

# PEPITA - A prospective cohort study assessing the efficacy and safety of Tarceva® in 2nd line in patients with locally advanced or metastatic squamous Non-Small Cell Lung Cancer (NSCLC) - PEPiTA study

Head :Roche Medical Data Center

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## General

### Identification

Detailed name A prospective cohort study assessing the efficacy and safety of Tarceva® in 2nd line in patients with locally advanced or metastatic squamous Non-Small Cell Lung Cancer (NSCLC) - PEPiTA study

Sign or acronym PEPITA

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

ML28195

### General Aspects

Medical area Cancer research

Study in connection with Covid-19 No

Pathology (details) Non-Small Cell Lung Cancer (NSCLC)

Health determinants Iatrogenic  
Medicine

Keywords ERLOTINIB

### Scientific investigator(s) (Contact)

Name of the director Roche Medical Data Center

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Organization Roche SAS

## Collaborations

Participation in projects, networks and consortia No

## Funding

Funding status Private

## Governance of the database

Sponsor(s) or organisation(s) responsible Roche SAS

Organisation status Private

Presence of scientific or steering committees Yes

## Additional contact

Name of the contact <https://www.roche.fr/fr/innovation-recherche-medicale/data-sharing-portail-d-information-partage-des-donnees.html>

## Main features

### Type of database

Type of database Study databases

Study databases (details) Cohort study

Database recruitment is carried out by an intermediary A selection of health institutions and services

Database recruitment is made on the basis of: Medication(s) taken

Database recruitment is carried out as part of an interventional study No

## Database objective

Main objective Primary objective: To describe Progression Free Survival (PFS) in patients with stage IIIB or IV squamous NSCLC initiating treatment with Tarceva® after failure of first-line platinum-based chemotherapy.

Secondary objectives:

- To describe characteristics of patients treated with Tarceva®;
- To describe Tarceva® treatment modalities in patients with squamous NSCLC after failure of first-line platinum-based chemotherapy;
- To evaluate Overall Survival (OS);
- To describe the evolution of QoL;
- To describe the safety profile of Tarceva®.

#### Inclusion criteria

##### Inclusion criteria:

1. Adult patients (age  $\geq$  18 years);
2. Histologically and/or cytologically confirmed advanced (stage IIIB) or metastatic (stage IV) NSCLC with predominant squamous component (basaloid carcinomas allowed), after failure of first-line platinum-based chemotherapy;
3. For whom the treating physician decided to initiate treatment with Tarceva®;
4. Having received oral and written information about the study and having raised no objections to the collection and analysis of his/her personal data.

##### Exclusion criteria:

1. Mixed non-small cell and small cell lung carcinoma or mixed squamous cell carcinoma with a predominant adenocarcinoma component;
2. Concomitant participation in a clinical trial evaluating an antineoplastic treatment.

#### 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

##### Pathology

D02 - Carcinoma in situ of middle ear and respiratory system

##### Gender

Male  
 Woman

##### Geography area

National

#### Data collection

##### Dates

Date of first collection (YYYY or MM/YYYY)

2012

Date of last collection (YYYY or MM/YYYY)	2014
<b>Size of the database</b>	
Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	152
<b>Data</b>	
Database activity	Data collection completed
Type of data collected	Clinical data Biological data
Clinical data (detail)	Medical registration
Details of collected clinical data	Date of visit - Inclusion/exclusion criteria - Demographic data - ECOG - SAP/DAP - Social and occupational data - Risk factors (tobacco use) - Medical history and concomitant diseases - Treatment associated with initiation of Tarceva® - Disease history: primary lung tumor evaluation - Disease history: diagnosis of locally advanced or metastatic disease - EGFR mutation status - First-line treatment of metastatic NSCLC.
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services Quality of life/health perception
Care consumption (detail)	Medicines consumption
<b>Procedures</b>	
Data collection method	eCRF
Classifications used	CDISC
Quality procedure(s) used	GCP/GVP
Participant monitoring	Yes
Monitoring procedures	Monitoring by contact with the referring doctor
Links to administrative sources	No

## Promotion and access

### Promotion

### Access

Dedicated website	<a href="https://www.roche.fr/fr/innovation-recherche-medicale/data-sharing-portail-d-information-partage-des-donnees.html">https://www.roche.fr/fr/innovation-recherche-medicale/data-sharing-portail-d-information-partage-des-donnees.html</a>
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Presence of document that lists variables and coding procedures	Yes
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Access to aggregated data	Access on specific project only
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Access to individual data	Access on specific project only
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