or utilisation for research purposes).

https://www.eurapinternational.org/

Biospecimen access

Are biospecimens available in the data source (e.g., tissue samples)?

No

Access to subject details

Can individual patients/practitioners/practices included in the data source be contacted?

No

Description of data collection

see study protocol at www.eurapinternational.org

Event triggering registration

Event triggering registration of a person in the data source

Other

Event triggering registration of a person in the data source, other

Member of EURAP network reporting pregnancy in consenting patient exposed to antiseizuremedication at time of conception

Event triggering de-registration of a person in the data source

Other

Event triggering de-registration of a person in the data source, other

patient withdrawing consent.

Event triggering creation of a record in the data source

Member of EURAP network reporting pregnancy in consenting patient exposed to antiseizure medication at time of conception. Updates provided by reporting physicians from the network every trimester, after delivery, and at one year

after birth.

Data source linkage

Linkage

Is the data source described created by the linkage of other data sources (prelinked data source) and/or can the data source be linked to other data source on an ad-hoc basis?

No

Data management specifications that apply for the data source

Data source refresh

Every 6 months

Informed consent for use of data for research

Other

Possibility of data validation

Can validity of the data in the data source be verified (e.g., access to original medical charts)?

No

Data source preservation

Are records preserved in the data source indefinitely?

No

Data source preservation length (years)

25 years

Approval for publication

Is an approval needed for publishing the results of a study using the data source?

Yes

Informed consent, other

There is a committee to evaluate requests for data access

Data source last refresh

15/05/2023

Common Data Model (CDM) mapping

CDM mapping

Has the data source been converted (ETL-ed) to a common data model?

No