

EUROmediCAT central database

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Data source

Disease registry

Administrative details

Administrative details

PURI

<https://redirect.ema.europa.eu/resource/50788>

Data source ID

50788

Data source acronym

EUROmediCAT

Data holder

[Ulster University](#)

Data source type

Disease registry

Main financial support

Other

Care setting

Other

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

<https://www.euromedicat.eu>

Contact details

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Data source regions and languages

Data source countries

Belgium

Croatia

Denmark

France

Germany

Ireland

Italy

Malta

Netherlands

Norway

Poland

Spain

Switzerland

Data source languages

English

Data source establishment

Data source established

15/06/2011

Data source time span

First collection: 01/01/1995

The date when data started to be collected or extracted.

Publications

Data source publications

Cavadino A, Sandberg L, Öhman I, Bergvall et al. Signal Detection in EUROmediCAT: Identification and Evaluation of Medication-Congenital Anomaly Associations and Use of VigiBase as a Complementary Source of Reference. *Drug Saf.* 2021 Jul;44(7):765-785. doi: 10.1007/s40264-021-01073-z. Epub 2021 May 9. PMID: 33966183.

Leke AZ, Dolk H, Loane M, et al. Macrolide and lincosamide antibiotic exposure in the first trimester of pregnancy and risk of congenital anomaly: A European case-control study. *Reprod Toxicol.* 2021 Mar;100:101-108

Dolk H, Damase-Michel C, Morris JK, Loane M. COVID-19 in pregnancy—what study designs can we use to assess the risk of congenital anomalies in relation to COVID-19 disease, treatment and vaccination? *Paediatr Perinat Epidemiol.* 2022; 36: 493–507

Given JE, Loane M, Garne E, Addor MC et al. Metformin exposure in first trimester of pregnancy and risk of all or specific congenital anomalies: exploratory case-control study. *BMJ* 2018;361:k2477

Dolk, H., Wang, H., Loane, M., Morris, J et al. Lamotrigine use in pregnancy and risk of orofacial cleft and other congenital anomalies. *Neurology*, 86(18), 1716-25. (Full text)

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

Methods for controlling by indication for prescriptions: application to medications for neuropathic pain

Exposure to SSRI/SNRI and depression in pregnancy and long-term childhood outcomes: the effect of modifying factors

Novel statistics to handle rare diseases and small sample sizes using Bayesian techniques: Application to Multiple Sclerosis (MS) and Systemic Lupus Erythematosus (SLE) in pregnancy

Improving detection of associations between congenital anomalies and medicines taken in the first trimester of pregnancy, using data derived hierarchies.

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

Congenital anomaly

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.

Yes

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

Not Captured

Prescriptions of medicines

Captured

Prescriptions vocabulary

ATC

Dispensing of medicines

Not Captured

Advance 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?

No

Indication for use

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

Captured

Indication vocabulary

ICD

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)?

Not Captured

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.

No

Clinical measurements

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

No

Genetic data

Are data related to genotyping, genome sequencing available?

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?

No

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?

Yes

Diagnostic codes

Captured

Diagnosis / medical event vocabulary

ICD-10

ICD-9

Medicinal product information

Captured

Medicinal product vocabulary

ATC

Quality of life measurements

Not Captured

Lifestyle factors

Not Captured

Sociodemographic information

Captured

Sociodemographic information collected

Age

Country of origin

Education level

Gender

Type of residency

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)

Children (2 to < 12 years)

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

The data source is population-based and covers all births in the areas covered by the participating registries.

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 - Some of the participating countries have a national registry which cover the entire country, others are restricted to a specific population region within the country.

Population

Population size

288446

Active population

Active population size

288446

Median observation time

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

1.00

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

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).

<http://www.EUROmediCAT.eu/currentresearchanddata>

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

Each registry collects data on cases with congenital anomalies (livebirths, fetal deaths from 20 weeks gestational age and terminations of pregnancy for fetal anomaly at any gestation), according to their own local registry processes and governance.

Event triggering registration

Event triggering registration of a person in the data source

Disease diagnosis

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

Other

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

Case does not have a major congenital anomaly

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?

Yes

Linkage description, possible linkage

Some registries can link their congenital anomaly data to local prescription or administrative databases in order to obtain more accurate information on medications dispensed during pregnancy. Data have also been previously linked to diabetic cohorts and population cohorts.

Linked data sources

Pre linked

Is the data source described created by the linkage of other data sources?

No

Data source, other

20 EUROCAT registries contribute data to the EUROmediCAT central database.

Linkage variable

Available upon request

Linkage completeness

Available upon request

Data management specifications that apply for the data source

Data source refresh

Yearly

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)?

Yes

Data source preservation

Are records preserved in the data source indefinitely?

Yes

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

31/10/2022

Common Data Model (CDM) mapping

CDM mapping

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

Yes

CDM Mappings

CDM name

EUROCAT

CDM website

<https://eu-rd-platform.jrc.ec.europa.eu/eurocat/Data-collection/guidelines-for-...>

Data source ETL specifications (link)

<https://eu-rd-platform.jrc.ec.europa.eu/eurocat/data-collection/guidelines-for-...>