

Pharmacovigilance Program from Laboratory Signals at La Paz University Hospital

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Data source

Human

Hospital inpatient records

Administrative details

Administrative details

Data source ID

1000000013

Data source acronym

PPLS-LPUH

Data holder

[Hospital La Paz](#)

Data source type

Hospital inpatient records

Main financial support

Funding by own institution

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.

No

Contact details

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Data source regions and languages

Data source countries

Spain

Data source languages

Spanish

Data source regions

Madrid, Comunidad de

Data source establishment

Data source established

01/07/2007

Data source time span

First collection: 01/07/2007

The date when data started to be collected or extracted.

Publications

Data source publications

[Characterisation of Drug-Induced Liver Injury in Patients with COVID-19 Detected by a Proactive Pharmacovigilance Program from Laboratory Signals](#)

[Drug Induced Liver Injury in Geriatric Patients Detected by a Two-Hospital Prospective Pharmacovigilance Program: A Comprehensive Analysis Using the Roussel Uclaf Causality Assessment Method](#)

[Valproic Acid-Induced Liver Injury: A Case-Control Study from a Prospective Pharmacovigilance Program in a Tertiary Hospital](#)

[Incidence of Suspected Serious Adverse Drug Reactions in Corona Virus Disease-19 Patients Detected by a Pharmacovigilance Program by Laboratory Signals in a Tertiary Hospital in Spain: Cautionary Data](#)

[Severe Hyponatremia Is Often Drug Induced: 10-Year Results of a Prospective Pharmacovigilance Program](#)

[Martín-López S, Rogozina O, Aguilar-Concepción D, Álvarez-Montero M, Pardo-Puras R, Akatbach-Bousaid I, Jiménez-González M, Martínez Feito A, González-Muñoz M, Ramírez E. Impact of lymphocyte transformation test on the diagnostic accuracy of the culprit drug in drug-induced cytopenias: a case-control study](#)

Dueñas Lopez FC, del Solar Moreno Z, Aguilar-Concepción D, Ruiz-Fernández C, Akatbach-Bousaid I, Rogozina O, Martín-López S, Martínez Feito A, González-Muñoz M, Ramírez E. The Role of the Lymphocyte Transformation Test in Immune-Related Adverse Events from Immune Checkpoint Inhibitors: A Case Series

Stewart S, Gómez López de Las Huertas A, Jiménez-González M, Carcas AJ, Borobia AM, Ramírez E. ALDRESS: A Retrospective Pilot Study to Develop a Pharmacological Causality Algorithm for Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)

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

Adverse drug reaction

Disease details (other)

Phenotyping of serious adverse drug reactions (ADRs) and their validation through advanced diagnostic testing

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

Yes

ICU admission

Is information on intensive care unit admission available?

Yes

Cause of death

Captured

Cause of death vocabulary

ICD-10-CM

ICD-9

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)].

Yes

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

ICD-10-CM

ICD-9

MedDRA

Medical devices

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

Yes

Administration of vaccines

Yes

Procedures

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

Captured

Procedures vocabulary

ICD

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?

Captured

Genetic data vocabulary

EGO

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

Other

SNOMED

Diagnosis / medical event vocabulary, other

ICD-O

Medicinal product information

Not Captured

Medicinal product information Other

The data source captures comprehensive drug exposure details including the active substance, commercial name, dose, route of administration, and duration of treatment. Specifically, it records both the suspected drug (culprit drug) and all concomitant med

Medicinal product vocabulary

ART 57

Quality of life measurements

Captured

Quality of life measurements vocabulary

EQ5D

Lifestyle factors

Captured

Lifestyle factors

Alcohol use

Diet

Frequency of exercise

Other

Tobacco use

Lifestyle factors included other

Abuse drugs

Sociodemographic information

Not Captured

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 < 65 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

As of January 1, 2024, the total registered population in the Community of Madrid reached 7,058,041 inhabitants (according to the latest official figures from the National Institute of Statistics, INE). Within this regional framework, La Paz University Hospital serves a specifically assigned catchment area of 527,566 people . This represents approximately 7.47% of the total population of the Community of Madrid.

In accordance with the Spanish National Health System's structure, the population is geographically allocated to specific health areas . La Paz University Hospital provides 100% coverage for specialized and hospital care to the residents within its assigned district . Furthermore, as a high-complexity

tertiary hospital, it also provides care to 'displaced' patients (those from other health areas or regions), all of whom are uniquely identified and tracked within the electronic medical record system, ensuring complete data traceability for pharmacovigilance and research purposes .

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 subset: Hospital La Paz (527,566 assigned residents; 7.47% of the Community of Madrid), with tertiary referral coverage for the entire regional population

Population

Population size

537566

Active population size

527566

Population by age group

Age group	Active population size
Adults (85 years and over)	15827

Median observation time

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

12.50

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

8.20

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.agpd.es/portalwebAGPD/english_resources/regulations/common/pdfs/Ley_Organica_3_2001_ingles.pdf

Biospecimen access

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

Yes

Biospecimen access conditions

Approved study

Access to subject details

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

Yes

Description of data collection

From laboratory signals of the hospital:

Laboratory signal definitions:

(1) Agranulocytosis

Neutrophils < 500/mm³, hemoglobin >10g/dl and platelets >100,000x10⁹/L

(2) Pancytopenia

Leukocytes < 3.5 10⁹/L, hemoglobin < 10 mg/dl platelets < 50,000 10⁹/L

(3) Thrombocytopenia

Platelets <20 00010⁹/L

(4) Anaemia

Hemoglobin < 6.5 with leukocytes >3.5x10³ mcl and platelets >50e9/l

(5) Eosinophilia

Absolute and relative eosinophils > upper limit of normal (ULN)

(6) Hepatotoxicity

GPT (ALAT) x 3ULN or ALP x 2 ULN or GGT x2 ULN or BiT x2 ULN.

- Hepatocellular R (ALT/ALP) > 5.

- Cholestatic R < 2.

- or Mixed 2<R <5.

(7) Pancreatitis or mumps

Amylase x3 LSN or lipase x3 LSN

(8) Hyponatremia II**(2)

Sodium < 123 mEq/l

(9) Rhabdomyolysis

Creatine kinase (CK) x5 ULN

(10) Aute Kidney injury AKIN 3

Creatinine x3 ULN

(11) Encephalitis or meningitis

CSF Leukocytes > 10 mm³

Event triggering registration

Event triggering registration of a person in the data source

Disease diagnosis

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

Other

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

Died more than 25 years ago

Event triggering creation of a record in the data source

The event that triggers the creation of a record in the data source was the diagnosis of an adverse drug reaction.

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

Medical record number

Social security number

National identity document (Spain)

Linkage description, possible linkage

Electronic Prescriptions

Electronic dispensation

Laboratory

Pathological anatomy

Microbiology

Radiodiagnosis

Primary care

Data management specifications that apply for the data source

Data source refresh

Monthly

Informed consent for use of data for research

Waiver

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?

No

Data source preservation length (years)

25 years

Approval for publication

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

Yes

Data source last refresh

01/01/2025

Common Data Model (CDM) mapping

CDM mapping

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

No

CDM Mappings