

# Medical Records Review to Describe the Patterns of KRAS Testing and Vectibix Use in Europe (20101120)

**First published:** 11/02/2014

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

Study

Finalised

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/20214>

---

### EU PAS number

EUPAS5681

---

### Study ID

20214

---

### DARWIN EU® study

No

---

### Study countries

Belgium

- Czechia
  - Denmark
  - France
  - Germany
  - Italy
  - Netherlands
  - Spain
  - Sweden
- 

### **Study description**

This non-interventional cross-sectional medical record review study will assess the prevalence of KRAS testing and the impact of the KRAS test result on patterns of Vectibix use in patients with metastatic colorectal cancer (mCRC) treated with Vectibix in selected European countries over 3 rounds. As the optimal use of Vectibix also requires accurate KRAS mutation testing, this study will also assess data from the laboratory that performed the KRAS test. The study will also monitor changes in the pattern of Vectibix treatment between the different rounds of the study.

---

### **Study status**

Finalised

## Research institutions and networks

### Institutions

**Amgen**

- United States

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

**Last updated:** 21/02/2024

**Institution**

## Contact details

### Study institution contact

Global Development Leader Amgen, Inc

**Study contact**

[medinfo@amgen.com](mailto:medinfo@amgen.com)

### Primary lead investigator

Global Development Leader Amgen, Inc

**Primary lead investigator**

## Study timelines

### Date when funding contract was signed

Actual: 15/09/2011

---

### Study start date

Actual: 19/09/2012

---

### Data analysis start date

Actual: 12/09/2013

---

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

Planned: 05/05/2014

Actual: 30/06/2014

---

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

Planned: 26/11/2015

Actual: 23/11/2015

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

## Study protocol

[Vectibix\\_20101120\\_Protocol\\_11Feb14.pdf](#)(312.98 KB)

## Regulatory

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

Yes

---

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

EU RMP category 1 (imposed as condition of marketing authorisation)

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition  
Human medicinal product  
Other

---

**Study topic, other:**

Diagnostic procedure - KRAS testing

**Study type:**

Non-interventional study

---

**Scope of the study:**

Drug utilisation  
Other

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

Describe patterns of KRAS biomarker testing prior to initiating treatment

**Data collection methods:**

Secondary use of data

---

**Main study objective:**

This non-interventional cross-sectional medical record review study will assess the prevalence of KRAS testing and the impact of the KRAS test result on patterns of Vectibix use in patients with metastatic colorectal cancer (mCRC) treated with Vectibix over 3 rounds. The study will also monitor changes in the pattern of Vectibix treatment between the different rounds of the study.

## Study Design

## **Non-interventional study design**

Cross-sectional

# Study drug and medical condition

## **Name of medicine**

VECTIBIX

---

## **Medical condition to be studied**

Colorectal cancer metastatic

# Population studied

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

Patients with metastatic colorectal cancer (mCRC) treated with Vectibix following the changes of label about the risk of Vectibix use in mCRC patients with mutant KRAS tumors in selected European countries.

Patients who had received Vectibix for the treatment of mCRC during the 6-month period prior to the time when medical records were obtained, not have been in any experimental clinical trial at time of receiving Vectibix, and not have participated in this study, in an earlier round were included.

---

## **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

Other

---

## Special population of interest, other

Colorectal cancer patients

---

## Estimated number of subjects

450

# Study design details

## Outcomes

The prevalence of KRAS testing and impact of the KRAS test results on patterns of Vectibix use in patients with metastatic colorectal cancer (mCRC) treated with Vectibix Timeframe: 3 Years, The proportion of oncologists who participate in the study. The proportion of oncologists who conduct a KRAS test prior to initiating Vectibix treatment. The proportion of labs that are part of an European Society of Pathology Quality Assurance scheme. The proportion of labs that use a validated KRAS testing method. To assess the change in pattern of Vectibix administration over the 3 rounds.

---

## Data analysis plan

Analysis will be conducted on 3 levels - patient level, oncologist level and laboratory level. Descriptive statistics will be calculated at each level.

# Documents

## Study results

[Observational Research Study Report 20101120 - Abstract.pdf\(35.72 KB\)](#)

---

## Data management

## Data sources

## **Data sources (types)**

Other

---

### **Data sources (types), other**

Cross-sectional medical chart review

## 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