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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Last update : 09/07/2020 | Version : 1 | ID : 149

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 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