# The European HBV Registry: A joint initiative of TherVacB and DZIF (HBV Registry)

First published: 03/09/2021

**Last updated:** 25/03/2025





# Administrative details

U PAS number
UPAS42767
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9036
PARWIN EU® study
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tudy countries
Germany
Italy
Spain
United Kingdom

#### Study description

In order to tackle the unmet needs in chronic HBV infection, a consortium of clinical partners has gathered to establish a registry for patients with hepatitis B mono- and co-infections.

The partners will build up a European-wide registry to be able to stratify patients for upcoming clinical trials. Extensive analyses of virus and host-specific parameters are to be carried out from these patients.

The knowledge gained thereby should contribute to a better understanding of the HBV control and enable patient stratification with regard to immunomodulatory therapies.

Furthermore, hepatitis B patients are to be identified who are willing to participate in future studies to investigate immunotherapies to cure HBV infections (e.g. therapeutic vaccines).

## **Study status**

Ongoing

## Research institutions and networks

## Institutions

## Hannover Medical School (MHH)

First published: 01/02/2024

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

Institution

**Educational Institution** 

Hospital/Clinic/Other health care facility

UKE Hamburg, Germany, TUM-MRI Munich,
Germany, UK Leipzig Leipzig, Germany, FCRB
Barcelona, Spain, AOP Parma, Italy, RFH London,
UK, BLT London, UK

## **Networks**

TherVacB, DZIF

## Contact details

#### **Study institution contact**

Julia Kahlhöfer kahlhoefer.julia@mh-hannover.de

 $\Big($  Study contact  $\Big)$ 

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## **Primary lead investigator**

Markus Cornberg

**Primary lead investigator** 

## Study timelines

Date when funding contract was signed

Actual: 01/01/2020

#### Study start date

Actual: 06/05/2021

#### **Date of final study report**

Planned: 31/12/2026

# Sources of funding

- EU institutional research programme
- Other

## More details on funding

BMBF, Horizon 2020

# Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

# Methodological aspects

Study type

Study type list

#### **Study topic:**

Other

## Study type:

Non-interventional study

## **Scope of the study:**

Other

#### If 'other', further details on the scope of the study

Establishment and immunological characterisation of a patient cohort and associated viral markers

## Main study objective:

Characterization of viral and immunological markers in hepatitis B patients. The knowledge gained should contribute to a better understanding of HBV control and enable patient stratification with regard to immunomodulatory therapies.

# Study Design

## Non-interventional study design

Cohort

# Population studied

## Age groups

• Adults (18 to < 46 years)

- Adults (46 to < 65 years)</li>
- Adults (65 to < 75 years)</li>
- Adults (75 to < 85 years)</li>
- Adults (85 years and over)

#### **Estimated number of subjects**

3000

# Study design details

#### **Outcomes**

HBsAg decline/loss, seroconversion to anti-HBs, Quantification of soluble immune mediators, Hepatitis B related Quality of Life (SF36), hepatocellular carcinoma (HCC), liver cirrhosis, death

#### Data analysis plan

Quantification and characterization of viral markers and immunological patient markers.

# 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)

The European HBV Registry - A joint initiative of TherVacB and DZIF

#### **Data sources (types)**

Disease registry

Other

#### 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

## **Check completeness**

Unknown

## **Check stability**

Unknown

## **Check logical consistency**

Unknown

## Data characterisation

## **Data characterisation conducted**

No