

# CASSIOPEE - Non Interventional Study Evaluating Efficacy and Safety in a Cohort of Elderly Patients of First Line Therapy With Avastin ® Regimen for Metastatic Colorectal Cancer

Head :Roche Medical data center

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## General

### Identification

Detailed name Non Interventional Study Evaluating Efficacy and Safety in a Cohort of Elderly Patients of First Line Therapy With Avastin ® Regimen for Metastatic Colorectal Cancer

Sign or acronym CASSIOPEE

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

ML27829

### General Aspects

Medical area Cancer research  
Gastroenterology et hepatology

Study in connection with Covid-19 No

Pathology (details) Onco digestive, 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 - 92100 Boulogne Billancourt

Email data\_sharing.france@roche.com

Organization Roche SAS

### Collaborations

Participation in projects, networks and consortia	No
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## Funding

Funding status	Private
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## Governance of the database

Sponsor(s) or organisation(s) responsible	Roche SAS
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Organisation status	Private
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Presence of scientific or steering committees	Yes
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## Additional contact

## Main features

## Type of database

Type of database	Study databases
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Study databases (details)	Cohort study
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Database recruitment is carried out by an intermediary	A selection of health institutions and services
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Database recruitment is made on the basis of:	Medication(s) taken
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Database recruitment is carried out as part of an interventional study	No
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## Database objective

Main objective	<p>Primary Objective: Progression-free survival in patients aged <math>\geq 75</math> years with metastatic colorectal cancer initiating first line treatment with Avastin®</p> <p>Secondary Objectives:</p> <ul style="list-style-type: none"><li>- To describe the demographic, clinical and nutritional profiles of the patients and their living conditions and degree of autonomy;</li><li>- To describe the change in autonomy criteria;</li><li>- To describe the OS;</li><li>- To describe Avastin® dosage and regimen;</li><li>- To describe the safety profile of Avastin®.</li></ul>
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Inclusion criteria	Inclusion criteria:
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- Adult patient aged  $\geq 75$  years,
  - With metastatic adenocarcinoma of the colon or rectum,
  - For whom it has been decided to initiate first line treatment with Avastin®, concomitant to or no more than 2 months after the start of first line chemotherapy
  - Having received oral and written information about the study objectives and methods and having raised no objections to computer processing of the data in the medical record (indirectly named data).
- Exclusion criteria:
- Patient previously treated with Avastin®.
  - Patient already participating in a clinical trial evaluating a cytotoxic anticancer therapy and/or an investigational new drug.

## Population type

Age 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) 2012

Date of last collection (YYYY or MM/YYYY) 2016

### Size of the database

Size of the database (number of individuals) < 500 individuals

Details of the number of individuals 402

## Data

Database activity	Data collection completed
Type of data collected	Clinical data Declarative data
Clinical data (detail)	Medical registration
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality

## Procedures

Data collection method	eCRF
Classifications used	CDISC like
Quality procedure(s) used	GCP/GVP
Participant monitoring	Yes
Monitoring procedures	Monitoring by contact with the referring doctor
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>
Presence of document that lists variables and coding procedures	Yes
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only