# 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

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| 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

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| Medical area | Cancer research |
| Pathology (details) | economy, social |
| Health determinants | Lifestyle and behavior<br>Medicine<br>Occupation<br>Social and psychosocial factors |
| Keywords | oral therapy, HER2+, Tyverb |

### Scientific investigator(s) (Contact)



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|---|---|
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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 |

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| | ? 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).<br>? Subject accepting to participate in the survey |
| **Population type** | |
| Age | Adulthood (19 to 24 years)<br>Adulthood (25 to 44 years)<br>Adulthood (45 to 64 years)<br>Elderly (65 to 79 years)<br>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<br>Declarative data |
| Clinical data (detail) | Direct physical measures<br>Medical registration |
| Declarative data (detail) | Paper self-questionnaire |

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| Presence of a biobank | No |
| Health parameters studied | Health event/morbidity<br>Health event/mortality<br>Health care consumption and services<br>Quality of life/health perception |
| Care consumption (detail) | Hospitalization<br>Medical/paramedical consultation<br>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 |