# Real-world Comparative Effectiveness of Anti-EGFRs with Doublet Chemotherapy Versus Doublet Chemotherapy with or without Bevacizumab in Firstline Among RAS/RAF Wild-type, non-dMMR/MSI High mCRC Patients with Left-sided Primary Tumors in the Flatiron Health CRC Enhanced Datamart (20240215)

**First published:** 21/02/2025

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Study    Discontinued

## Administrative details

**EU PAS number**

EUPAS1000000470

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**Study ID**

1000000470

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**DARWIN EU® study**

No

**Study countries**

☐ United States

**Study status**

Discontinued

# Research institutions and networks

## Institutions

### Amgen

☐ United States

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Institution

## Contact details

**Study institution contact**

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**Primary lead investigator**

# Global Development Leader Amgen Inc.

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 15/11/2024

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**Study start date**

Planned: 29/01/2025

Actual: 29/01/2025

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**Data analysis start date**

Planned: 03/03/2025

Actual: 03/03/2025

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**Date of final study report**

Planned: 01/12/2025

## Sources of funding

- Pharmaceutical company and other private sector

## 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:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Study design:**

Retrospective, active comparator, new user cohort study.

**Main study objective:**

The main study objectives are:

- To compare overall survival in Rat sarcoma (RAS)/ Rapidly accelerated fibrosarcoma (RAF) Wild-type (WT), non-Mismatch repair deficient (dMMR)/ Microsatellite instability (MSI) high mCRC patients with left-sided primary tumors initiating treatment with panitumumab in combination with FOLFOX

versus bevacizumab in combination with FOLFOX in the front-line (1L) setting, within the US Flatiron Health Enhanced Datamart (FH EDM).

- To compare overall survival in RAS/RAF WT, non-dMMR/MSI high mCRC patients with left-sided primary tumors initiating treatment with panitumumab in combination with FOLFOX versus FOLFOX alone in the front-line setting, within the US FH EDM.

# Study Design

## Non-interventional study design

Cohort

# Study drug and medical condition

## Medicinal product name

VECTIBIX

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

PANITUMUMAB

## Anatomical Therapeutic Chemical (ATC) code

(L01FE02) panitumumab

panitumumab

## Medical condition to be studied

Colorectal cancer metastatic

# Population studied

**Short description of the study population**

Adults with diagnosis of metastatic (Stage IV) mCRC

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**Age groups**

- Adults (18 to < 65 years)
- Elderly (≥ 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)

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**Estimated number of subjects**

22000

# Study design details

**Comparators**

FOLFOX (Leucovorin, fluorouracil, oxaliplatin)

Bevacizumab

FOLFIRI (Leucovorin, fluorouracil, irinotecan)

CAPEOX (Capecitabine and oxaliplatin)

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**Outcomes**

Overall Survival (OS)

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**Data analysis plan**

The study will use propensity score weighting (inverse probability of treatment weights – IPTW) to create treatment cohorts for evaluation of the comparative effectiveness (i.e. OS) of:

1) panitumumab plus FOLFOX versus FOLFOX with or without bevacizumab in

the 1L setting (primary objective); and

2) anti-epidermal growth factor receptor (EGFR) agent (panitumumab/cetuximab) versus doublet chemotherapy (FOLFOX/FOLFIRI/CAPEOX) with or without bevacizumab in the 1L setting (secondary objective).

# 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)**

Electronic healthcare records (EHR)

# Use of a Common Data Model (CDM)

**CDM mapping**

No

# Data quality specifications

**Check conformance**

Yes

**Check completeness**

Yes

**Check stability**

Yes

**Check logical consistency**

Yes

# Data characterisation

**Data characterisation conducted**

Yes

**Data characterisation moment**

after data extraction