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

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# Administrative details

EU PAS number	
EUPAS4215	
Study ID	
17262	
DARWIN EU® study	
No	
Study countries	
Germany	

#### 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 GEMINISStudy Size: 150 patientsLocation: Germany, 23 sites

### **Study status**

Finalised

# Research institutions and networks

# Institutions

# Gilead Sciences

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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

Study contact

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

#### **Study start date**

Planned: 17/07/2013

Actual: 29/07/2013

#### Data analysis start date

Planned: 18/06/2014

Actual: 22/06/2015

### Date of interim report, if expected

Planned: 30/09/2014

Actual: 21/09/2015

### 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

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

Not applicable

# Methodological aspects

#### Study type

### **Study topic:**

Disease /health condition

Human medicinal product

### Study type:

Non-interventional study

### Scope of the study:

Drug utilisation

#### **Data collection methods:**

Secondary use of data

### 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

### Non-interventional study design, other

Case-series

# Study drug and medical condition

#### Name of medicine

**VIREAD** 

#### 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®.

#### 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)

### **Special population of interest**

Hepatic impaired

# **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

#### 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)

# 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

### 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**

Unknown