

# Vargatef in 2nd-line therapy of advanced or metastatic adenocarcinoma of the lung (VARGADO)

**First published:** 14/03/2016

**Last updated:** 04/07/2024

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS12795

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### Study ID

38264

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### DARWIN EU® study

No

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### Study countries

 Germany

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### Study description

This observational study will investigate the efficacy and tolerability of Vargatef (Nintedanib) plus docetaxel in daily routine second-line treatment in patients with locally advanced, metastatic or locally recurrent NSCLC. Treatment with Vargatef in eligible NSCLC patients, for whom the treating physician has decided to initiate treatment with Vargatef in second line according to the local label, will be observed for up to 24 months. Survival follow-up will be done until the end of the study.

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### Study status

Ongoing

## Research institutions and networks

### Institutions

**Boehringer Ingelheim**

**First published:** 01/02/2024

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Institution

## Contact details

### Study institution contact

Boehringer Ingelheim Pharma GmbH  
Boehringer Ingelheim  
Pharma GmbH  
info@boehringer-ingelheim.com

Study contact

[info@boehringer-ingenelheim.com](mailto:info@boehringer-ingenelheim.com)

### **Primary lead investigator**

Boehringer Ingelheim Pharma GmbH  
Boehringer Ingelheim  
Pharma GmbH

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Planned: 31/01/2015

Actual: 31/01/2015

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### **Study start date**

Planned: 27/04/2015

Actual: 27/04/2015

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### **Date of final study report**

Planned: 31/12/2025

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Boehringer Ingelheim Pharma GmbH

## Regulatory

## Was the study required by a regulatory body?

No

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## Is the study required by a Risk Management Plan (RMP)?

Not applicable

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Drug utilisation

Effectiveness study (incl. comparative)

#### **Main study objective:**

Assess 1-year survival rate

## Study Design

### **Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

VARGATEF

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**Medical condition to be studied**

Lung adenocarcinoma

## Population studied

**Age groups**

- Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)
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**Estimated number of subjects**

700

## Study design details

**Outcomes**

Assess 1-year survival rate, Assess 1-year progression-free survival rate in patients with early progression of first-line therapy. Median overall survival. Median progression free survival. Tumor controll rate. Duration of therapy and modifications. Incidence of adverse events related to Vargatef

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**Data analysis plan**

All analyses are descriptive, SAS software will be used. Frequency tables for categorical variables will depict all possible categories and will report the

number of observations and the percentage per characteristic feature. The number of patients with missing values and the percentage of the total patient population will also be presented (if necessary). All analyses are presented in the overall population. These analyses are also performed additionally according to further subgroups in the event of special interests. The details of the statistical analyses are described in the statistical analysis plan (TSAP) which is produced in a completed form before database lock. The main diagnosis must be met. The primary endpoint of this NIS is the survival rate one year after the beginning of treatment with Vargatef® + docetaxel. Relative frequency of patients who have not died after 12 months will be presented, together with the 95% confidence interval.

## Data management

### ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

### Data sources (types)

[Other](#)

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### Data sources (types), other

Prospective patient-based data collection

## Use of a Common Data Model (CDM)

## **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No