# EREBUS - Evaluation of targeted therapies in patients receiving first-line treatment for metastatic colorectal cancer: cetuximab in the real-life conditions of use

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## General

### Identification

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|---|---|
| Detailed name | Evaluation of targeted therapies in patients receiving first-line treatment for metastatic colorectal cancer: cetuximab in the real-life conditions of use |
| Sign or acronym | EREBUS |
| CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation | CCTI-RS 09.206, CNIL 909177 |

### General Aspects

| | |
|---|---|
| Medical area | Cancer research |
| Health determinants | Iatrogenic |
| Others (details) | Metastatic colorectal cancer |
| Keywords | cetuximab, Erbitux®, Metastatic colorectal cancer, conditions of use, first-line, tolerance, survival, pharmacoepidemiology, cohort, Department of Pharmacology, Bordeaux |

### Scientific investigator(s) (Contact)



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## Collaborations

## Funding

| | |
|---|---|
| Funding status | Mixed |
| Details | Merck Lipha Santé |

## Governance of the database

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|---|---|
| Sponsor(s) or organisation(s) responsible | Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen |
| Organisation status | Public |

## Additional contact

# Main features

## Type of database

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|---|---|
| Type of database | Study databases |
| Study databases (details) | Longitudinal study (except cohorts) |
| Database recruitment is carried out by an intermediary | A selection of health institutions and services |
| Database recruitment is is made | Medication(s) taken |

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| on the basis of: | |
| Database recruitment is carried out as part of an interventional study | No |
| Additional information regarding sample selection. | Pharmacies of centres performing at least one session of chemotherapy for metastatic colorectal cancer in 2007 according to data from the PMSI (Programme de Médicalisation des Systèmes d'Information), were contacted to participate in the study. The identification of patients and prescribing physicians is performed by hospital pharmacists through nominative dispensations. A request to participate is then made to the prescribing physicians or their head of department to inform identified patients. Physicians who accepted then informed patients of the study and allowed CRAs in charge of data collection access to medical records . |

## Database objective

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| Main objective | The main objective is to evaluate the rate of secondary metastases resection at 12 months in real-life conditions of use in patients with colorectal cancer treated by Cetuximab® first line metastatic. |
| Inclusion criteria | Patient with metastatic colorectal cancer initiating first-line treatment with cetuximab® between 1 January 2009 and 31 December 2010, whether or not treatment is continued; Patient not previously treated by cetuximab®, including during a clinical trial or Temporary Authorisation for Use; Patient naive to palliative metastatic chemotherapyd; No neoadjuvant chemotherapy / adjuvant of primary cancer or interval between the latter and the initiation of first-line treatment with cetuximab® ?6 months (with a tolerance of 15 days); No neoadjuvant / adjuvant of chemotherapy for metastatic cancer between or interval between the latter and initiation of first-line treatment with cetuximab® ?12 months (with a tolerance of 1 month ); Patient with unresectable metastases immediately before initiation of cetuximab®; Patient with non-mutated K-RAS; Patient not participating in a clinical trial or treatment conditions considered to be unaffected by the coordinating center; Patient without locoregional relapse; Patient not objecting to data collection. |

## Population type

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|---|---|
| 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 |
| Gender | Male<br>Woman |
| Geography area | National |
| Detail of the geography area | Hospital pharmacists and physicians in metropolitan France |

## Data collection

### Dates

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|---|---|
| Date of first collection (YYYY or MM/YYYY) | 2010 |
| Date of last collection (YYYY or MM/YYYY) | 2012 |

### Size of the database

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|---|---|
| Size of the database (number of individuals) | < 500 individuals |
| Details of the number of individuals | En cours de recrutement, 2755 patients identifiés par les pharmaciens hospitaliers, dont 1047 patients pour lesquels le médecin a accepté de participer à l'étude, dont 205 éligibles pour le suivi en 2009 - Currently being recruited, 2755 patients identified by hospital pharmacists, including 1047 patients for whom their physician agreed to participate in the study, 205 eligible for follow-up in 2009. |

### Data

| | |
|---|---|
| Database activity | Data collection completed |
| Type of data collected | Clinical data |
| Clinical data (detail) | Direct physical measures |
| Presence of a biobank | No |
| Health parameters studied | Health event/morbidity<br>Health event/mortality |

| | |
|---|---|
| | Health care consumption and services |
| Care consumption (detail) | Hospitalization<br>Medicines consumption |
| **Procedures** | |
| Data collection method | During the inclusion period and follow-up, coordinating centre CRAs organize visits to the hospital to collect on an e-CRF information from the medical records of included patients. |
| Participant monitoring | Yes |
| Details on monitoring of participants | The characteristics of all patients initiating treatment with Cetuximab® in 2009 are described and only patients with unresectable metastatic colorectal cancer, non-mutated K-RAS, and starting therapy with cetuximab® between 2009 and 2010 as first-line treatment are followed over a period of 12 months from the date of first cetuximab® administration. Follow-up is performed using data available in medical records. |
| Links to administrative sources | No |
| **Promotion and access** | |
| **Promotion** | |
| Link to the document | http://www.snfge.com/JFHOD2011/5645.html |
| Link to the document | http://www.asco.org/ASCOv2/Meetings/Abstracts?&vmview |
| Link to the document | http://www.snfge.com/jfhod2012/5996.html |
| **Access** | |
| Terms of data access (charter for data provision, format of data, availability delay) | A confidential study report will be delivered to the pharmaceutical company. The study report and scientific communications (posters, paper, ...) are validated by the study Scientific Committee. Ownership of study data is the subject of an agreement between the University of Bordeaux Segalen and the pharmaceutical company. Terms for third-party access to the database are to be defined. |
| Access to aggregated data | Access on specific project only |
| Access to individual data | Access on specific project only |