

CHORALE - Observational study on compliance, social consequences, management and costs of oral therapy in advanced or metastatic ErbB2+ (HER2+) breast cancer

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General

Identification

Detailed name Observational study on compliance, social consequences, management and costs of oral therapy in advanced or metastatic ErbB2+ (HER2+) breast cancer

Sign or acronym CHORALE

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

1493177

General Aspects

Medical area Cancer research

Pathology (details) economy, social

Health determinants Lifestyle and behavior
Medicine
Occupation
Social and psychosocial factors

Keywords oral therapy, HER2+, Tyverb

Scientific investigator(s) (Contact)

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Unit Laboratoire GSK

Collaborations

Funding	
Funding status	Private
Details	GSK laboratory
Governance of the database	
Sponsor(s) or organisation(s) responsible	Laboratoire GSK
Organisation status	Private
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 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
Additional information regarding sample selection.	Doctors who have accepted to participate in the study will include all eligible patients with a maximum of 7 patients per doctor. Patient-follow-up will be 9 months starting from the day of inclusion, even in the event oral treatment is stopped. Data collection concerning this follow-up after inclusion will be carried out every 3 months during 3 visits carried out in the framework of the normal follow-up of patients
Database objective	
Main objective	The main objective of this study is to assess the economic and social consequences of oral cancer therapies in patients with advanced or metastatic breast cancer overexpressing Her2
Inclusion criteria	? Adult patient with metastatic breast cancer overexpressing Her2

? Patient for whom oral therapy (other than hormone therapy) has to be initiated on the day of inclusion (alone or combined with targeted therapeutic or cytotoxic chemotherapy administered intravenously).
 ? Subject accepting to participate in the survey

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 Woman

Geography area National

Detail of the geography area France

Data collection

Dates

Date of first collection (YYYY or MM/YYYY) 2011

Date of last collection (YYYY or MM/YYYY) 2012

Size of the database

Size of the database (number of individuals) < 500 individuals

Details of the number of individuals 400

Data

Database activity Data collection completed

Type of data collected
 Clinical data
 Declarative data

Clinical data (detail)
 Direct physical measures
 Medical registration

Declarative data (detail) Paper self-questionnaire

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)	Hospitalization Medical/paramedical consultation Medicines consumption
Procedures	
Data collection method	Inclusion and follow-up questionnaire, and patient self-questionnaire
Participant monitoring	Yes
Details on monitoring of participants	9 months during which follow-up data will be collected (status of the patient, professional activity, sick leave, progression of the disease, ECOG score, current posology and changes in dosage of the oral treatment, temporary or definitive stopping of the oral treatment, reasons for stopping and changing dosage, weight, associated treatments, other medical visits, home care, hospitalizations, observance).
Links to administrative sources	No
Promotion and access	
Promotion	
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Publications
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only