

# METACOST - Observational Study on the management of HER2-positive breast cancer with brain metastases and its associated costs

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## General

### Identification

Detailed name Observational Study on the management of HER2-positive breast cancer with brain metastases and its associated costs

Sign or acronym METACOST

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation CNIL : 1410836

### General Aspects

Medical area Cancer research

Keywords breast, oncology, metastasis, retrospective, cost

### 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 carried out as part of an interventional study | No                                                                                                                                                                                                                                                                                                                                           |
| Additional information regarding sample selection.                     | Selection in each center (via PMSI and the DIM (medical information department) doctor of the investigating center) of a list of potentially eligible patients (patients who have had breast cancer with SNC metastases between 2006 and 2008). The presence or not of an overexpression of the HER2 status is then codes by the oncologist. |
| Database objective                                                     |                                                                                                                                                                                                                                                                                                                                              |
| Main objective                                                         | Describe the medical care of patients who have one or several secondary brain metastases to a primary breast cancer overexpressing HER2 and evaluate the cost of this from a health insurance standpoint                                                                                                                                     |
| Inclusion criteria                                                     | ? Patients from breast cancer with brain metastase(s)<br>? with overexpressing the HER2 receptor<br>? with brain metastases diagnosed between January 1, 2006 and December 31, 2008                                                                                                                                                          |
| 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)   | 2010                                                                                                     |
| Date of last collection (YYYY or MM/YYYY)    | 2011                                                                                                     |
| Size of the database                         |                                                                                                          |
| Size of the database (number of individuals) | < 500 individuals                                                                                        |
| Details of the number of individuals         | 220                                                                                                      |
| Data                                         |                                                                                                          |
| Database activity                            | Data collection completed                                                                                |
| Type of data collected                       | Clinical data<br>Biological data<br>Administrative data                                                  |
| Clinical data (detail)                       | Direct physical measures                                                                                 |
| Biological data (detail)                     | Histology of the tumor, mitotic index and presence of specific receptors (estrogens, progesterone, HER2) |
| Administrative data (detail)                 | PMSI (GHM, drugs)                                                                                        |
| Presence of a biobank                        | No                                                                                                       |
| Health parameters studied                    | Health event/morbidity<br>Health event/mortality<br>Health care consumption and services                 |
| Care consumption (detail)                    | Hospitalization<br>Medical/paramedical consultation<br>Medicines consumption                             |
| Procedures                                   |                                                                                                          |

|                                                                                       |                                                                                                          |
|---------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|
| Data collection method                                                                | Filling out e-CRFs by a CRA of the CRU of the investigating center in collaboration with the oncologist. |
| Participant monitoring                                                                | Yes                                                                                                      |
| Details on monitoring of participants                                                 | 6 months, 12 months, 18 months and 24 months                                                             |
| Links to administrative sources                                                       | Yes                                                                                                      |
| Linked administrative sources (detail)                                                | PMSI                                                                                                     |
| 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                                                                          |