

Drug claims information system

First published: 01/02/2024

Last updated: 17/10/2024

Data source

Human

Administrative healthcare records (e.g., claims)

Administrative details

Administrative details

PURI

<https://redirect.ema.europa.eu/resource/24591>

Data source ID

24591

Data source acronym

PHARM

Data holder

[Department of Epidemiology of the Regional Health Service - Lazio](#)

Data source type

Administrative healthcare records (e.g., claims)

Main financial support

National, regional, or municipal public funding

Care setting

Primary care – GP, community pharmacist level

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

<http://www.deplazio.net>

Contact details

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Data source regions and languages

Data source countries

Italy

Data source languages

Italian

Data source regions

Lazio

Data source establishment

Data source established

15/06/2005

Data source time span

First collection: 15/06/2005

The date when data started to be collected or extracted.

Publications

Data source publications

Rosa AC, Pacchiarotti A, Addis A, Ciardulli A, Belleudi V, Davoli M, Kirchmayer U. Effectiveness and safety of gonadotropins used in female infertility: a population-based study in the Lazio region, Italy. *Eur J Clin Pharmacol*. 2022 Jul;78(7):1185-1196. doi: 10.1007/s00228-022-03330-1. Epub 2022 May 4. PMID: 35507074; PMCID: PMC9184418.

Massari M, Spila Alegiani S, Morciano C, Spuri M, Marchione P, Felicetti P, Belleudi V, Poggi FR, Lazzeretti M, Ercolanoni M, Clagnan E, Bovo E, Trifirò G, Moretti U, Monaco G, Leoni O, Da Cas R, Petronzelli F, Tartaglia L, Mores N, Zanoni G, Rossi P, Samez S, Zappetti C, Marra AR, Menniti Ippolito F; TheShinISS-Vax|COVID Surveillance Group. Postmarketing active surveillance of myocarditis and pericarditis following vaccination with COVID-19 mRNA vaccines in persons aged 12 to 39 years in Italy: A multi-database, self-controlled case series study. *PLoS Med*. 2022 Jul 28;19(7):e1004056. doi: 10.1371/journal.pmed.1004056. PMID: 35900992; PMCID: PMC9333264.

Crescioli G, Finocchietti M, Cascini S, Paoletti O, Franchini D, Cappello E, Valdiserra G, Sciancalepore F, Celani MG, Tuccori M, Vannacci A, Lombardi N, Kirchmayer U and the CAESAR Study Group (2022). Riluzole use in presence of

contraindications in adults affected by amyotrophic lateral sclerosis and its off-label use in other motor neuron diseases: Findings from an Italian multicentre study (the CAESAR project). *Front. Drug Saf. Regul.*, 25 October 2022 Sec. Advanced Methods in Pharmacovigilance and Pharmacoepidemiology Volume 2 - 2022 | <https://doi.org/10.3389/fdsfr.2022.1041275>

Belleudi V, Finocchietti M, Fortinguerra F, Di Filippo A, Trotta F, Davoli M, Addis A. Drug Prescriptions in the Outpatient Management of COVID-19: Evidence-Based Recommendations Versus Real Practice. *Front Pharmacol.* 2022 Mar 24;13:825479. doi: 10.3389/fphar.2022.825479. PMID: 35401220; PMCID: PMC8988061.

Belleudi V, Rosa AC, Finocchietti M, Poggi FR, Marino ML, Massari M, Spila Alegiani S, Masiero L, Ricci A, Bedeschi G, Puoti F, Cardillo M, Pierobon S, Nordio M, Ferroni E, Zanforlini M, Piccolo G, Leone O, Ledda S, Carta P, Garau D, Lucenteforte E, Davoli M, Addis A; CESIT Study Group. An Italian multicentre distributed data research network to study the use, effectiveness, and safety of immunosuppressive drugs in transplant patients: Framework and perspectives of the CESIT project. *Front Pharmacol.* 2022 Sep 15;13:959267. doi: 10.3389/fphar.2022.959267. PMID: 36188626; PMCID: PMC9521186.

Studies

List of studies that have been conducted using the data source

Risk of cardiac valve disorders associated with the use of biphosphonates (Cardiac valve disorders and biphosphonate use)

Arrhythmogenic Potential of Drugs (ARITMO) project

Comparative Effectiveness and Safety of Drugs used in Rare Neuromuscular and Neurodegenerative Diseases (CAESAR)

Prescriber and Pharmacist Understanding of the Risk of Urinary Retention with POTIGA (116490)

Comparative Effectiveness and Safety of Immunosuppressive Drugs in Transplant patients (CESIT)

WEUKBRE5744: European Survey of Patient and Prescriber Understanding of Risks Associated with TROBALT™ (116771)

The BRodalumab Assessment of Hazards: A Multinational Safety (BRAHMS) study in electronic healthcare databases

5ARI and Prostate Cancer Mortality Study (116059)

An epidemiological investigation of high-risk children for Respiratory Syncytial Virus infections - RWE palivizumab utilization as a RSV preventive treatment in Lazio (Italy)

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.

No

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

No

ICU admission

Is information on intensive care unit admission available?

No

Cause of death

Not Captured

Prescriptions of medicines

Captured

Prescriptions vocabulary

ATC

Dispensing of medicines

Captured

Dispensing vocabulary

ATC

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?

No

Administration of vaccines

No

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.

No

Clinical measurements

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

No

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

Not Captured

Medicinal product information

Captured

Medicinal product information collected

Active ingredient(s)

Dose

Package size

Brand name

Formulation

Medicinal product vocabulary

AIC

ATC

Quality of life measurements

Not Captured

Lifestyle factors

Not Captured

Sociodemographic information

Captured

Sociodemographic information collected

Age

Gender

Health area

Pharmaceutical copayment

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 (\geq 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

95%

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)

Regional sub-set - Lazio region

Population

Population size

6983762

Active population size

5599534

Population by age group

Age group	Population size	Active population size
Paediatric Population (< 18 years)	953684	846375
Preterm newborn infants (0 – 27 days)	73	73

Age group	Population size	Active population size
Term newborn infants (0 – 27 days)	1388	1388
Infants and toddlers (28 days – 23 months)	72000	69342
Children (2 to < 12 years)	516696	463290
Adolescents (12 to < 18 years)	363527	312282
Adults (18 to < 46 years)	2114341	1722877
Adults (46 to < 65 years)	1953805	1710593
Elderly (\geq 65 years)	1961932	1319689
Adults (65 to < 75 years)	754897	645999
Adults (75 to < 85 years)	622617	466321
Adults (85 years and over)	584418	207369

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) captured

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?

No

Description of data collection

Administrative Data

Event triggering registration

Event triggering registration of a person in the data source

Residency obtained

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

Death

Emigration

Event triggering creation of a record in the data source

Medicinal product dispensing

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, possible linkage

Record linkage can be performed with all other available information systems (MIS, HIS, HEIS) through an individual patient code

Linked data sources

Pre linked

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

No

Data source, other

HEIS

Linkage strategy

Deterministic

Linkage variable

Anonymous Patient Identifier

Linkage completeness

All mostly completed

Pre linked

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

No

Data source, other

HIS

Linkage strategy

Deterministic

Linkage variable

Anonymous Patient Identifier

Linkage completeness

All mostly completed

Pre linked

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

No

Data source, other

MIS

Linkage strategy

Deterministic

Linkage variable

Anonymous Patient Identifier

Linkage completeness

All mostly completed

Data management specifications that apply for the data source

Data source refresh

Every 6 months

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)?

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?

Yes

Informed consent, other

Upon DPO consent

Data source last refresh

31/12/2022

Common Data Model (CDM) mapping

CDM mapping

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

No