

# WP6 replication study: The risk of liver injury associated with the use of antibiotics: A study using a US database with linkage with hospital data

**First published:** 26/09/2012

**Last updated:** 01/04/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS2999

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### Study ID

28271

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### DARWIN EU® study

No

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### Study countries

 United States

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### Study status

Finalised

## Research institutions and networks

## Institutions

### Sanofi


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


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

Institution

## Networks

### PROTECT


 Belgium

 Denmark

 France


 Germany

 Italy


 Netherlands

 Poland

 Spain

 Sweden

 Switzerland

 United Kingdom

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Network

## Contact details

### Study institution contact

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Study contact

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### Primary lead investigator

Stéphanie Tcherny-Lessenot

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 02/02/2012

Actual: 02/02/2012

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### Study start date

Planned: 02/04/2012

Actual: 02/04/2012

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### Data analysis start date

Planned: 01/05/2012

Actual: 01/05/2012

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### Date of final study report

Planned: 31/12/2013

Actual: 17/04/2014

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Sanofi

## 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 topic:**

Disease /health condition

Human medicinal product

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#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Validation of study variables (exposure outcome covariate)

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To assess the association between antibiotics use and idiopathic acute liver injury by replicating a nested case-control design in a US claims database

## Study Design

**Non-interventional study design**

Case-control

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(J01) ANTIBACTERIALS FOR SYSTEMIC USE

ANTIBACTERIALS FOR SYSTEMIC USE

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**Medical condition to be studied**

Liver injury

## Population studied

**Short description of the study population**

Patients of all ages with an active or died registration status during the study period of January 1st, 2004 to December 31st, 2009 in the Clinformatics Data Mart. Patients had to attained one year of enrolment in the database at the beginning of the study period.

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### **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**

80000

## **Study design details**

### **Outcomes**

To estimate the risk of acute liver injury associated with antibiotics exposure (users and non-users), To estimate the risk of acute liver injury associated with various antibiotics classes, To estimate the risk of acute liver injury associated with specific individual antibiotics, To assess the effect of dose and duration of use for specific individual antibiotics, To validate cases of liver injury using information from patients' hospital records, To describe the patterns of use of various antibiotics classes and of specific individual antibiotics in the US and to compare with patterns of use in the UK as observed in GPRD, To replicate the analysis using a population-based case-control design

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### **Data analysis plan**

We will compute odds ratios (OR) and 95% confidence intervals of first occurrence of idiopathic acute liver injury associated with current use of antibiotics (as a group and different classes and individual drugs when possible) as compared to non-use with conditional logistic regression.

## Documents

### Study report

[PROTECT WP6 ATB ALI report v1\\_final 17 april 2014.pdf](#) (197.6 KB)

### Study publications

[Udo R, Tcherny-Lessenot S, Brauer R, Dolin P, Irvine D, Wang Y, Auclert L, Juha...](#)

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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)

[Administrative healthcare records \(e.g., claims\)](#)

## 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**

Unknown