

# VIR-Life: Prospective assessment of the real-life treatment outcomes of six years of Viread® in CHB following-up on the German Multicenter Non-Interventional Study GEMINIS

**First published:** 28/06/2013

**Last updated:** 29/03/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS4215

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### Study ID

17262

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### DARWIN EU® study

No

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### Study countries

 Germany

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## Study description

The real-life treatment outcomes of Viread® have been investigated in GEMINIS for a period of 3 years. VIR-Life is the roll-over non-interventional study from GEMINIS to allow the prospective evaluation of the real-life treatment outcomes for additional 3 years. The primary objective of this study is as follows: Prospectively describe the virological response, defined as HBV-DNA concentration, during 6 years Viread® treatment for CHB in a real life setting. The secondary objectives of this study are to evaluate the: Safety and tolerability of 6 years of Viread® in CHB in a real life setting (Adverse drug reactions (AR) (unrelated Adverse Events (AEs) will also be listed in the report), Renal safety, Estimated creatinine clearance (eCrCl), Serum creatinine level, Serum phosphorus level), and histological improvement of the liver. Duration of Study: 3 years after rolling over from GEMINIS Study Size: 150 patients Location: Germany, 23 sites

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## Study status

Finalised

## Research institutions and networks

### Institutions

#### Gilead Sciences

**First published:** 12/02/2024

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**Institution**

**Pharmaceutical company**

Multiple centres: 23 centres are involved in the study

## Contact details

### Study institution contact

Gilead Study Director [GileadClinicalTrials@gilead.com](mailto:GileadClinicalTrials@gilead.com)

Study contact

[GileadClinicalTrials@gilead.com](mailto:GileadClinicalTrials@gilead.com)

### Primary lead investigator

Gilead Study Director

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 15/05/2013

Actual: 15/05/2013

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### Study start date

Planned: 17/07/2013

Actual: 29/07/2013

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### Data analysis start date

Planned: 18/06/2014

Actual: 22/06/2015

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### **Date of interim report, if expected**

Planned: 30/09/2014

Actual: 21/09/2015

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

Planned: 28/04/2017

Actual: 16/12/2016

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Gilead Sciences GmbH

## Study protocol

[protocol GS-DE-174-0225 FINAL COMPLETE.pdf](#) (743.85 KB)

## 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 topic:**

Disease /health condition  
Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

**Data collection methods:**

Secondary use of data

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**Main study objective:**

Describe the virological response, defined as HBV-DNA concentration, during 6 years Viread® treatment for CHB in a real life setting.

## Study Design

**Non-interventional study design**

Cohort  
Other

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**Non-interventional study design, other**

Case-series

## Study drug and medical condition

**Medicinal product name**

VIREAD

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**Medical condition to be studied**

Chronic hepatitis B

## Population studied

**Short description of the study population**

Adult, Hepatitis B Virus (HBV)-mono-infected Chronic hepatitis B (CHB) patients who started CHB treatment with Viread® in GEMINIS and completing 3 years in GEMINIS and still receiving a Viread®.

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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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**Special population of interest**

Hepatic impaired

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**Estimated number of subjects**

150

## Study design details

## Outcomes

HBV-DNA concentration after 6 year TDF, ALT levels throughout 6 years  
TDFRenal function parameters throughout 6 years TDFLiver synthesis  
parameters throughout 6 years TDFLiver histology improvements throughout 6  
years TDFAdverse Reactions to TDF throughout 6 years TDF

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## Data analysis plan

Descriptive analysis: Categorical and ordinal variables will be described by sample size and the frequency of each modality (over the total number of responses). Quantitative variables will be described by the number of responses, mean, standard deviation, minimum, maximum, median of all available data. Inferential analysis: When deemed necessary, sub-group comparisons and/or between time point comparisons may be implemented. Patients who are lost to follow-up or discontinue therapy for any reason, including leaving the study for non-medical reasons will be censored at the discontinuation date. Person time will be computed from baseline to discontinuation and used as such for any time to event analysis. Multivariate analysis: The potential dependence of treatment outcome frequency with other variables or baseline characteristics will be investigated through multivariate analysis.

## Documents

### Study results

[VIR\\_life\\_synopsis\\_16Dec2016.pdf](#) (329.34 KB)

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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**

Unknown