

# Identification of drug-induced liver injury (DILI) cases in Spain, a national DILI registry (Spanish DILI Registry)

**First published:** 09/11/2012

**Last updated:** 25/08/2022

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS3145

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### Study ID

48726

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### DARWIN EU® study

No

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### Study countries

 Spain

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### Study description

This is a national study that aims to identify drug-induced liver injury (DILI) cases in Hepatology and Clinical Pharmacology units in Spain. This study contains more than 50 clinical units that has sent potential hepatotoxicity cases to the coordinating center in Malaga (using a structured protocol), where the cases are diagnosed as being or not being drug-induced liver injury cases based on the corresponding clinical data acquired by the physician in charge at the collaborating unit. Clinical and demographical data are entered in to a common data base to be used for epidemiological and causality assessment studies. With the patients consent biological samples are also collected, stored in a biobank and used in biomarker identification studies

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### Study status

Ongoing

## Research institutions and networks

### Institutions

#### Spanish DILI Registry

 Spain

**First published:** 13/12/2010

**Last updated:** 28/08/2023

**Institution**

**Educational Institution**

**Hospital/Clinic/Other health care facility**

**ENCePP partner**

### Networks

# Centro de Investigación Biomédica en Red de Enfermedades Hepáticas y Digestivas (CIBERehd)

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Network

## Contact details

### Study institution contact

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Study contact

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### Primary lead investigator

M Isabel Lucena

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 01/06/1999

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### Study start date

Actual: 03/01/1994

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**Data analysis start date**

Actual: 01/06/2001

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**Date of final study report**

Planned: 30/06/2025

## Sources of funding

- EU institutional research programme
- Other

## More details on funding

Agencia Española del Medicamentos y Productos Sanitarios, FISS, MINIM, SAFE-T

## Regulatory

**Was the study required by a regulatory body?**

No

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study type:**

Not applicable

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**Scope of the study:**

Disease epidemiology

**Main study objective:**

Define the main characteristics of patients, type of liver injury, outcome and culprit drugs involved in drug-induced liver injury (DILI), which will serve to guide epidemiologic and genetic studies in order to improve DILI causality assessment and diagnosis

## Study drug and medical condition

**Medical condition to be studied**

Drug-induced liver injury

## Population studied

**Age groups**

- Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)
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**Estimated number of subjects**

1500

## Study design details

## Outcomes

Enhance the knowledge of DILI using collected data for epidemiology and underlying mechanism studies. Generate/amplify signals of risk with the use of new and old drugs that can lead to adoption of regulatory measures ranging from changes in product labeling information to drug withdrawal.

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## Data analysis plan

All data will be analysed in a descriptive manner, no formal hypotheses will be tested. DILI frequencies and incidence rates will be summarized and reported to the Spanish Medicines Agency (Agencia Española del Medicamentos y Productos Santiarios). Clinical characteristics will be analyzed by frequency and percentages for categorical variables and by mean with standard deviation for continuous variables. Risk estimations will be calculated in the form of Odds Ratio. Multiple regression logistic models will be used for identification of independent variables associated with risk.

## Documents

### Study publications

[Medina-Caliz I, Garcia-Cortes M, Gonzalez-Jimenez A, Cabello MR, Robles-Diaz M,...](#)

[Andrade RJ, Lucena MI, Fernández MC, Pelaez G, Pachkoria K, García-Ruiz E, et a...](#)

[Medina-Cáliz I, Robles-Díaz M, García-Muñoz B, Stephens C, Ortega-Alonso A, Gar...](#)

[Stephens C, Robles-Diaz M, Medina-Caliz I, Garcia-Cortes M, Ortega-Alonso A, Sa...](#)

[Robles-Díaz M, Lucena MI, Kaplowitz N, Stephens C, Medina-Cáliz I, González-Jim...](#)

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## Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

### Data sources (types)

Other

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### Data sources (types), other

Prospective patient-based data collection

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

### Check conformance

Unknown

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### Check completeness

Unknown

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### Check stability

Unknown

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## **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No