# Canadian Retrospective Observational Study of MVASI in metastatic Colorectal Cancer (20180360)

**First published:** 17/04/2020

**Last updated:** 20/04/2023

Study Finalised

## Administrative details

**EU PAS number**

EUPAS34590

**Study ID**

103370

**DARWIN EU® study**

No

**Study countries**

☐ Canada

**Study description**

This retrospective observational chart review will describe the safety and effectiveness of treatment with MVASI in patients with metastatic Colorectal Cancer (mCRC) in Canada. The study will include adult patients, with confirmed histological or cytological adenocarcinoma of rectum or colon, stage 4, previously untreated, who receive MVASI as a part of their initial (first line) treatment for mCRC. The Data Collection will include data from the patient's first dose of MVASI (the index date) until the date of the chart review. In addition, patients will have a look-back period including a 6-month look-back for patient demographics and baseline data, and a 5-year look back for prior adjuvant treatment and diagnosis of CRC

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Amgen

United States

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

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

**Institution**

Multiple centres: 12 centres are involved in the study

## Contact details

**Study institution contact**

Global Development Leader Amgen Inc.

medinfo@amgen.com

**Study contact**

medinfo@amgen.com

**Primary lead investigator**

Global Development Leader Amgen Inc.

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 11/09/2018

Actual: 11/09/2018

**Study start date**

Planned: 20/03/2021

Actual: 16/03/2021

**Data analysis start date**
Planned: 10/11/2022

Actual: 10/11/2022

**Date of interim report, if expected**
Planned: 31/10/2021

**Date of final study report**
Planned: 14/04/2023

Actual: 06/04/2023

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen Inc.

## Study protocol

EUPAS34590-35092.pdf(454.21 KB)

## Regulatory

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

No

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

Not applicable

# Methodological aspects

## Study type

**Study topic:**

Human medicinal product

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Safety study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To describe the safety of MVASI treatment by assessing the frequency of Events of Interest (EOIs), in first-line mCRC patients in Canada

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Retrospective chart review

## Study drug and medical condition

**Name of medicine**

MVASI

**Medical condition to be studied**

Colorectal cancer metastatic

# Population studied

**Short description of the study population**

The study population included patients aged 18 years or older diagnosed with metastatic colorectal cancer treated with MVASI in Canada.

Inclusion criteria:

1. Adult patients ≥ 18 years of age at the Index date (first dose of MVASI)
2. Metastatic CRC ie, confirmed histological or cytological adenocarcinoma of rectum or colon, stage 4
3. Previously untreated patients who receive MVASI as a part of their initial (first line) treatment for metastatic CRC
4. Patient has received at least 1 cycle of MVASI treatment as a part of their initial (first line) treatment for metastatic CRC
5. Index date (first dose of MVASI) is at least 1 month prior to chart review date

Exclusion Criteria:

1. Patient received an investigational product or participated in an investigational device or drug study at any time between 90 days pre-index date to 30 days post-last dose of MVASI
2. Patient previously treated with bevacizumab for metastatic CRC, prior to Index Date (first dose of MVASI)
3. Patient is pregnant at any time during treatment with MVASI

**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**

Metastatic colorectal cancer patients

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**Estimated number of subjects**

300

## Study design details

**Outcomes**

• Infusion reactions • Thromboembolic events • Gastrointestinal (GI) perforations • Hypertension • Hemorrhages • Wound-healing complications • Proteinuria • Ovarian Failure, Objective Response (RECIST criteria), Disease progression (if applicable)

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**Data analysis plan**

The analysis is entirely descriptive in nature with no hypothesis testing. Frequency estimation for each of the EOIs will be based on the number of patients who experience the events (at least one event per patient) divided by the total number of patients under observation. A frequency estimate for each EOI will also be provided by treatment cycle. Confidence intervals, 2-sided 95%

will be provided. An additional frequency estimate of patients experiencing at least one instance of each EOI adjusted for duration of observation will also be provided

## Documents

**Study results**

20180360 ORSR_Redacted.pdf(162.4 KB)

# 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**

Hospital retrospective 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**

No