Ambulatory EMR - OMOP

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Data source

Primary care medical records

Specialist ambulatory care records

Administrative details

Administrative details

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

Care setting

Primary care – GP, community pharmacist level 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://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

Data source languages

English

Data source establishment

Data source established

01/01/2006

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 ? 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

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

No

ICU admission

Is information on intensive care unit admission available?

No

Cause of death

Not Captured

Prescriptions of medicines

Captured

Prescriptions vocabulary

other

Dispensing of medicines

Captured

Dispensing vocabulary

other

Advance 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?

Yes

Indication for use

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

Captured

Indication vocabulary

SNOMED

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)?

Captured

Procedures vocabulary

Other

SNOMED

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?

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.

Captured

Biomarker data vocabulary

Other

Patient-reported outcomes

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

No

Patient-generated data

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

SNOMED

Medicinal product information

Captured

Medicinal product information collected

Active ingredient(s)

Brand name

Route of administration

Strength

Medicinal product vocabulary

Other

RxNorm

Quality of life measurements

Captured

Quality of life measurements vocabulary

other

Lifestyle factors

Captured

Lifestyle factors

Alcohol use

Other

Tobacco use

Sociodemographic information

Captured

Sociodemographic information collected

Ethnicity

Gender

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 (? 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

8%

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

Population

Population size

87159583

Active population

Median observation time

Median time (years) between first and last available records for unique individuals captured in the data source 830.00

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

Access to subject details

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

No

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

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

Death

Emigration

Loss to follow up

Practice deregistration

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

Data source, other

Pharmetrics

Linkage strategy

Deterministic

Data management specifications that apply for the data source

Data source refresh

Quarterly

Informed consent for use of data for research

Not Required

Possibility of data validation

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

No

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?

No

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

CDM website

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

Data source ETL CDM version

5.3.1

Data source ETL frequency

4,00 months

Data source ETL status

Completed