

# Prospective Observational Cohort Study to Describe the Use of Vectibix® in Combination With Chemotherapy in Routine Clinical Practice for Patients With Wild-type KRAS Metastatic Colorectal Cancer (20120100)

**First published:** 30/11/2012

**Last updated:** 31/03/2024

Study

Finalised

## Administrative details

### **PURI**

<https://redirect.ema.europa.eu/resource/20948>

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### **EU PAS number**

EUPAS3180

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### **Study ID**

20948

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## DARWIN EU® study

No

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### Study countries

France

Germany

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### Study description

This is a multicenter, observational prospective cohort study in France and Germany. Treatment centres with a focus on treating subjects with mCRC will be prospectively defined for potential inclusion in the study. Eligible subjects will be enrolled and have retrospective data collected from Baseline up to the point of enrolment. All subsequent chemotherapy cycles and Vectibix® doses will be recorded prospectively. Each subject will have data collected until approximately 30 days after the end of Vectibix® treatment, death, withdrawal of consent, loss to follow-up or up to 12 months from the first dose of Vectibix®, whichever occurs first.

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### Study status

Finalised

## Research institutions and networks

### Institutions

**Amgen**

United States

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

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

**Institution**

Vitanus GmbH Germany, Vinzenz von Paul Kliniken  
gGmbH Marienhospital Stuttgart Germany,  
Gemeinschaftspraxis Dr. Maintz, Groschek Hinske  
Germany, Onkologische Gemeinschaftspraxis  
Germany, Schwerpunktpraxis Hamatologie  
Onkologie Germany, Zentrum fur Onkologie und  
Urologie Rostock Germany, Onkologisches  
Zentrum Drs. Bauer and Kremers Germany, Dres.  
Kailhori/Langer/Nusch Germany,  
Schwerpunktpraxis Hamatologie und Onkologie  
German, Universitätsklinikum Magdeburg  
Germany

## 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: 01/06/2012

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**Study start date**

Planned: 10/12/2012

Actual: 10/12/2012

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**Data analysis start date**

Planned: 21/04/2017

Actual: 12/04/2017

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**Date of final study report**

Planned: 28/08/2017

Actual: 28/08/2017

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

## Study protocol

[Vectibix\\_20120100\\_Protocol\\_113012.pdf](#)(569.55 KB)

[20120100 Protocol Amend 4 2015-04-09 English\\_2.pdf](#)(754.68 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 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

Healthcare resource utilisation

**Data collection methods:**

Combined primary data collection and secondary use of data

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**Main study objective:**

Treatment patterns of Vectibix® and concomitant chemotherapy for mCRC  
(12mo)

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medical condition to be studied**

Colorectal cancer metastatic

## Population studied

**Short description of the study population**

Subjects with wild-type RAS metastatic colorectal cancer CRC treated with Vectibix® according to the SmPC in France and Germany.

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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**

Other

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## **Special population of interest, other**

Colorectal cancer patients

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## **Estimated number of subjects**

740

# Study design details

## **Outcomes**

Treatment patterns of Vectibix® and concomitant chemotherapy for mCRC (12mo), Healthcare resource utilization (12mo)Demography of disease population (12mo)Response to Vectibix® (12mo)Planned anti-cancer treatment initiated post Vectibix (12 mo)

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## **Data analysis plan**

The analysis of this study will be descriptive in nature. The data will be summarized for patients with metastatic colorectal cancer (mCRC) with tumour expressing wild type (non-mutated) KRAS who received Vectibix® in combination with FOLFOX as first-line treatment and subjects who received Vectibix® in combination with FOLFIRI as second line treatment and received

first-line fluoropyrimidine-based chemotherapy (excluding irinotecan). The data will be summarized by country to fulfil local post reimbursement requirements. For continuous outcomes, the mean, standard deviation, median, and range will be provided. For categorical variables, the frequency and percentage, with two-sided 95% CI, will be displayed for the treatment pattern of Vectibix®. Summary tables and analyses will be based on FLFAS and SLFAS and corresponding local tumour response analysis sets. Summary statistics will be reported for the significant covariates. Selected sensitivity analyses may be performed.

## Documents

### Study results

[CICERO\\_ORSR\\_abstract\\_20170816 \(002\).pdf\(112.78 KB\)](#)

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## Data management

### Data sources

#### Data sources (types)

[Other](#)

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#### Data sources (types), other

Prospective patient-based data collection, Retrospective data will be collected to verify eligibility up to Baseline (baseline equals the first dose of Vectibix®). All subsequent chemotherapy cycles and Vectibix® doses will be recorded prospectively.

### 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