FranceCoag

First published: 01/02/2024

Last updated: 17/10/2024

Data source | Human | Biobank | Hospital outpatient visit records | Other | Registration with healthcare system

Administrative details

Administrative details

PURI

https://redirect.ema.europa.eu/resource/24427

Data source ID

24427

Data source acronym

FranceCoag

Data holder

Assitance Publique des Hopitaux de Marseille (APHM)

Data source type

Biobank

Hospital outpatient visit records

Other

Registration with healthcare system

Data source type, other

exposure registry

Main financial support

Funding from public-private partnership

National, regional, or municipal public funding

Care setting

Hospital inpatient care

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

https://www.francecoag.org/

Contact details

Hervé Chambost

Main

Herve.chambost@ap-hm.fr

Pascal Auquier

Alternate

Pascal.auquier@univ-amu.fr

Data source regions and languages

Data source countries

France

Data source languages

French

Data source establishment

Data source established

15/06/2003

Data source time span

First collection: 18/10/1994

The date when data started to be collected or extracted.

Publications

Data source publications

FranceCoag: a 22-year prospective follow-up of the national French cohort of patients with inherited bleeding disorders

Epidemiology of hereditary bleeding disorders: input of FranceCoag Network

The French haemophilia cohort: rationale and organization of a long-term national pharmacosurveillance system

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

LONG-TERM NON-INTERVENTIONAL SAFETY STUDY OF EMICIZUMAB TREATMENT IN PATIENTS WITH MODERATE HAEMOPHILIA A AND SEVERE BLEEDING PHENOTYPE (STUDY BO44691, PASS)

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

Haemophilia

Von Willebrand's disease

Disease details (other)

Platelet disorders such as Glanzmann thrombastenia, other inherited rare clotting factor deficiencies

---

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

ICD-10-CM

Not coded (Free text)

Prescriptions of medicines

Captured

Prescriptions vocabulary

ATC

other

Prescriptions vocabulary, other

THERIAQUE

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?

Yes

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?

No

Administration of vaccines

Yes

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.

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?

Captured

Genetic data vocabulary

Other

Genetic data vocabulary, other

HGVS, EAHAD-DB

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.

No

Unique identifier for persons

Are patients uniquely identified in the data source?

Yes

Diagnostic codes

Captured

Diagnosis / medical event vocabulary

ICD-10-CM

Orphacode

Orphanet Rare Disease Ontology (ORDO)

Medicinal product information

Captured

Medicinal product information collected

Brand name

Dosage regime

Medicinal product vocabulary

ATC

Other

If 'other,' what vocabulary is used?

THERIAQUE

Quality of life measurements

Captured

Quality of life measurements vocabulary

EQ5D

WHOQOL

Lifestyle factors

Captured

Lifestyle factors

Frequency of exercise

Sociodemographic information

Captured

Sociodemographic information collected

Age

Country of origin

Education level

Ethnicity

Gender

Health area

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

80% for registrable people: severe and moderate hemophilia, severe von Willebrand disease, FI and FXIII deficiencies, Glanzmann thrombastenia, Bernard–Soulier syndrome

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)

Nation-wide

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

Household

Population

Population size

14246

Active population size

13394

Population by age group

Age group	Population size	Active population size
Paediatric Population (< 18 years)	3793	3769

Age group	Population size	Active population size
Term newborn infants (0 – 27 days)	20	16
Infants and toddlers (28 days – 23 months)	249	242
Children (2 to < 12 years)	1942	1935
Adolescents (12 to < 18 years)	1582	1576
Adults (18 to < 46 years)	5825	5693
Adults (46 to < 65 years)	2865	2591
Elderly (≥ 65 years)	1763	1341
Adults (65 to < 75 years)	1049	888
Adults (75 to < 85 years)	537	378
Adults (85 years and over)	177	75

Median observation time

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

33.10

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

31.30

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.francecoag.org/SiteWebPublic/html/documentsTele.html

Biospecimen access

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

Yes

Biospecimen access conditions

Scientific council agreement + patients consent + committee for the protection of individuals agreement

Access to subject details

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

Yes

Description of data collection

Periodic collection of data carried out by physicians on the medical patient file and/or the health record, during medical consultations + periodic collection of self-reported data by patient

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

Patient opposition to FranceCoag follow-up

Event triggering creation of a record in the data source

Patient with all inclusion criteria, and followed-up according to the MHEMO recommended schedule

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

Patient personal data from the FranceCoag database and the CépiDC can be directly matched using the "Responsable de Traitement (RT)" scheme recommended by the French Data Protection Authority (CNIL). Deterministic linkage for CépiDc, in order to determine death causes.

Linkage description, possible linkage

Patient personal data from the FranceCoag database and the SNDS (national health data system) can be directly matched using the "Responsable de Traitement (RT)" scheme recommended by the French Data Protection Authority (CNIL). All linkages for further researches.
Deterministic linkage for SNDS via NIR (social insurance number).
Probabilistic linkage for CRMW.

Linked data sources

Pre linked

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

Yes

Data source, other

CépiDC

Linkage strategy

Deterministic

Linkage variable

NIR (social insurance number),date of birth,gender

Linkage completeness

100.00%

Pre linked

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

No

Data source, other

CRMW

Linkage strategy

Probabilistic

Linkage variable

NIR (social insurance number),date of birth,gender,diagnosis,disease severity

Linkage completeness

80%

Pre linked

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

No

Data source, other

SNDS

Linkage strategy

Deterministic

Linkage variable

NIR (social insurance number),date of birth,gender,diagnosis,disease severity

Linkage completeness

100%

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?

No

Data source preservation length (years)

20 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; it depends on the nature of the research (information +/- consent is required)

Data source last refresh

12/10/2022

Common Data Model (CDM) mapping

CDM mapping

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

No