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

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General

Identification

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)

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Unit	Sanofi Aventis

Collaborations

Funding

Funding status	Private

Details	Sanofi-aventis France
Governance of the database	
Sponsor(s) or organisation(s) responsible	Sanofi-aventis France
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
Database objective	
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	Patients having breast cancer operated on that has spread to the lymph nodes. For whom the decision of a adjuvant chemotherapy with Taxotere® base was taken. Who have given their agreement to participate in the study.
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	Metropolitan France
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2008
Date of last collection (YYYY or MM/YYYY)	2010
Size of the database	
Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	321
Data	
Database activity	Current data collection
Type of data collected	Clinical data Biological data 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 Health event/mortality
Procedures	

Data collection method	observance of chemo treatment, operable breast cancer
Participant monitoring	Yes
Links to administrative sources	No
Promotion and access	
Promotion	
Access	
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