

# Comparing Common Safety Outcomes in Locally Advanced or Metastatic Non-small Cell Lung Cancer Patients Treated with Various First-line Platinum-containing Chemotherapy Combination Regimens (H3E-MC-B026)

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Study

Finalised

## Administrative details

### EU PAS number

EUPAS10688

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### Study ID

27984

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### DARWIN EU® study

No

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### Study countries

## Study status

Finalised

## Research institutions and networks

### Institutions

#### Eli Lilly and Company

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

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**Institution**

## Contact details

### Study institution contact

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**Study contact**

[kim\\_sangmi@lilly.com](mailto:kim_sangmi@lilly.com)

### Primary lead investigator

Sangmi Kim

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 05/02/2015

Actual: 05/02/2015

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**Study start date**

Planned: 15/01/2016

Actual: 15/01/2016

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**Date of final study report**

Planned: 31/05/2016

Actual: 01/03/2018

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Eli Lilly and Company

## Study protocol

[H3E-MC-B026 AE in NSCLC Platinum Combos\\_Redacted.pdf](#) (847.17 KB)

## 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 topic:**

Disease /health condition

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To evaluate the safety outcomes among Stage IIIB/IV NSCLC patients treated with Pemetrexed+Cisplatin, Pemetrexed+Carboplatin, Pemetrexed+Bevacizumab+Carboplatin, Paclitaxel+Carboplatin, Paclitaxel+Bevacizumab+Carboplatin, or Docetaxel+Carboplatin

### Study Design

## **Non-interventional study design**

Cohort

## Study drug and medical condition

### **Study drug International non-proprietary name (INN) or common name**

BEVACIZUMAB

CARBOPLATIN

CISPLATIN

DOCETAXEL

PEMETREXED

PACLITAXEL

## Population studied

### **Short description of the study population**

Stage IIIB/IV NSCLC patients who received one of the selected chemotherapy regimens on or after the date of NSCLC diagnosis. From 26 September 2008 (the date that Pemetrexed was first approved for first-line treatment of NSCLC by the FDA in the US) and 30 November 2014 (1 month before the last date that the data are available in the database), among all patients with only one primary tumor type and valid age information, those who meet the following criteria were included in the study:

1) Patients were diagnosed with lung cancer as a primary cancer (at least one ICD-9-CM code indicating lung cancer, or a TUMOR TYPE value of “Lung Cancer”) with at least an ICD-O-3 code indicating non-small cell histology (Howlader et al. 2014), or a cancer subtype recorded as “NSCLC” records in the IMS Oncology electronic medical records (EMR); and

- 2) The staging information indicating locally advanced or metastatic disease
  - 3) Patients initiated the first-line treatment including Pem/Cis, Pem/Carbo, Pem/Bev/Carbo, Pac/Carbo, Pac/Bev/Carbo, or Doc/Carbo after the lung cancer diagnosis. The date of any of the above first-line treatment initiation is the index date; and
  - 4) Patients must be 18 years of age or older on the index date; and
  - 5) Patient's oncology practice must be stable between the index date and end of record in the database, or 31 December 2014, whichever comes first.
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### **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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### **Special population of interest**

Other

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### **Special population of interest, other**

Non-small cell lung cancer patients

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### **Estimated number of subjects**

2600

## **Study design details**

### **Outcomes**

To estimate the crude incidence proportions and rates of the safety outcomes among the NSCLC patients receiving 1st line treatment with selected chemotherapy regimens, to describe demographic and clinical characteristics of each treatment group, if sample size allows, to compare the safety outcomes between the treatment groups by hazard ratio by adjusting patient and clinical characteristics. If sample size allows, to conduct subgroup analyses to further examine the safety profiles of the NSCLC patients treated with the regimens in those who were below 70 and who were 70 years or older.

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### **Data analysis plan**

The primary analysis of this protocol is to describe the incident safety outcomes after index date in patients who were administered at least one of the selected chemotherapy regimens. If sample size allows, adjusted incidence rates, rate difference and hazard ratios will be estimated among the comparable patients with the application of the propensity score stratification method.

## Documents

### **Study results**

[B026 PASS\(1\\_Redacted.pdf\)](#) (375.69 KB)

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## 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 source(s), other**

IMS Oncology United States

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**Data sources (types)**

[Administrative healthcare records \(e.g., claims\)](#)

## 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**

Unknown