# A Real World Evidence prospective cohort study in the management of metastatic colorectal cancer: a clinical and patient perspective (PROMETCO)

**First published:** 02/03/2020

**Last updated:** 27/05/2025

Study Finalised

## Administrative details

**EU PAS number**

EUPAS33865

**Study ID**

40302

**DARWIN EU® study**

No

**Study countries**

- [ ] Argentina
- [ ] Austria
- [ ] Belgium

- [ ] Croatia
- [ ] Czechia
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Ireland
- [ ] Italy
- [ ] Netherlands
- [ ] Portugal
- [ ] Slovenia
- [ ] Spain
- [ ] Sweden
- [ ] Switzerland
- [ ] United Kingdom

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**Study description**

This is an observational study to describe the following for mCRC patients in a real world setting:

- Overall survival
- Treatment patterns for mCRC throughout the continuum of care

Effectiveness/safety of treatments

- Reasons for therapy discontinuations and choice of subsequent treatment
- Adherence to National and European Society for Medical Oncology (ESMO) Guidelines
- Healthcare resource utilization
- Patient reported outcomes

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**Study status**

Finalised

## Research institutions and networks

## Institutions

### University Medical Center Utrecht (UMCU)

Netherlands

**First published:** 24/11/2021

**Last updated:** 22/02/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility | ENCePP partner

## Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

Miriam Koopman

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Actual: 23/07/2018

**Study start date**
Actual: 08/03/2019

**Date of final study report**
Planned: 30/09/2024

Actual: 21/11/2024

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Servier

## Regulatory

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

No

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

EU RMP category 3 (required)

## Other study registration identification numbers and links

ClinicalTrials.gov Identifier:

NCT03935763,https://clinicaltrials.gov/ct2/show/NCT03935763?term=PROMETCO&draw=

# Methodological aspects

## Study type

**Study topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

Other

**If ‘other’, further details on the scope of the study**

Overall survival in real world setting

**Data collection methods:**

Primary data collection

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**Study design:**

This was a prospective, observational, non-interventional, international multi-center, cohort study designed to collect data on patients with mCRC after two disease progressions since diagnosis of first metastasis that led to systemic treatment.

**Main study objective:**

To describe the following for mCRC patients in a real world setting:

- Overall survival
- Treatment patterns for mCRC throughout the continuum of care
- Effectiveness/safety of treatments
- Reasons for therapy discontinuations and choice of subsequent treatment
- Adherence to National and European Guidelines
- Healthcare resource utilization
- Patient reported outcomes

## 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**

The target population was adults with mCRC who are eligible and willing to receive subsequent
treatment, having had two prior disease progressions since diagnosis of first metastasis.

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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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**Estimated number of subjects**

1000

## Study design details

**Setting**

The study was conducted in 18 countries. Investigators at academic or community based medical sites in the selected countries of interest that were experienced in the treatment and management of CRC and in conducting observational studies were approached for potential participation in the study.

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**Data analysis plan**

descriptive statistics

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**Summary results**

This large real world study helped define the current landscape of mCRC patients and therapy, and provided both clinical information and patient reported outcomes for a robust and complete profile of global mCRC management.

## Documents

**Study report**

DIM-95005-001_PROMETCO_CSR Version 1.0_Abstract.pdf (498.51 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)**

Electronic healthcare records (EHR)

Other

**Data sources (types), other**

Prospective patient-based data collection

## 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