# 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

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|---|---|
| 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<br>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'Ile 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 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.<br>Secondary Objectives:<br>- To describe characteristics of patients treated with Avastin®<br>- To describe the use of Avastin® over the study period<br>- To assess the overall survival of patients treated with Avastin®<br>- To describe the Avastin® safety profile (serious adverse events and/or unexpected related to Avastin®, and/or adverse events of special interest) |

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| | - To describe the quality of life of patients treated with Avastin®.<br>Exploratory Objective:<br>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:<br>- Adult patient (aged >= 18 years)<br>- 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<br>- Patient who received about the study both oral and written information and who did not object to his/her personal data being processed<br>Exclusion criteria:<br>- 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)<br>Adulthood (25 to 44 years)<br>Adulthood (45 to 64 years)<br>Elderly (65 to 79 years)<br>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<br>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<br>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 | https://www.roche.fr/fr/innovation-recherche-medicale/data-sharing-portail-d-information-partage-des-donnees.html |
| 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 |