World Bleeding Disorders Registry

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Data source **Human** **Disease registry**

Administrative details

Administrative details

PURI

https://redirect.ema.europa.eu/resource/48312

Data source ID

48312

Data source acronym

World Bleeding Disorders Registry

Data holder

World Federation of Hemophilia (WFH)

Data source type

Disease registry

Main financial support

Funding from industry or contract research

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://wfh.org/research-and-data-collection/world-bleeding-disorders-registry/

Contact details

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Main

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Data source regions and languages

Data source countries

Algeria

Argentina

Bangladesh

Barbados

Belgium

Bolivia, Plurinational State of

Cameroon

Cuba

Czechia

Côte d’Ivoire

Egypt

Ethiopia

Ghana

Guinea

India

Indonesia

Iran, Islamic Republic of

Iraq

Japan

Kenya

Kyrgyzstan

Madagascar

Malawi

Morocco

Nepal

New Zealand

Nigeria

Pakistan

Panama

Philippines

Portugal

Senegal

Serbia

South Africa

Sudan

Syria

Thailand

Tunisia

Uganda

United States

Venezuela, Bolivarian Republic of

Viet Nam

Zambia

Data source languages

English

French

Russian

Spanish

Data source establishment

Data source established

01/01/2018

Data source time span

First collection: 26/01/2018

The date when data started to be collected or extracted.

Publications

Data source publications

Coffin D, Herr C, O'Hara J, Diop S, Hollingsworth R, Srivastava A, LillicrapD, van den Berg HM, Iorio A, Pierce GF. World bleeding disorders registry: Thepilot study. Haemophilia. 2018 May,24(3):e113-e116.

Data elements collected

The data source contains the following

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

Von Willebrand's disease

Disease details (other)

Hemophilia

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

Captured

Cause of death vocabulary

Not coded (Free text)

Other

Cause of death vocabulary, other

Bespoke list of options including common death reasons, and resons seen in bleeding disorders patients.

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)].

Yes

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

Other

Indication vocabulary, other

Hemophilia specific indication vocabulary

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

ICD-10

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

Other

Genetic data vocabulary, other

Bespoke list of options including types of genetic mutations.

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?

Yes

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.

Yes

Unique identifier for persons

Are patients uniquely identified in the data source?

Yes

Diagnostic codes

Captured

Diagnosis / medical event vocabulary

ICD-10

Medicinal product information

Captured

Medicinal product information collected

Brand name

Dosage regime

Dose

Medicinal product vocabulary

Other

If 'other,' what vocabulary is used?

All hemophilia products are provided in a dropdown list, which is based on the WFH CFC Registry.

Quality of life measurements

Captured

Quality of life measurements vocabulary

EQ5D

Lifestyle factors

Not Captured

Sociodemographic information

Captured

Sociodemographic information collected

Age

Country of origin

Gender

Marital status

Socioeconomic status

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

11% (average percentage based on available disease population data collected though the WFH Annual Global Survey from 43 countries in 2021)

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 - We currently have 115 treatment centres from 44 countries, data is not national

Population

Population size

12857

Active population size

12743

Population by age group

Age group	Population size	Active population size
Paediatric Population (< 18 years)	5369	5354

Age group	Population size	Active population size
Preterm newborn infants (0 – 27 days)	0	0
Term newborn infants (0 – 27 days)	0	0
Infants and toddlers (28 days – 23 months)	152	152
Children (2 to < 12 years)	3081	3071
Adolescents (12 to < 18 years)	2136	2131
Adults (18 to < 46 years)	6816	5782
Adults (46 to < 65 years)	970	958
Elderly (≥ 65 years)	305	283
Adults (65 to < 75 years)	230	216
Adults (75 to < 85 years)	62	58
Adults (85 years and over)	13	9

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://wfh.org/research-and-data-collection/world-bleeding-disorders-registry/

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

Online custom-made database where each participating site has their private portal and access to their site's data only.

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

Loss to follow up

Event triggering creation of a record in the data source

Treatment, medical consultation, regular follow up visits

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, pre-linked

Deterministic data linkage method for both linkages. All data is de-identified. Each patient is identified through a unique patient identifier, which is developed through a cryptogenic hashing process, if the same cryptogenic hashing process is applied to data from another database, the 2 databases can be linked, while keeping data de-identified.

Linked data sources

Pre linked

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

Yes

Data source, other

Czechia National Hemophilia Program (CNHP) Registry - Czechia

Linkage strategy

Deterministic

Linkage variable

Unique patient identifier

Linkage completeness

All mapped data and core dataset are collected annually from each national registry.

Pre linked

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

Yes

Data source, other

Hereditary Bleeding Disorders Registry (HBDR) of the Thai Society of Hematology (TSH) - Thailand

Linkage strategy

Deterministic

Linkage variable

Unique patient identifier

Linkage completeness

All mapped data and core dataset are collected annually from each national registry.

Data management specifications that apply for the data source

Data source refresh

Every 6 months

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)?

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

Data source last refresh

15/11/2022

Common Data Model (CDM) mapping

CDM mapping

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

No