

# CONCERT - Cohort of patients with metastatic colorectal cancer initiating a chemotherapy in combination with Avastin®

Head :Roche Medical data center

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## General

### Identification

Detailed name Cohort of patients with metastatic colorectal cancer initiating a chemotherapy in combination with Avastin®

Sign or acronym CONCERT

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation

ML21696

### General Aspects

Medical area Cancer research  
Gastroenterology et hepatology

Study in connection with Covid-19 No

Pathology (details) Metastatic colorectal cancer

Health determinants Medicine

Keywords bevacizumab

### Scientific investigator(s) (Contact)

Name of the director Roche Medical data center

Address 4 cours de l'Île Seguin

Email data\_sharing.france@roche.com

Organization Roche SAS

### Collaborations

Participation in projects, networks and consortia No

## Funding

Funding status Private

## Governance of the database

Sponsor(s) or organisation(s) responsible Roche SAS

Organisation status Private

Presence of scientific or steering committees Yes

## Additional contact

## Main features

## Type of database

Type of database Study databases

Study databases (details) Longitudinal study (except cohorts)

Database recruitment is carried out by an intermediary A selection of health care professionals

Database recruitment is made on the basis of: Medication(s) taken

Database recruitment is carried out as part of an interventional study No

## Database objective

Main objective Primary Objective: To assess in real life the Progression-Free Survival at a maximum of 36 months follow-up, in patients suffering from metastatic colorectal cancer and initiating a treatment with Avastin® combined with chemotherapy.  
Secondary Objectives:  
- To describe characteristics of patients treated with Avastin®  
- To describe the use of Avastin® over the study period  
- To assess the overall survival of patients treated with Avastin®  
- To describe the Avastin® safety profile (serious adverse events and/or unexpected related to Avastin®, and/or adverse events of special interest)

- To describe the quality of life of patients treated with Avastin®.

Exploratory Objective:

A search for the prognostic factors of PFS and OS was performed using a Cox model in patients treated with 1st line of chemotherapy (overall and in the subgroup of patients with synchronous metastases). These factors were determined from the characteristics of patients at inclusion.

#### Inclusion criteria

Inclusion criteria:

- Adult patient (aged  $\geq 18$  years)
- Patient suffering from metastatic colic or rectal carcinoma for which the physician decided to start a treatment with Avastin® combined with chemotherapy, at the inclusion time
- Patient who received about the study both oral and written information and who did not object to his/her personal data being processed

Exclusion criteria:

- Participation in a clinical trial designed to assess a cytotoxic anticancer treatment and/or an innovative therapy

#### Population type

##### Age

Adulthood (19 to 24 years)  
Adulthood (25 to 44 years)  
Adulthood (45 to 64 years)  
Elderly (65 to 79 years)  
Great age (80 years and more)

##### Population covered

Sick population

##### Pathology

C00-C75 - Malignant neoplasms, stated or presumed to be primary, of specified sites, except of lymphoid, haematopoietic and related tissue

##### Gender

Male  
Woman

##### Geography area

National

#### Data collection

##### Dates

Date of first collection (YYYY or MM/YYYY)

2008

Date of last collection (YYYY or MM/YYYY)

2012

## Size of the database

Size of the database (number of individuals) [500-1000[ individuals

Details of the number of individuals 765

## Data

Database activity Data collection completed

Type of data collected Clinical data  
Declarative data

Clinical data (detail) Medical registration

Details of collected clinical data Type of data collected : validation of selection criteria, information about the study, demographic and general data, disease history, previous treatments of colorectal cancer, last available laboratory tests, treatment with Avastin® and combined chemotherapy, other treatments, first disease progression, surgery for colorectal cancer, patient reported outcomes, reason for early study withdrawal, adverse events related to Avastin®.

Declarative data (detail) Paper self-questionnaire

Presence of a biobank No

## Procedures

Data collection method paper questionnaire

Classifications used CDISC like

Quality procedure(s) used GCP/GVP

Participant monitoring Yes

Monitoring procedures Monitoring by contact with the referring doctor

Followed pathology C00-C75 - Malignant neoplasms, stated or presumed to be primary, of specified sites, except of lymphoid, haematopoietic and related tissue

Links to administrative sources No

## Promotion and access

### Promotion

## Access

Dedicated website	<a href="https://www.roche.fr/fr/innovation-recherche-medicale/data-sharing-portail-d-information-partage-des-donnees.html">https://www.roche.fr/fr/innovation-recherche-medicale/data-sharing-portail-d-information-partage-des-donnees.html</a>
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Presence of document that lists variables and coding procedures	Yes
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Access to aggregated data	Access on specific project only
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Access to individual data	Access on specific project only
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