IRCCS Policlinico San Donato

First published: 01/02/2024

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Data source   Human   Biobank   Hospital inpatient records

Hospital outpatient visit records   Other

Administrative details

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PURI

https://redirect.ema.europa.eu/resource/1111159

Data source ID

1111159

Data source acronym

PSD

Data holder

IRCCS Policlinico San Donato (PSD)

Data source type

Biobank

Hospital inpatient records

Hospital outpatient visit records

Other

Data source type, other

Lab measurements

Main financial support

European public funding

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.

Yes

Description of the qualification

UNI EN ISO 9001:2015

Data source website

https://www.grupposandonato.it/strutture/policlinico-san-donato

Contact details

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Data source regions and languages

Data source countries

Italy

Data source languages

English

Italian

Data source establishment

Data source established

01/01/2012

Data source time span

First collection: 01/01/2012

The date when data started to be collected or extracted.

Publications

Data source publications

Ross Operation in Pediatric Population: Impact of the Surgical Timing and the Native Pulmonary Diameter on the Outcome

Elucidating the mechanisms underlying left ventricular function recovery in patients with ischemic heart failure undergoing surgical remodeling: A 3-dimensional ultrasound analysis

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.

No

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)?

No

Hospital admission and/or discharge

Yes

ICU admission

Is information on intensive care unit admission available?

Yes

Cause of death

Not Captured

Prescriptions of medicines

Not 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?

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-9-CM

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.

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-9-CM

Medicinal product information

Not Captured

Quality of life measurements

Not Captured

Lifestyle factors

Not Captured

Sociodemographic information

Captured

Sociodemographic information collected

Age

Education level

Gender

Marital status

Quantitative descriptors

Population Qualitative Data

Population age groups

Paediatric Population (< 18 years)

Infants and toddlers (28 days – 23 months)

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

IRCCS Policlinico San Donato is a research hospital whose geographic coverage concerns mainly the Northern part of Italy, especially the Lombardy region, but as a hub for congenital and rare heart disease, it also covers paediatric and adult patients from Europe and outside European borders.

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)

IRCCS Policlinico San Donato is one of many hospitals in Lombardy and represents the excellence of the Italian Healthcare System for cardiovascular disease.

Population

Population size

403973

Active population size

86213

Population by age group

Age group	Population size	Active population size

Paediatric Population (< 18 years)	54717	12166
Infants and toddlers (28 days – 23 months)	8558	1147
Children (2 to < 12 years)	27360	5906
Adolescents (12 to < 18 years)	18799	5113
Adults (18 to < 46 years)	136276	28638
Adults (46 to < 65 years)	114416	25856
Elderly (≥ 65 years)	98564	19553
Adults (65 to < 75 years)	48503	9935
Adults (75 to < 85 years)	36725	7203
Adults (85 years and over)	13336	2415

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

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

Clinical practice data are collected and recorded in real time in EHR. The ETL procedure developed for the EHDEN project is performed weekly.

Event triggering registration

Event triggering registration of a person in the data source

Practice registration

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 request

Event triggering creation of a record in the data source

Inpatient visit, outpatient visit, laboratory measurement, diagnostic test, biobank specimen

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

Unique patient ID can collect data about inpatient and outpatient visit, diagnosis, procedures, devices, lab measurement, cardiological ultrasound test, biobank specimen, pathological anatomy report

Linkage description, possible linkage

We plan to capture drug information (active principle, dosage, route of administration, time of administration) starting on 2024.

Linked data sources

Pre linked

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

Yes

Data source, other

Currently our data source gathers data from four different internal EHR sources.

Linkage strategy

Deterministic

Linkage variable

Unique patient ID

Linkage completeness

Completed

Pre linked

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

No

Data source, other

EHR Drug administration module

Linkage variable

Unique patient ID, Inpatient visit ID

Linkage completeness

The linkage to this drug source data is planned for 2024

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)?

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

24/04/2023

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

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

Data source ETL CDM version

5.4

Data source ETL frequency

0,25 months

Data source ETL status

Completed