

# 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

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## Care setting

Hospital inpatient care

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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

## Contact details

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## Data source regions and languages

### Data source countries

Spain

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### Data source languages

Spanish

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### Data source regions

Madrid, Comunidad de

## Data source establishment

## Data source established

01/07/2007

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## 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](#)

### 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

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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**

Yes

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## **ICU admission**

Is information on intensive care unit admission available?

Yes

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## **Cause of death**

Captured

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## **Cause of death vocabulary**

ICD-10-CM

ICD-9

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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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## **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

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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**

ICD-10-CM

ICD-9

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## **Medical devices**

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

Yes

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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

ICD

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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?

Captured

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## Genetic data vocabulary

EGO

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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**

Captured

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### **Diagnosis / medical event vocabulary**

ICD

Other

SNOMED

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## **Diagnosis / medical event vocabulary, other**

ICD-O

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## **Medicinal product information**

Not Captured

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## **Quality of life measurements**

Not Captured

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## **Lifestyle factors**

Not Captured

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## **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)

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

The total population registered in the Community of Madrid in 2021 was 6,751,251. Additional data on the population of the Community of Madrid can be obtained from the National Institute of Statistics of Spain. Of this population, 536,448 are assigned to La Paz University Hospital. In Spain, the population is allocated to a designated health area that encompasses a designated referral hospital, determined by the administration based on the physical proximity of the population's residence. Consequently, individuals residing within a particular health area typically receive care at the corresponding referral hospital. However, patients residing outside their assigned health area or from other regions of Spain may seek treatment at a non-corresponding hospital if they are traveling through, but this is uncommon. Regardless, all treated patients have their corresponding health area recorded in their administrative data within the electronic medical record.

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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 - Hospital La Paz < 10%

## **Population**

**Population size**

536448

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**Active population size**

489002

## Median observation time

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

5.00

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

4.70

## 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\\_2018.pdf](https://www.agpd.es/portalwebAGPD/english_resources/regulations/common/pdfs/Ley_Organica_3_2018.pdf)

## **Biospecimen access**

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

Yes

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## **Biospecimen access conditions**

Approved study

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## **Access to subject details**

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

Yes

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## **Description of data collection**

From laboratory signals of the hospital:

Laboratory signal definitions:

(1) Agranulocytosis

Neutrophils  $< 500/\text{mm}^3$ , hemoglobin  $> 10\text{g/dl}$  and platelets  $> 100,000 \times 10^9/\text{L}$

(2) Pancytopenia

Leukocytes  $< 3.5 \times 10^9/\text{L}$ , hemoglobin  $< 10 \text{ mg/dl}$  platelets  $< 50,000 \times 10^9/\text{L}$

(3) Thrombocytopenia

Platelets  $< 20,000 \times 10^9/\text{L}$

(4) Anaemia

Hemoglobin  $< 6.5$  with leukocytes  $> 3.5 \times 10^9/\text{L}$  and platelets  $> 50 \times 10^9/\text{L}$

(5) Eosinophilia

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

(6) Hepatotoxicity

GPT (ALAT)  $\times 3$  ULN or ALP  $\times 2$  ULN or GGT  $\times 2$  ULN or Bilirubin  $\times 2$  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) Acute Kidney injury AKIN 3

Creatinine x3 ULN

(11) Encephalitis or meningitis

CSF Leukocytes > 10 mm<sup>3</sup>

## Event triggering registration

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

Disease diagnosis

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

Other

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

Died more than 25 years ago

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### **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

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### **Linkage description, pre-linked**

Medical record number

Social security number

National identity document (Spain)

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### **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

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

Waiver

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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)?

Yes

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### **Data source preservation**

Are records preserved in the data source indefinitely?

No

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### **Data source preservation length (years)**

25 years

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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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### **Data source last refresh**

31/03/2024

## **Common Data Model (CDM) mapping**

### **CDM mapping**

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

No

### **CDM Mappings**