

# Practicalities of Using Boceprevir and Early Responses to Treatment: Experience of the First Eighteen Months In the UK. The Boceprevir Real Life Treatment (BRIT) study

**First published:** 01/10/2013

**Last updated:** 17/04/2014

Study

Planned

## Administrative details

### EU PAS number

EUPAS3669

---

### Study ID

6373

---

### DARWIN EU® study

No

---

### Study countries

 United Kingdom

---

### Study description

Evaluate the outcomes of the first two years' use of boceprevir in the UK and the early responses to treatment. This will be a retrospective study, based on data from the records of patients who received up to 12 weeks' treatment for hepatitis C (genotype 1 infection) within a 2-year period.

---


## Study status

Planned

## Research institutions and networks

### Institutions

#### Merck Sharp & Dohme LLC

 United States

**First published:** 01/02/2024

**Last updated:** 08/07/2025

Institution

Pharmaceutical company

#### Chelsea and Westminster Hospital

**First published:** 01/02/2024

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

Institution

#### Royal Free Hospital

**First published:** 01/02/2024

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

**Institution**

Freeman Hospital Newcastle upon Tyne, Royal Bournemouth Hospital Bournemouth, Queen Elizabeth Hospital Birmingham, Derriford Hospital Plymouth, Glasgow Royal Infirmary Glasgow, Stirling Community Hospital Stirling, Chelsea & Westminster Hospital London, Royal Free Hospital London, Guy's & St Thomas' Hospital London

## Contact details

### **Study institution contact**

Mayes Amazigom [amazigom.okafor@merck.com](mailto:amazigom.okafor@merck.com)

**Study contact**

[amazigom.okafor@merck.com](mailto:amazigom.okafor@merck.com)

### **Primary lead investigator**

Mayes Amazigom

**Primary lead investigator**

# Study timelines

## **Date when funding contract was signed**

Planned: 05/11/2012

---

## **Study start date**

Planned: 25/03/2013

---

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

Planned: 17/04/2014

Actual: 04/09/2013

---

## **Date of final study report**

Planned: 14/08/2014

# Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

MSD

## Study protocol

[10'4'13 BRIT Study\\_3rd amendment.pdf](#) (465.78 KB)

## Regulatory

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

No

## Methodological aspects

**Study type:**

Non-interventional study

---

**Scope of the study:**

Drug utilisation

Effectiveness study (incl. comparative)

**Main study objective:**

Explore how clinical management of HCV patients on triple therapy with boceprevir is being implemented in the UK, outside of the clinical trial setting.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medical condition to be studied**

Hepatitis C

## Population studied

**Age groups**

- Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
  - Adults (65 to < 75 years)
-

## Estimated number of subjects

100

## Study design details

### Outcomes

Assess PCR turnaround times, limits of detection (LOD) of PCR assays, and the length of the lead-in period, in clinical practice, estimate the proportion of subjects with early virologic responses at Weeks 4 ( $\geq 1$  log<sub>10</sub> drop), 8 and 12, determine the proportion of subjects adhering to futility rules (patients who discontinue all treatment at Week 12 due to insufficient viral response)

---

### Data analysis plan

Descriptive analysis. Centre information and patient demographics summarised using tables and summary statistics.

## 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**

Retrospective data from hospital records of eligible patients who have received treatment for hepatitis C. Data to be reviewed by treating clinicians.

## 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