# DARWIN EU® Characterization of patients with chronic hepatitis B and C

**First published:** 28/11/2023

**Last updated:** 25/09/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS107650

**Study ID**

107783

**DARWIN EU® study**

Yes

**Study countries**

- [ ] Estonia
- [ ] France
- [ ] Germany
- [ ] Netherlands
- [ ] Spain
- [ ] United Kingdom

**Study description**

Sustainable Development Goals for 2030 set by UN Member States include Target 3.3 states, calling for an end to epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases. The 2016 WHO Global Health Sector Strategy (GHSS) aims to eliminate viral hepatitis by 2030, and WHO EU has developed a hepatitis action plan to steer the implementation of the GHSS in Europe. The European Centre for Disease Prevention and Control (ECDC) has developed a monitoring system for Hepatitis B Viral Infection (HBV) and Hepatitis C Viral Infection (HCV) aligned with indicators and targets of the GHSS and the WHO European Region Action Plan. Comprehensive data on the prevalence of chronic HBV or HCV infections and utilisation of antiviral treatments for chronic HBV or HCV infections are important to monitor progress towards the elimination targets related to treatment, to adjust prevalence estimates over time, and to support effective planning of prevention and control activities by countries. This DARWIN EU imitative aims to provide robust and timely data at national or subnational level. The aims are to report the number and percentage of patients diagnosed with chronic HBV or HCV infection who initiate or undergo treatment with interferon or any specified antivirals, to characterize patients with chronic HBV or HCV infection at the initiation of treatment with interferon or specified antivirals and to estimate the proportion of all patients with chronic HBV or HCV infection. All the analyses will be stratified by age, sex, calendar year, and database during the study period 2012 to 2022.

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**Study status**

Finalised

## Research institutions and networks

## Networks

### Data Analysis and Real World Interrogation Network (DARWIN EU®)

- [ ] Belgium
- [ ] Croatia
- [ ] Denmark
- [ ] Estonia
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Portugal
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

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Network

## Contact details

**Study institution contact**

Ilse Schuemie study@darwin-eu.org

**Study contact**

study@darwin-eu.org

**Primary lead investigator**

Katia Verhamme

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 30/08/2023

Actual: 30/08/2023

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**Study start date**

Planned: 30/08/2023

Actual: 30/08/2023

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**Date of final study report**

Planned: 18/12/2023

Actual: 16/02/2024

## Sources of funding

- EMA

# Study protocol

DARWIN EU_D2.2.3_Protocol_P2-C1-010_HBV_HCV_Pts_Characterisation_v2.1.pdf(951.11 KB)

# Regulatory

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

Yes

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

Not applicable

# Methodological aspects

## Study type

## Study type list

**Study type:**

Non-interventional study

**Main study objective:**

To estimate the number and percentage of individuals initiating or undergoing treatment with interferon or any of the specific antivirals of interests among patients with chronic HBV HCV infection, stratified by age, sex, calendar year and country/database during the study period.

## Study Design

**Non-interventional study design**

Other

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(J05AP) Antivirals for treatment of HCV infections

Antivirals for treatment of HCV infections

(L03AB61) peginterferon alfa-2a, combinations

peginterferon alfa-2a, combinations

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**Medical condition to be studied**

Chronic hepatitis B

Chronic hepatitis C

## Population studied

**Age groups**

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)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

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**Estimated number of subjects**

15800000

## Study design details

**Data analysis plan**

Analyses will be conducted separately for each database. Before study initiation, test runs of the analytics are performed on a subset of the data sources or on a simulated set of patients and quality control checks are performed. Once all the tests are passed, the final package is released in the version-controlled Study Repository for execution against all the participating data sources. The data partners locally execute the analytics against the OMOP CDM in R Studio and review and approve the by default aggregated results before returning them to the Coordination Centre. Sometimes multiple execution iterations are performed, and additional fine tuning of the code base is needed. A service desk will be available during the study execution for support. The study results of all data sources are checked after which they are made available to the team in the Digital Research Environment DRE and the Study Dissemination Phase can start. All results are locked and timestamped for repro.

## Documents

**Study report**

DARWIN EU_D2.2.4_Report_P2-C1-010_HBV_HCV_Pts_Characterisation_v2.1.pdf (2.12 MB)

# 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 source(s)**

Institut Municipal d'Assistència Sanitària Information System

Integrated Primary Care Information (IPCI)

Clinical Practice Research Datalink (CPRD) GOLD

Estonian Biobank

IQVIA Disease Analyzer Germany

Clinical Data Warehouse of the Bordeaux University Hospital

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**Data sources (types)**

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

# Use of a Common Data Model (CDM)

**CDM mapping**

Yes

**CDM Mappings**

**CDM name**

OMOP

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**CDM website**

https://www.ohdsi.org/Data-standardization/

## Data quality specifications

**Check conformance**

Unknown

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No