

# HERABLE - HER-2 Status in Gastric and Gastro-Oesophageal Junction Cancer

Head :Roche Medical Data Center

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## General

### Identification

Detailed name HER-2 Status in Gastric and Gastro-Oesophageal Junction Cancer

Sign or acronym HERABLE

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

ML27940

### General Aspects

Medical area Cancer research

Study in connection with Covid-19 No

Pathology (details) Gastric and gastro-oesophageal junction cancer

Health determinants Medicine

Keywords HER2

### Scientific investigator(s) (Contact)

Name of the director Roche Medical Data Center

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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

Name of the contact <https://www.roche.fr/fr/innovation-recherche-medicale/data-sharing-portail-d-information-partage-des-donnees.html>

## Main features

### Type of database

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 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: Positive HER2 status is defined as IHC3+ or IHC2+/ISH+, as per the Herceptin® SPC.

Secondary objectives:  
Evaluated according to HER2 status determined by the centralized laboratory

- Describe pathological features of the tumors (assessed locally) according to HER2 status;
- Evaluate concordance between IHC 4B5 and SISH results for each sample;
- Evaluate concordance between HER2 status determined on biopsies and surgical specimens (globally and according to use or not of

neoadjuvant chemotherapy);  
- Describe expression of the following markers:  
HER3, HER4, PTEN, cMET, Bcl2, p53.

#### Inclusion criteria

Inclusion criteria:

- Gastric or GEJ adenocarcinoma specimens, regardless of stage, histologically documented (biopsy, surgical specimen, lymph node or distant metastasis);
- Enough tumor material available to allow for the centralized analysis;
- Specimens fixed and embedded in paraffin;
- From a patient who was informed about the study orally and in writing by the oncologist or gastroenterologist, with a signed certificate of no objection.

Exclusion criteria:

- Fixatives not allowed: Bouin's solution.

#### 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

D00 - Carcinoma in situ of oral cavity, oesophagus and stomach

##### 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)

2014

##### Size of the database

Size of the database (number of individuals)

< 500 individuals

Details of the number of individuals

421

## Data

Database activity Data collection completed

Type of data collected Clinical data  
Biological data

Clinical data (detail) Medical registration

Details of collected clinical data Validation of inclusion and exclusion criteria - Dates of visits (or data of last contact with the patient) - Demographic - CKD history and evolution - Comorbidities - Most recent clinical and biological data - Previous and/or ongoing CKD treatments - Other specific treatments - Previous and/or ongoing anemia treatments - Treatment with Micera® - Adverses events - Reason for early study discontinuation.

Presence of a biobank No

Health parameters studied Health event/morbidity  
Health event/mortality  
Health care consumption and services

Care consumption (detail) Medicines consumption

## Procedures

Data collection method eCRF

Classifications used CDISC

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 <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