

# Ambulatory EMR - OMOP

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Data source

Human

Primary care medical records

Specialist ambulatory care records

## Administrative details

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#### PURI

<https://redirect.ema.europa.eu/resource/1111118>

#### Data source ID

1111118

#### Data holder

[IQVIA](#)

#### Data source type

Primary care medical records

Specialist ambulatory care records

## Main financial support

Funding by own institution

Funding from industry or contract research

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## Care setting

Primary care – GP, community pharmacist level

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

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## 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

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## Data source website

<https://www.iqvia.com/solutions/real-world-evidence/real-world-data-and-insights>

# Contact details

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# Data source regions and languages

## Data source countries

United States

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## Data source languages

English

# Data source establishment

## Data source established

01/01/2006

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## Data source time span

**First collection:** 01/01/2006

The date when data started to be collected or extracted.

# Publications

## Data source publications

[Analysis of Dual Combination Therapies Used in Treatment of Hypertension in a Multinational Cohort. JAMA Netw Open. 2022;5\(3\):e223877. doi:10.1001/jamanetworkopen.2022.3877.](#)

[Risk of depression, suicide and psychosis with hydroxychloroquine treatment for rheumatoid arthritis: a multinational network cohort study. Rheumatology, Volume 60, Issue 7, July 2021, Pages 3222–3234,](#)

[Comparative Effectiveness and Safety Between Apixaban, Dabigatran, Edoxaban, and Rivaroxaban Among Patients With Atrial Fibrillation: A Multinational Population-Based Cohort Study. Ann Intern Med. 2022 Nov;175\(11\):1515-1524. doi: 10.7326/M22-0511. Epub 2022 Nov 1.](#)

# Studies

## List of studies that have been conducted using the data source

[Sodium-Glucose Cotransporter-2 Inhibitor \(SGLT-2i\) Use and Risk of Subsequent Amputation](#)

Characteristics of IPF patients initiating nintedanib, pirfenidone or no antifibrotic treatment in the US

The risk of musculoskeletal adverse outcomes after treatment with endocrine blocking treatments for breast cancer (MSKAI)

Ozanimod Real-World Safety - A Post-Authorisation Multi-National Long-term Non-Interventional Study (ORION)

Safety Profile of the NVX-CoV2373 Vaccine in Individuals  $\geq 12$  Years of Age in the United States

## 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

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#### **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

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#### **Pregnancy and/or neonates**

Does the data source collect information on pregnant women and/or neonatal subpopulation (under 28 days of age)?

Yes

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## **Hospital admission and/or discharge**

No

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## **ICU admission**

Is information on intensive care unit admission available?

No

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## **Cause of death**

Not Captured

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## **Prescriptions of medicines**

Captured

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## **Prescriptions vocabulary**

other

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## **Dispensing of medicines**

Captured

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## **Dispensing vocabulary**

other

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## **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

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## **Contraception**

Is information on the use of any type of contraception (oral, injectable, devices etc.) available?

Yes

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## Indication for use

Does the data source capture information on the therapeutic indication for the use of medicinal products?

Captured

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## Indication vocabulary

SNOMED

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## Medical devices

Is information on medicinal devices (e.g., pens, syringes, inhalers) available?

No

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## Administration of vaccines

Yes

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## Procedures

Does the data source capture information on procedures (e.g., diagnostic tests, therapeutic, surgical interventions)?

Captured

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## Procedures vocabulary

Other

SNOMED

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## Procedures vocabulary, other

CPT4

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## 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

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### **Clinical measurements**

Is information on clinical measurements (e.g., BMI, blood pressure, height) available?

Yes

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### **Genetic data**

Are data related to genotyping, genome sequencing available?

Not Captured

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### **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

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### **Biomarker data vocabulary**

Other

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### **Biomarker vocabulary, other**

SNOMED, LOINC, CPT4

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### **Patient-reported outcomes**

Is information on patient-reported outcomes (e.g., quality of life) available?

No

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### **Patient-generated data**

Is patient-generated information (e.g., from wearable devices) available?

Yes

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## 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

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## Unique identifier for persons

Are patients uniquely identified in the data source?

Yes

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## Diagnostic codes

Captured

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## Diagnosis / medical event vocabulary

SNOMED

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## Medicinal product information

Captured

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## Medicinal product information collected

Active ingredient(s)

Brand name

Route of administration

Strength

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## Medicinal product vocabulary

Other

RxNorm

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**If 'other,' what vocabulary is used?**

CVX

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**Quality of life measurements**

Captured

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**Quality of life measurements vocabulary**

other

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**Quality of life measurements, other**

SNOMED

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**Lifestyle factors**

Captured

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**Lifestyle factors**

Alcohol use

Other

Tobacco use

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**Sociodemographic information**

Captured

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**Sociodemographic information collected**

Ethnicity

Gender

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Quantitative descriptors

Population Qualitative Data

## **Population age groups**

Paediatric Population (< 18 years)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly ( $\geq$  65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

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

8%

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## **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)**

General population

## Family linkage

### **Family linkage available in the data source permanently or can be created on an ad hoc basis**

Ad hoc

## Population

**Population size**

87159583

**Active population size**

15715618

Population by age group

Age group	Population size	Active population size
Paediatric Population (< 18 years)	11492338	1847848
Children (2 to < 12 years)	6119659	982579
Adolescents (12 to < 18 years)	4358590	687931
Adults (18 to < 46 years)	28855067	4316033
Adults (46 to < 65 years)	23905728	4483941
Elderly (≥ 65 years)	22906450	5067796
Adults (65 to < 75 years)	12377075	2722610
Adults (75 to < 85 years)	10434495	2251632
Adults (85 years and over)	94880	93554

Median observation time

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

830.00

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

1920.00

## 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://www.pharmacoepi.org/resources/policies/guidelines-08027/>

#### **Biospecimen access**

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

No

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#### **Access to subject details**

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

No

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## **Description of data collection**

Anonymized patient records collected from patient management software used by GPs and selected specialists to document patients' clinical encounters. These records are sent to a central location then processed and aggregated by Ambulatory EMR vendor

## Event triggering registration

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

Practice registration

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

Death

Emigration

Loss to follow up

Practice deregistration

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

Physician encounter

## 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

## Linked data sources

**Pre linked**

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

No

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**Data source, other**

Pharmetrics

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**Linkage strategy**

Deterministic

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## Data management specifications that apply for the data source

**Data source refresh**

Quarterly

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**Informed consent for use of data for research**

Not Required

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**Possibility of data validation**

Can validity of the data in the data source be verified (e.g., access to original medical charts)?

No

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**Data source preservation**

Are records preserved in the data source indefinitely?

Yes

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**Approval for publication**

Is an approval needed for publishing the results of a study using the data source?

No

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**Data source last refresh**

01/11/2022

## 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

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**CDM website**

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

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**Data source ETL CDM version**

5.3.1

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**Data source ETL frequency**

4,00 months

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**Data source ETL status**

Completed