FRAME - First-line treatment of non-small cell lung cancer under routine conditions: observational study on overall survival

Head :Médecin pharmacoépidémiologiste , Eli Lilly France

Last update : 08/01/2012 | Version : 2 | ID : 74

General

Identification

Detailed name	First-line treatment of non-small cell lung cancer under routine conditions: observational study on overall survival
Sign or acronym	FRAME
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL N°909066

General Aspects

Medical area	Cancer research Pneumology
Keywords	Non-small cell lung cancer, first-line chemotherapy, platinum salt, survival, pemetrexed

Scientific investigator(s) (Contact)

Name of the director	Médecin pharmacoépidémiologiste
Email	fr_mail_pharmacoepi@lilly.com
Unit	Eli Lilly France

Collaborations

Funding

Funding status	Private
Details	Eli Lilly and Company

Governance of the database

Sponsor(s) or organisation(s)	Eli Lilly

responsible	
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.	Patients recruited by practitioners. Oncologists and pneumologists caring for patients suffering from non-small cell lung cancer. Random selection of practitioners using a professional file.

Database objective

Main objective	Primary objective: evaluate the overall survival of patients with a diagnosis of locally advanced or metastatic non-small cell lung cancer (stage IIIb or IV) initiating first-line chemotherapy combined with a platinum salt, whether or not combined with a targeted agent, in a daily practice setting. Secondary objectives: - Survival at 1 year, survival without progression and tumor response: according to histological subgroup and whether or not a target edagent is used; - Diagnosis of histopathological/cytopathological subtype; - Care pathway and use of resources.
Inclusion criteria	Have a histopathological or cytopathological diagnosis of locally advanced or metastatic non-small cell lung cancer (stage IIIb or IV). - Initiate first-line chemotherapy for a non-small cell lung cancer combined with a platinum salt, whether or not combined with a targeted agent.

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	Male Woman
Geography area	International
Detail of the geography area	Europe

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	2009
Date of last collection (YYYY or MM/YYYY)	2012

Size of the database

Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	5667

Data

Database activity	Current data collection
Type of data collected	Clinical data Biological data
Clinical data (detail)	Direct physical measures Medical registration
Biological data (detail)	histology, cytomarkers
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services
Care consumption (detail)	Hospitalization Medical/paramedical consultation

	Medicines consumption
Procedures	
Data collection method	Study data collection form
Participant monitoring	Yes
Details on monitoring of participants	18 months follow up
Links to administrative sources	No
Promotion and access	
Promotion	
Link to the document	http://tinyurl.com/Pubmed-FRAME
Description	List of publications in Pubmed
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Report and publication
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only