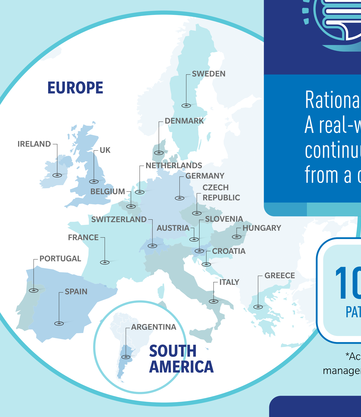
PROMETCO

Rationale and design of the PROMETCO study: A real-world, prospective longitudinal cohort on the continuum of care of metastatic colorectal cancer from a clinical and patient perspective*



1000 PATIENTS

125 INVESTIGATIONAL SITES*

18 COUNTRIES

*Academic or community-based medical sites experienced in the management of colorectal cancer and in conducting observational studies.

Background

Real-world studies resemble real clinical practice

Increasing understanding of treatment efficacy and safety, disease and treatment patterns, and patient behaviors in everyday clinical practice

Establishing a broad picture of a medication's place in the treatment pathway

Including patients who have poor performance status or comorbid conditions who are likely to be excluded from randomized controlled trials

It is currently unclear how agents are used in clinical practice to treat patients with mCRC who have progressed twice with available therapies since their first diagnosis of metastatic disease. This is due to limited real-world data on OS, treatment patterns, effectiveness, safety, and QoL in such patients.

Study aims

CONTINUUM OF CARE

To provide valuable real-world data on the management of mCRC throughout the continuum of care, addressing current gaps in knowledge including real-world OS

Study design

- International
- Observational prospective cohort study
- Real-world evidence

Objectives

- Overall survival
- Treatment patterns throughout the continuum of care
- Adherence to local and ESMO treatment guidelines
- Effectiveness and safety of mCRC treatments
- Reasons for changes or discontinuation of treatment
- Healthcare resource utilization in patients with mCRC
- Patient-reported outcomes (including but not limited to QoL)

Eligibility criteria

Inclusion

- Aged ≥18 years
- Diagnosis of mCRC
- Two disease progressions since diagnosis of first metastasis that led to first systemic treatment
- Willing to receive subsequent treatment
- Willing and able to sign an informed consent form

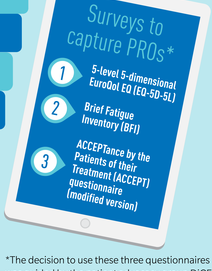
mCRC patient

Exclusion

- Currently participating in an investigational clinical trial (excluding observational cohort studies)
- Currently being treated for other cancer(s)
- Does not have mental capacity and/or ability to participate in the study

Evaluations

	Retrospective chart review	Prospective visit
Demographic and clinical characteristics	✓	✓
Disease characteristics	✓	✓
mCRC treatment characteristics	✓	✓
Efficacy	✓	✓
Safety/tolerability	✓	✓
Resource utilization	✓	
Patient-reported outcomes	✓	



*The decision to use these three questionnaires was guided by the patient advocacy group DiCE

DiCE, Digestive Cancers Europe; EQ-5D, EuroQol 5-Dimension; ESMO, European Society for Medical Oncology; mCRC, metastatic colorectal cancer; OS, overall survival; PRO, patient-reported outcomes; RCT, randomized controlled trial; QoL, quality of life

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