

# ADAGIO - Observational study of the observance of the adjuvant treatment with Taxotere® in the operable breast cancer

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## General

### Identification

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|--|--|
| Detailed name  | Observational study of the observance of the adjuvant treatment with Taxotere® in the operable breast cancer |
| Sign or acronym  | ADAGIO   |
| CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation | Numéro CNIL = 907177, Numéro CPP = NA, Afssaps = NA  |

### General Aspects

|                  |  |
|------------------|--|
| Medical area     | Cancer research  |
| Others (details) | breast cancer  |
| Keywords         | docetaxel observance in adjuvant treatment, operable breast cancer that has spread to the lymph nodes. |

### Scientific investigator(s) (Contact)

|                      |                                  |
|----------------------|----------------------------------|
| Name of the director | VIGNAL                           |
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| Unit                 | Sanofi Aventis                   |

### Collaborations

### Funding

|                |         |
|----------------|---------|
| Funding status | Private |
|----------------|---------|

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|--|--|
| Details  | Sanofi-aventis France  |
| <b>Governance of the database</b>                                      |  |
| Sponsor(s) or organisation(s) responsible                              | Sanofi-aventis France  |
| Organisation status  | Private  |
| <b>Additional contact</b>  |  |
| <b>Main features</b>   |  |
| <b>Type of database</b>  |  |
| 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   |
| <b>Database objective</b>  |  |
| Main objective   | Evaluate the observance of the adjuvant treatment with Taxotere® in the operable breast cancer that has spread to the lymph nodes.   |
| Inclusion criteria   | <p>Patients having breast cancer operated on that has spread to the lymph nodes.</p> <p>For whom the decision of a adjuvant chemotherapy with Taxotere® base was taken.</p> <p>Who have given their agreement to participate in the study.</p> |
| <b>Population type</b>   |  |
| Age  | <p>Adulthood (19 to 24 years)</p> <p>Adulthood (25 to 44 years)</p> <p>Adulthood (45 to 64 years)</p> <p>Elderly (65 to 79 years)</p> <p>Great age (80 years and more)</p>   |
| Population covered   | Sick population  |
| Gender   | Woman  |
| Geography area   | National   |

|  |  |
|--|--|
| Detail of the geography area                 | Metropolitan France  |
| <b>Data collection</b>                       |  |
| <b>Dates</b>                                 |  |
| Date of first collection (YYYY or MM/YYYY)   | 2008   |
| Date of last collection (YYYY or MM/YYYY)    | 2010   |
| <b>Size of the database</b>                  |  |
| Size of the database (number of individuals) | < 500 individuals  |
| Details of the number of individuals         | 321  |
| <b>Data</b>                                  |  |
| Database activity                            | Current data collection  |
| Type of data collected                       | Clinical data<br>Biological data<br>Administrative data  |
| Clinical data (detail)                       | Direct physical measures   |
| Details of collected clinical data           | ---  |
| Declarative data (detail)                    | Phone interview  |
| Details of collected declarative data        | ---  |
| Biological data (detail)                     | ? Biological-hepatic balance carried out (Yes/No) and where applicable, variable(s) disturbed (transaminases, bilirubin, gamma-GT, alkaline phosphatases), |
| Administrative data (detail)                 | ? Social and occupational category, ? Professional activity. ? Lost work time (Yes/no) if activity.  |
| Presence of a biobank                        | No   |
| Health parameters studied                    | Health event/morbidity<br>Health event/mortality   |
| <b>Procedures</b>                            |  |

|   |  |
|---|--|
| Data collection method  | observance of chemo treatment, operable breast cancer          |
| Participant monitoring  | Yes  |
| Links to administrative sources   | No   |
| <b>Promotion and access</b>   |  |
| <b>Promotion</b>  |  |
| <b>Access</b>   |  |
| Terms of data access (charter for data provision, format of data, availability delay) | methods for accessing the database are currently being defined |
| Access to aggregated data   | Access on specific project only                                |
| Access to individual data   | Access on specific project only                                |