ERN eUROGEN registry

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Data source | Congenital anomaly registry | Disease registry

Administrative details

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PURI
https://redirect.ema.europa.eu/resource/1000000048

Data source ID
1000000048

Data source acronym
ERN eUROGEN registry

Data holder
Radboud University Medical Center (Radboudumc)

Data source type
Congenital anomaly registry
Disease registry

Main financial support
European public funding

Care setting
Hospital inpatient care
Hospital outpatient care
Primary care – specialist level (e.g. paediatricians)

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://eurogen-ern.eu/what-we-do/registry/

Contact details

Loes van der Zanden

Main

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Data source regions and languages

Data source countries

Austria
Belgium
Croatia
Czechia
Denmark
Finland
France
Germany
Italy
Lithuania
Netherlands
Poland
Portugal
Spain
Sweden

Data source languages

English

Data source establishment

Data source established

01/01/2022

Data source time span

First collection: 26/01/2022

The date when data started to be collected or extracted.

Publications

Data source publications

Development of the ERN eUROGEN registry

Overview of Workstream 1 Expertise Areas, Conditions & ORPHA/ICD-10 codes

Overview of Workstream 2 Expertise Areas, Conditions & ORPHA/ICD-10 codes

Overview of Workstream 3 Expertise Areas, Conditions & ORPHA/ICD-10 codes

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)

Rare urogenital diseases & complex conditions, related to either ‘Rare congenital uro-recto-genital anomalies (Workstream 1)’, ‘Functional urogenital conditions requiring highly specialised surgery (Workstream 2)’ & ‘Rare urogenital tumours (Workstream 3)’

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
Yes

ICU admission
Is information on intensive care unit admission available?
No

Cause of death
Not Captured

Prescriptions of medicines
Captured

Prescriptions vocabulary
not coded

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?
Not Captured

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

Administration of vaccines
No

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

Procedures vocabulary
ICD-10
Not coded (Free text)
Orphacode

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?
Yes

Genetic data
Are data related to genotyping, genome sequencing available?
Captured

Genetic data vocabulary
HGNC
HGVS
OMIM

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.
Captured

Biomarker data vocabulary
Other

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
Orphacode

Medicinal product information

Not Captured

Quality of life measurements

Not Captured

Quality of life measurements vocabulary

other

Lifestyle factors

Not Captured

Sociodemographic information

Captured

Sociodemographic information collected

Age
Gender
Sex

Quantitative descriptors

Population Qualitative Data

Population age groups
Paediatric Population (< 18 years)
Adult and elderly population (>18 years)

Estimated percentage of the population covered by the data source in the catchment area
2% as baseline, target is 10% in 2027.

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)
Only patients who give informed consent are registered in the ERN eUROGEN registry.

Population

Population size
823

Active population

Active population size
823

Median observation time

Median time (years) between first and last available records for unique individuals captured in the data source
2.10

Median time (years) between first and last available records for unique active individuals (alive and currently registered) capt
2.10

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).
See tab 'Project Management'

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?

Yes

Description of data collection

Data is collected and entered by trained medical staff at each Health Care Provider into the central database. The Castor database is used to store the data. For each patient, information about the Informed Consent is gathered, as well as the Common Data Elements that were developed by the EJP RD. Based on the diagnosis of the patient, specific clinical questions need to be filled out as well. Soon, patients will receive surveys to fill out themselves.

Event triggering registration

Event triggering registration of a person in the data source

Disease diagnosis
Other

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

Signed Informed Consent

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

Other

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

Withdrawal of Informed Consent

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
Linkage with other data sources using the Common Data Elements (SPIDER pseudonym) as developed by the Joint Research Centre (JRC)

Data management specifications that apply for the data source

Data source refresh
Monthly

Informed consent for use of data for research
Required for general use

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?
Yes

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

Data source last refresh
01/04/2024

Common Data Model (CDM) mapping

CDM mapping
Has the data source been converted (ETL-ed) to a common data model?
No