

# - FREGAT

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## General

### Identification

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| Detailed name  | FREGAT  |
| CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation | Accord CPP (10 décembre 2013) , ANSM (13 janvier 2014) ,CCTIRS (12 mars 2014) CNIL (23 décembre 2014) |

### General Aspects

|                     |  |
|---------------------|--|
| Medical area        | Cancer research  |
| Health determinants | Iatrogenic<br>Nutrition  |
| Keywords            | Tumour of the oesophagus, stomach tumour, diseases of the oesophagus, digestive system diseases, gastroesophageal cancer, digestive system, clinical and biological records, surgery |

### Scientific investigator(s) (Contact)

|                      |  |
|----------------------|--|
| Name of the director | Mariette   |
| Surname              | Christophe   |
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| Email                | christophe.mariette@chru-lille.fr  |
| Organization         | CHRU   |

### Collaborations

#### Funding

|                |        |
|----------------|--------|
| Funding status | Public |
|----------------|--------|

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|--|---|
| Details  | appel à projet INCa 2012  |
| <b>Governance of the database</b>                                      |   |
| Sponsor(s) or organisation(s) responsible                              | CHRU Lille  |
| Organisation status  | Public  |
| <b>Additional contact</b>  |   |
| <b>Main features</b>   |   |
| <b>Type of database</b>  |   |
| Type of database   | Study databases   |
| Study databases (details)  | Cohort study  |
| Database recruitment is carried out by an intermediary                 | A selection of health institutions and services   |
| Database recruitment is carried out as part of an interventional study | Yes   |
| Details  | Performed at individual level   |
| Additional information regarding sample selection.                     | All newly diagnosed patients in participating centres with gastro-oesophageal treatment-naive cancer will be included after acceptance and signed consent, whether they undergo surgery or not, regardless of histological type, tumour stage or therapeutic strategy. Exclusion criteria: - Men or women under the age of 18. - People deprived of liberty or under guardianship (including temporary guardianship). - People who do not speak French. - Adults unable to express their consent. - Patients already included in the FREGAT database. - Patients who refuse to participate. |
| <b>Database objective</b>  |   |
| Main objective   | Main Objective: To identify, through the creation of a clinico-biological, prospective, multicentric French database, the clinical, biological and tumour factors linked to anti-tumour therapy resistance in patients treated for stage I to IV oesophageal or stomach cancer. Secondary Objectives: - To assess the impact of different current therapeutic strategies for recurrence, survival and quality of life. - To identify predictive factors for patient treatment   |

resistance in order to identify the most efficient and least toxic therapeutic combination. - To describe individual, social and behavioural characteristics of patients included in the study. - To identify individual and collective determinants that influence possible access to care and initiation of treatment. - To identify new prognostic and predictive relapse factors.

#### Inclusion criteria

- Men or women ? 18 ans. - Presenting with oesophageal or gastro-oesophageal junction carcinoma recently diagnosed by biopsy, regardless of cancer subtype, tumour stage or proposed treatment. - Treatment-naïve cancer. - Have given clear and written consent for blood samples, various questionnaires and the collection of patient information. N.B.: Patients participating in a clinical trial can be included in the FREGAT trial. There is no exclusion period.

#### 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

Gender  
Male  
Woman

Geography area National

Detail of the geography area Metropolitan France (33 centres, 46 teams)

#### Data collection

#### Dates

Date of first collection (YYYY or MM/YYYY) 2014

#### Size of the database

Size of the database (number of individuals) Greater than 20 000 individuals

Details of the number of individuals 135 patients au 20/01/2015

#### Data

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|------------------------------|---|
| Database activity            | Current data collection   |
| Type of data collected       | Clinical data<br>Declarative data<br>Biological data<br>Administrative data   |
| Clinical data (detail)       | Direct physical measures<br>Medical registration  |
| Declarative data (detail)    | Paper self-questionnaire  |
| Biological data (detail)     | - a collection of tumour samples (pre-treatment biopsies, post-treatment biopsies, surgical specimens) collected in accordance with current quality charters. These samples will be stored in the corresponding investigation centre. Samples will ideally be frozen. However, paraffin conservation will also be acceptable. - blood sample collection to be put in place in 6 centres with high recruitment potential that have a Biological Resource Centre (CRB) (approximately 3,000 patients). These approved CRBs will ensure sample quality control as per usual. |
| Administrative data (detail) | The investigating party will issue the patient a FREGAT cohort registration form to be completed by the patient and posted to the Caen Cancéropôle Nord-Ouest Data Processing Centre (CTD/CNO).   |
| Presence of a biobank        | Yes   |
| Contents of biobank          | Whole blood<br>Serum<br>Plasma<br>Tissues   |
| Details of biobank content   | Consult the scientist in charge (Professor Christophe MARIETTE)   |
| Health parameters studied    | Health event/morbidity<br>Health event/mortality<br>Health care consumption and services<br>Quality of life/health perception<br>Others   |
| Care consumption (detail)    | Hospitalization<br>Medical/paramedical consultation<br>Medicines consumption  |
| Other (detail)               | socio-economic questionnaire.   |

## Procedures

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| Data collection method | The collection of clinical, biological and epidemiological data as well as the characteristics of patient treatment will be stored in the electronic case report form (e-CRF) for the study |
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| Participant monitoring | Yes |
|------------------------|-----|

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|---------------------------------------|---|
| Details on monitoring of participants | Follow-up for 3 years after inclusion. All information in the database is gathered during patient clinical follow-up, according to usual visit and follow-up practices in each investigating centre. Annual updates to information is required systematically. Updates to information regarding events such as death or recurrence will be also required. |
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| Links to administrative sources | Yes |
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## Promotion and access

### Promotion

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|----------------------|---|
| Link to the document | <a href="http://www.ncbi.nlm.nih.gov/pubmed/25062398">http://www.ncbi.nlm.nih.gov/pubmed/25062398</a> |
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| Link to the document | <a href="http://www.ncbi.nlm.nih.gov/pubmed/25012732">http://www.ncbi.nlm.nih.gov/pubmed/25012732</a> |
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| Link to the document | <a href="http://www.ncbi.nlm.nih.gov/pubmed/24919373">http://www.ncbi.nlm.nih.gov/pubmed/24919373</a> |
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| Link to the document | <a href="http://www.ncbi.nlm.nih.gov/pubmed/24075273">http://www.ncbi.nlm.nih.gov/pubmed/24075273</a> |
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| Link to the document | <a href="http://www.ncbi.nlm.nih.gov/pubmed/23313257">http://www.ncbi.nlm.nih.gov/pubmed/23313257</a> |
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| Link to the document | <a href="http://www.ncbi.nlm.nih.gov/pubmed/23064779">http://www.ncbi.nlm.nih.gov/pubmed/23064779</a> |
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| Link to the document | <a href="http://www.ncbi.nlm.nih.gov/pubmed/22005144">http://www.ncbi.nlm.nih.gov/pubmed/22005144</a> |
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### Access

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|---|---|
| Terms of data access (charter for data provision, format of data, availability delay) | Publication or presentation of results from this trial is not permitted without prior agreement from the sponsor (CHRU de Lille) and coordinating researcher (Prof. Christophe MARIETTE). |
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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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