

# HERMIONE - An Observational Study of the Safety of Herceptin Given Subcutaneously in Patients With Early HER2-positive Breast Cancer

Head :Roche Medical Data Center

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## General

### Identification

Detailed name	An Observational Study of the Safety of Herceptin Given Subcutaneously in Patients With Early HER2-positive Breast Cancer
Sign or acronym	HERMIONE
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	ML28983

### General Aspects

Medical area	Cancer research
Study in connection with Covid-19	No
Pathology (details)	Early HER2+ Breast cancer
Health determinants	Iatrogenic Medicine
Keywords	Herceptin® SC

### Scientific investigator(s) (Contact)

Name of the director	Roche Medical Data Center
Address	4 cours de l'Île Seguin - 92650 BOULOGNE-BILLANCOURT
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

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: To describe the systemic safety and local tolerability of subcutaneous Herceptin® (SC) in patients with HER2-positive early breast cancer (eBC), naive and non-naive of HER2+ treatment, treated in the neoadjuvant and adjuvant setting in routine clinical practice use.

Secondary objective:  
To describe the quality of life (QoL) of patients (using the European Organization for Research and

## Treatment of Cancer [EORTC] QLQ-C30 questionnaire)

- The description of the baseline and disease characteristics of patients with HER2+ eBC initiating a treatment with Herceptin® SC;
- The description of use of Herceptin® SC (treatment duration, frequency of injections and sites of injection).

### Inclusion criteria

#### Inclusion criteria:

- Woman suffering from HER2+ early-stage Breast cancer (Stage I, stage IIA, stage IIB, or stage IIIA breast cancer);
- Woman eligible for neoadjuvant or adjuvant HER2+ treatment, according to national guidelines;
- Woman aged 18 years or older;
- Woman having received oral and written information about the study, without any objections for the use of her personal data and having signed a written informed consent form.

#### Exclusion criteria:

- Woman previously treated with Herceptin® subcutaneous;
- Woman participating in a clinical trial assessing an anticancer treatment.

### 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

D05 - Carcinoma in situ of breast

#### Gender

Woman

#### Geography area

National

### Data collection

#### Dates

Date of first collection (YYYY or MM/YYYY)

2015

Date of last collection (YYYY or MM/YYYY)

2016

## Size of the database

Size of the database (number of individuals) [500-1000] individuals

Details of the number of individuals 511

## 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  
Quality of life/health perception

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

Followed pathology D05 - Carcinoma in situ of breast

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>
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Presence of document that lists variables and coding procedures	Yes
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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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