# Istituti Clinici Scientifici Maugeri IRCCS (ICSM)

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Data source

Human

**Hospital discharge records** 

**Hospital inpatient records** 

**Pharmacy dispensing records** 

# Administrative details

### Administrative details

#### **Data source ID**

1000000574

#### Data source acronym

**ICSM** 

#### **Data holder**

Istituti Clinici Scientifici Maugeri IRCCS (ICSM)

#### **Data source type**

Hospital discharge records

Hospital inpatient records

Pharmacy dispensing records

#### Main financial support

Funding by own institution

National, regional, or municipal public funding

#### **Care setting**

Hospital inpatient 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**

During the ETL development process to implement the OMOP CDM, we worked with an EHEDEN-certified SME (Biomeris SRL) who helped us configure the virtual machines (VMs) hosting the OMOP database and web API, and implement the OMOP database structure on the VMs.

Biomeris SRL also supported us during the ETL development and quality control process, ensuring that the OMOP database was correct in every aspect.

We are currently working on the official certification.

#### **Data source website**

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## Contact details

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# Data source regions and languages

#### **Data source countries**

Italy

#### **Data source languages**

Italian

#### **Data source regions**

Abruzzo

Basilicata

Calabria

Campania

Emilia-Romagna

Friuli Venezia Giulia

Lazio

Liguria

Lombardia

Marche

Molise

Piemonte

**Puglia** 

Sardegna

Sicilia

Toscana

Trentino-Alto Adige

Umbria

Valle d'Aosta

Veneto

#### 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

An ICT infrastructure to integrate clinical and molecular data in oncology research

The ONCO-I2b2 Project: Integrating Biobank Information and Clinical Data to Support Translational Research in Oncology

International electronic health record-derived COVID-19 clinical course profiles: the 4CE consortium

# 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)

In the ICSM, specific disease information is collected in a vertical database, such as cardiology information, polysomnography information, sleep medicine, neurological diseases and Parkinson's disease. However, these data aren't currently included in the OMOP CDM because, being rare diseases, they relate to a smaller number of patients compared to the number of inpatients.

#### 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?

No

# Not Captured **Prescriptions of medicines** Captured **Prescriptions vocabulary ATC** other RxNorm Prescriptions vocabulary, other **RxNorm Extension Dispensing of medicines** Captured **Dispensing vocabulary ATC** other RxNorm Dispensing vocabulary, other **RxNorm Extension**

#### 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

Cause of death

#### 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?

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-9-CM

Other

**SNOMED** 

#### Procedures vocabulary, other

ICD9-Proc

#### **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.

Yes

Unique identifier for persons
Are patients uniquely identified in the data source?

Yes

Diagnostic codes

Captured

Diagnosis / medical event vocabulary

ICD-9-CM

SNOMED

#### **Medicinal product information**

Captured

#### Medicinal product information collected

Active ingredient(s)

Dose

Route of administration

Strength

#### **Medicinal product vocabulary**

**ATC** 

Other

**RxNorm** 

RxNorm Extension
Quality of life measurements
Not Captured
Lifestyle factors
Captured
Lifestyle factors
Tobacco use
Sociodemographic information
Captured
Sociodemographic information collected
Age
Gender
Other
Sociodemographic information other
County

# Quantitative descriptors

If 'other,' what vocabulary is used?

Population Qualitative Data

#### Population age groups

ΑII

In utero

Paediatric Population (< 18 years)

Neonate

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)

Adult and elderly population (≥18 years)

Adults (18 to < 65 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

In our OMOP CDM we have collected clinical data from more than 60,000 patients from different Italian regions. ICSM is a rehabilitation institute in Northern Italy, which mainly collects patients from Lombardia and Piemonte, but there are also many patients from Southern Italy.

The age distribution of our patient population is mainly elderly: - 13-17: 8 patients - 18-45: 4220 - 46-64: 15330 - 64-75: 12540 - 74-84: 14760 - >= 85: 14600

The gender distribution is uniform: 51% of female patients and 49% of male

patients.

The Fondazione IRCCS Maugeri is an IRCCS network composed of 9 institutes with 21 sites in the north and south of Italy (https://www.icsmaugeri.it/dovesiamo). Currently, the OMOP database only contains data from the Pavia Institute, but we are working to include data from other institutes.

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)

As the ICSM is a rehabilitation hospital, acute care patients and emergency patients are not included in our data source.

# **Population**

#### **Population size**

61500

#### **Active population size**

52000

# Population by age group



## Median observation time

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

0.00

Median time (years) between first and last available records for unique active individuals (alive and currently registered) capt 0.00

# 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).

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#### **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

# Event triggering registration

#### Event triggering registration of a person in the data source

Other

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

Hospitalisation

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

Other

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

the patient never leaves the database

#### Event triggering creation of a record in the data source

A new hospitalisation or event, such as a new diagnosis, procedure, medication, laboratory test or death.

# 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

The OMOP CDM data warehouse contains thousands of patients from hospitalisations at the Pavia Institute since 2012, collected in the hospital information system. The data collected relate to diagnoses, procedures, demographic information, laboratory tests and therapies administered during hospitalisations.

ICSM is currently working on the representation of data coming from outpatient

visits, where the data are stored in unstructured formats.

The ICSM also collects vertical databases on specific diseases, such as cardiological diseases, neurological diseases and sleep medicine, using the REDCap repository. Upon request, it will be possible to create an ad hoc link to REDCap.

# Data management specifications that apply for the data source

#### **Data source refresh**

Quarterly

#### Informed consent for use of data for research

Required for all studies

#### 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

24/04/2025

# 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

V 5.4

#### **Data source ETL frequency**

0,08 months

#### **Data source ETL specifications (file)**

ETL specification.pdf(2.37 MB)

#### **Data source ETL status**

In progress