Patient-reported outcomes (PROs)

The patient survey includes three validated PRO instruments:

European Organisation for Research and Treatment of Cancer (EORTC) EQ-5D questionnaire	• Standardized instrument for use as a measure of health-related quality of life • Consists of two pages: – Descriptive system with five dimensions: mobility, self care, usual activities, pain/discomfort, anxiety/depression – Visual analog scale: to record patients' self-rated health, from 'best imaginable' to 'worst imaginable' • Advantages: used in a wide range of health conditions and treatments, quantitative measure of health outcome, reflects the patient's own judgement
Brief Fatigue Inventory (BFI)	• To assess the severity and impact of cancer-related fatigue on daily functioning in the past 24 hours • Consists of nine items rated on a 0–10 numeric rating scale: fatigue right now, usual level of fatigue in the last 24 hours, worst level of fatigue in the last 24 hours, interference with general activity, mood, walking ability, normal work, relations with other people, and enjoyment of life • Advantages: quick to complete, good reliability
ACCEPTance by the patients of their treatment (ACCEPT) questionnaire (modified version)	• Evaluates patients' acceptance of long-term medications • Consists of 25 items distributed in seven dimensions: medication inconvenience, long-term treatment, regimen constraints, numerous medications, side effects, effectiveness, general treatment acceptance • Advantages: generic, easy to complete, good psychometric properties

The questionnaires will be given to patients for self-administration at each scheduled site visit during the prospective follow-up. Patients will be provided with a tablet containing the questionnaires and will be asked to complete them electronically in the waiting room before the visit start. Each questionnaire should take only a few minutes to complete.

What is my role as a study investigator?

As a study investigator, your support will be needed for:

- Recruitment of study participants: identifying eligible patients prior to enrollment at regularly scheduled site visits
- Providing interested patients with the study information and consent form
- Ensuring patient enrollment meets the study inclusion and exclusion criteria
- Collecting data in accordance with the study protocol, maintaining compliance with study procedures and the schedule of assessments, which involves:
  - Conducting a retrospective review of patient medical charts for eligible and consenting participants, from diagnosis of mCRC to time of enrollment and after each site visit during the prospective follow-up
  - Providing instructions for and administering the patient survey (consisting of three PROs) to patients in the waiting room prior to their scheduled site visits during the prospective follow-up
- Treating the patients according to your center's local routine medical practices
- Implementing the highest medical and ethical standards
- Prioritizing patient safety and wellbeing

Participating investigators and support staff will undergo a site initiation and training session before patient selection and data collection commences.

References

1. PROMETCO. ClinicalTrials.gov Identifier: NCT03935763. Available from: https://clinicaltrials.gov/ct2/show/NCT03935763?term=PROMETCO&cond=Colorectal+Cancer+Metastatic&rank=1. Accessed June 2019.
2. Servier Affaires Médicales. mCRC NIS (PROMETCO) study protocol Amendment 1, Final V1.0 dated 16 November 2018.

PROMETCO

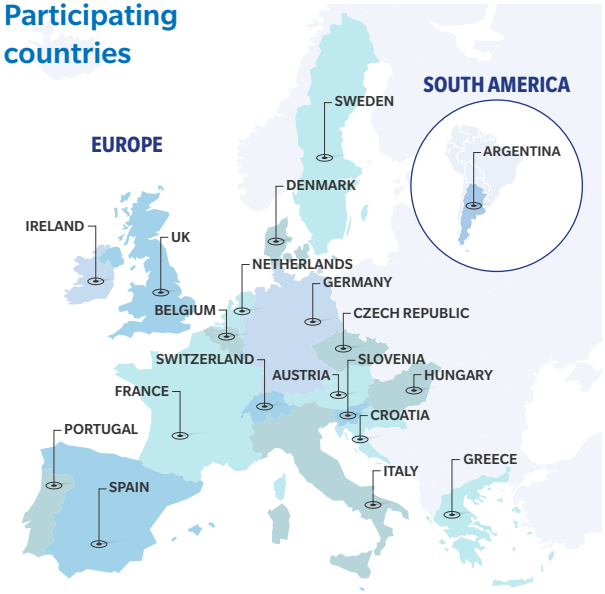
PROMETCO study: Collecting real-world data on the management of metastatic colorectal cancer (mCRC)

PROMETCO – A real-world evidence **PRO**spective cohort study in the management of **MET**astatic **CO**lorectal cancer: A clinical and patient perspective[1,2]

1000 PATIENTS • **123** INVESTIGATIONAL SITES * • **21** COUNTRIES

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

Participating countries



Study objectives

PROMETCO is an international, non-interventional, retrospective/prospective, longitudinal cohort study of patients with mCRC and two disease progressions, which aims to describe:[2]

- **Overall survival**
- **Treatment patterns** for mCRC throughout the continuum of care
- **Effectiveness/safety** of treatments in a **real-world setting**
- Reasons for **therapy discontinuations** and choice of **subsequent treatment**
- **Adherence** to national and European Society for Medical Oncology (ESMO) treatment guidelines
- Healthcare **resource utilization**
- **Patient-reported outcomes**

Study design

- **International**
- **Non-interventional**
- **Observational prospective cohort study**

Study population – who can be enrolled?

Adults with mCRC with two prior disease progressions since diagnosis of first metastases,* who are eligible and willing to receive subsequent treatment.

*Any disease progression should be recognized whatever its reason

Inclusion criteria	Exclusion criteria
Age ≥18 years of age	Currently participating in an investigational clinical trial (does not apply to observational cohort studies)
Diagnosis of mCRC	Currently being treated for other cancer(s)
Two disease progressions since diagnosis of first metastasis that led to first systemic treatment	Does not have mental capacity and/or ability to participate in the study
Willing to receive subsequent treatment	
Willing and able to sign an informed consent form	

Reminders:

- As the patient number is allocated by the system, all patients must be created in the electronic data capture system (EDC) on the day of the enrollment visit.
- For data entry, 28±7 days must be maintained between patient visits in the electronic case report form (eCRF)

Data collection – which outcomes will be assessed?

There are two parts to this study:

1. **Retrospective medical chart collection:** Medical history and baseline data will be collected from diagnosis of mCRC to time of study enrollment (at initiation of subsequent treatment following two prior disease progressions)
2. **Prospective observation period:** Comprising medical chart collection and patient survey at regularly scheduled clinic visits based on local standard clinical practice; data will be collected approximately once a month (28±7 days since previous clinic visit) until death (approximately 18 months)

Data to be collected	Retrospective chart review	Prospective visits
Demographic and clinical characteristics		
Date of birth, sex, race/ethnicity, socioeconomic factors	✓	✓
Height	✓	
Weight	✓	✓
Smoking status	✓	✓
Comorbidities (Charlson Index)	✓	✓
Disease characteristics		
ECOG performance status	✓	✓
Date of diagnosis	✓	
CRC stage at diagnosis	✓	
Date of first metastases (only metachronous)	✓	
Resection of metastases (including date)	✓	✓
Metastases (site, number, location, synchronous/metachronous)	✓	✓
Sidedness of primary tumor	✓	
Molecular testing/status (RAS, BRAF, MSS/MSI phenotype)	✓	
Surgery/radiotherapy of primary tumor	✓	
CT scan, MRI, biopsy/re-biopsy	✓	✓
mCRC treatment characteristics		
Systemic treatments received	✓	✓
Treatment start and end dates (or indication if ongoing)	✓	✓
Dose and dosing schedule		✓
Dose adjustments and reasons for modification		✓
Treatment discontinuation	✓	✓
Reasons for treatment discontinuation	✓	✓
Treatment setting (outpatient, hospital)	✓	✓
Reason for treatment initiation (patient- or tumor-related)		✓
Surgery, radiotherapy, and other local treatment of metastases	✓	✓
Efficacy		
Response to treatment (response, progression, stable disease)	✓	✓
Date of response	✓	✓
Method used to assess response	✓	✓
Date of death (if applicable)		✓
Safety/tolerability		
Adverse events		✓
Clinical progression (date, adverse events)		✓
Blood tests (abnormal results)	✓	✓
Resource utilization		
Hospitalizations (dates, reason, duration of stay, treatments)		✓
Emergency room visits		✓
Outpatient visits		✓
Hospice care (total days)		✓
Concomitant medications		✓
End of study		
Study end date		✓
Reason for end of study*		✓
Patient-reported outcomes		
EORTC EQ-5D questionnaire		✓
BFI		✓
ACCEPT® questionnaire (modified version)		✓

ACCEPT, ACCEPTance by the patient of their treatment; BFI, Brief Fatigue Inventory; CRC, colorectal cancer; CT, computerized tomography; ECOG, Eastern Cooperative Oncology Group; EORTC, European Organisation for Research and Treatment of Cancer; mCRC, metastatic colorectal cancer; MRI, magnetic resonance imaging. *Reason for end of study will be documented as loss to follow-up, study withdrawal, death, or study end date (defined as 18 months from the start of enrollment).