ERN RARE-LIVER prospective research registry

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Data source | Human | Disease registry | Other

Administrative details

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Data source ID

40246

Data source acronym

R-LIVER rare liver disease registry

Data holder

University Medical Centre Hamburg-Eppendorf

Data source type

Disease registry

Other

Data source type, other

Prospective studies database

Main financial support

European public funding

Care setting

Hospital inpatient care

Hospital outpatient care

Primary care – specialist level (e.g. paediatricians)

Secondary care – specialist level (ambulatory)

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://rare-liver.eu/registry

Contact details

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Data source regions and languages

Data source countries

Argentina

Belgium

Canada

Czechia

Denmark

Germany

Greece

Hungary

Israel

Italy

Lithuania

Netherlands

Poland

Slovakia

Spain

Switzerland

United Kingdom

Data source languages

English

Data source establishment

Data source established

15/06/2018

Data source time span

First collection: 01/05/2017

The date when data started to be collected or extracted.

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

Autoimmune hepatitis

Primary biliary cholangitis

Polycystic liver disease

Portal vein thrombosis

Disease details (other)

Primary sclerosing cholangitis (PSC), polycystic liver disease, biliary artresia, Budd-Chiari-Syndrome (BCS), Non cirrohtic portal hypertension (NCPIH), Sinusoidal Obstruction Syndrome (SOS)

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

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?

No

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.

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?

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.

Captured

Biomarker data vocabulary

Other

Biomarker vocabulary, other

Not coded (free text)

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

Medicinal product information

Captured

Medicinal product information collected

Active ingredient(s)

Dose

Medicinal product vocabulary

Not coded (Free text)

Quality of life measurements

Not Captured

Lifestyle factors

Captured

Lifestyle factors

Alcohol use

Tobacco use

Sociodemographic information

Captured

Sociodemographic information collected

Age

Ethnicity

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)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

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

We are not able to provide the percentage of population covered since this number is unknown.

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 - Data capture is restricted to participating centres in each country that are members and partners of European Reference Network on Hepatological, and thus do not represent nation-wide data sets.

Population

Population size

1678

Active population size

1534

Population by age group

Age group	Population size	Active population size
Paediatric Population (< 18 years)	162	154
Preterm newborn infants (0 – 27 days)	0	0
Term newborn infants (0 – 27 days)	0	0
Infants and toddlers (28 days – 23 months)	8	7
Children (2 to < 12 years)	43	41
Adolescents (12 to < 18 years)	111	106
Adults (18 to < 46 years)	501	456
Adults (46 to < 65 years)	667	619
Elderly (≥ 65 years)	348	305
Adults (65 to < 75 years)	252	224
Adults (75 to < 85 years)	85	74
Adults (85 years and over)	11	7

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) 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://rare-liver.eu/about/governance

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

eCRFs based on CastorEDC

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

Death

Loss to follow up

Other

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

Liver transplantation; study opt-out

Event triggering creation of a record in the data source

Updates of the exisiting patient entry are triggered by a yearly follow-up visit at the treating hospital

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

Quarterly

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

24/05/2021

Common Data Model (CDM) mapping

CDM mapping

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

No