

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: 14/03/2024

Study

Ongoing

Administrative details

PURI

<https://redirect.ema.europa.eu/resource/40302>

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

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

Study status

Ongoing

Research institution and networks

Institutions

University Medical Center Utrecht (UMCU)

Netherlands

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22/02/2024

Institution

Hospital/Clinic/Other health care facility

Educational Institution

ENCePP partner

Contact details

Study institution contact

Alice Vermeire

Study contact

alice.vermeire@servier.com

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

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=2&rank=1>

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

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

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

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)

Estimated number of subjects

1000

Study design details

Data analysis plan
descriptive statistics

Data management

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