

# Drug claims information system

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Data source

Administrative healthcare claims

## Administrative details

### Administrative details

**PURI**

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

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**Data source ID**

24591

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**Data source acronym**

PHARM

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**Data holder**

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

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**Data source type**

Administrative healthcare claims

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**Main financial support**

National, regional, or municipal public funding

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**Care setting**

Primary care – GP, community pharmacist level

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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

<http://www.deplazio.net>

## Contact details

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## Data source regions and languages

#### Data source countries

Italy

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#### Data source languages

Italian

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#### Data source regions

Lazio

## Data source establishment

#### Data source established

15/06/2005

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#### 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

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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.

No

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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)?

No

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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

ATC

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## Dispensing of medicines

Captured

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## Dispensing vocabulary

ATC

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## 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

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## Contraception

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

No

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## Indication for use

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

Not Captured

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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

No

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## Procedures

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

Not Captured

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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.

No

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### **Clinical measurements**

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

No

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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.

Not Captured

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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?

No

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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**

Not Captured

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### **Medicinal product information**

Captured

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**Medicinal product information collected**

Active ingredient(s)

Dose

Package size

Brand name

Formulation

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**Medicinal product vocabulary**

AIC

ATC

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**Quality of life measurements**

Not Captured

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**Lifestyle factors**

Not Captured

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**Sociodemographic information**

Captured

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**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 (? 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**

95%

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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)**  
Regional sub-set - Lazio region

## Population

**Population size**

6983762

## Active population

**Active population size**

5599534

## Median observation time

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

1.00

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**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

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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**

Administrative Data

# Event triggering registration

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

Residency obtained

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

Death

Emigration

# 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

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## **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

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## **Data source, other**

HEIS

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**Linkage strategy**

Deterministic

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**Linkage variable**

Anonymous Patient Identifier

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**Linkage completeness**

All mostly completed

**Pre linked**

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

No

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**Data source, other**

HIS

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**Linkage strategy**

Deterministic

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**Linkage variable**

Anonymous Patient Identifier

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**Linkage completeness**

All mostly completed

**Pre linked**

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

No

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**Data source, other**

MIS

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**Linkage strategy**

Deterministic

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**Linkage variable**

Anonymous Patient Identifier

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**Linkage completeness**

All mostly completed

## Data management specifications that apply for the data source

**Data source refresh**

Every 6 months

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

Other

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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?

Yes

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**Informed consent, other**

Upon DPO consent

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**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