

# Drug Utilization of Boceprevir and Clinical Management of Health Outcomes of Interest in Chronic Hepatitis C Patients (P08518)

**First published:** 13/07/2012

**Last updated:** 02/07/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS2768

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### Study ID

24508

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### DARWIN EU® study

No

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### Study countries

 France

 Germany

 Spain

## Study description

This will be an observational study of the routine clinical management of patients infected with Chronic Hepatitis C (CHC) genotype-1. Primary data collection on physicians treating CHC and patients infected with CHC will be performed in approximately 4 European countries (the exact number and final selection of countries will depend on market uptake of Victrelis™ (Boceprevir). This study is not intended to change the patient/physician relationship, nor influence the physician's drug prescription or therapeutic management of the patient. Physicians that treat CHC will provide aggregated site level information about current patterns of CHC treatment via a drug utilization questionnaire. Baseline patient information and data on the occurrence, clinical management of protocol-defined HOIs (anemia, neutropenia, thrombocytopenia, rash) will be collected via eCRF among patients initiating Victrelis in combination with P-R, Incivo in combination with P-R or P-R only regimens. Data will be collected every 8 weeks for up to 48 weeks of treatment.

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## Study status

Finalised

## Research institutions and networks

### Institutions

#### ICON Commercialisation & Outcomes



Germany



Ireland

**First published:** 19/03/2010

**Last updated:** 05/07/2024

**Institution**

**Non-Pharmaceutical company**

**ENCePP partner**

**Multiple centres: 80 centres are involved in the study**

## Contact details

### Study institution contact

Christopher Mast [christopher\\_mast@merck.com](mailto:christopher_mast@merck.com)

**Study contact**

[christopher\\_mast@merck.com](mailto:christopher_mast@merck.com)

### Primary lead investigator

Christopher Mast

**Primary lead investigator**

## Study timelines

### Date when funding contract was signed

Planned: 09/09/2011

Actual: 20/05/2011

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**Study start date**

Planned: 29/05/2012

Actual: 21/05/2012

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**Data analysis start date**

Planned: 30/06/2015

Actual: 06/07/2015

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**Date of interim report, if expected**

Planned: 16/12/2014

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**Date of final study report**

Planned: 30/04/2016

Actual: 10/05/2016

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Merck, Sharp & Dohme

## Study protocol

[Final Redactions Applied\\_ P08518 Victrelis PASS Protocol.pdf](#) (2.38 MB)

## Regulatory

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

Yes

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

EU RMP category 3 (required)

## 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:**

Drug utilisation

Other

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

This is a drug utilisation study, however, we will also assess the occurrence and management of pre-specified protocol defined HOIs (i.e. anemia, neutropenia, thrombocytopenia, and rash) in a real world clinical setting.

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

**Main study objective:**

Describe drug utilization patterns, baseline patient and disease characteristics, and clinical management of pre-specified protocol-defined health outcomes of interest (HOI): anemia, neutropenia, thrombocytopenia and rash - among genotype-1 treatment-naive and/or previous treatment failure patients initiating treatment with Victrelis™ with P-R, Incivo™ with P-R, or P-R alone (without other DAA).

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Study drug International non-proprietary name (INN) or common name**

BOCEPREVIR

TELAPREVIR

RIBAVIRIN

PEGINTERFERON ALFA-2A

PEGINTERFERON ALFA-2B

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**Medical condition to be studied**

Hepatitis C

Anaemia

Thrombocytopenia

Neutropenia

Rash

## Population studied

### **Short description of the study population**

Physicians and patients infected with chronic Hepatitis C genotype-1 from at least 4 European countries.

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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**

1000

## Study design details

### **Outcomes**

1st Primary: Proportion of CHC patients initiating Victrelis™ with P-R relative to Incivo™ with P-R or P-R only. 2nd primary: Proportion of CHC patients initiating any of the treatment above by patient and disease characteristics. 3rd primary: Description of the occurrence & clinical management of HOI's in the treatment

groups specified above. The secondary outcomes of interest are the incidence rates (per unit person time) for protocol defined anemia, neutropenia, thrombocytopenia and rash for the CHC treatment groups in the study.

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### **Data analysis plan**

All data will be analyzed in a descriptive manner, no formal hypotheses will be tested. Frequencies and incidence rates of Health outcomes of interest (HOIs) will be summarized. Clinical characteristics of the study population will be analyzed by frequency and percentages for categorical variables and by mean, standard deviation, minimum, median, and maximum for continuous variables.

## Documents

### **Study results**

[Final Redactions Applied\\_P08518 Victrelis PASS Report Abstract\\_Redacted.pdf](#)  
(560.3 KB)

[P08518 Victrelis PASS Final Report Summary 20170427.pdf](#) (1.23 MB)

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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