

# Real-world post-authorization effectiveness study (PAES) of pembrolizumab for the treatment of NSCLC across races, ethnicities, and age groups (MK-3475-G18)

**First published:** 03/06/2025

**Last updated:** 13/10/2025

Study

Planned

## Administrative details

### EU PAS number

EUPAS1000000576

### Study ID

1000000576

### DARWIN EU® study

No

### Study countries

☐ United States

### Study description

This is a real-world post-authorization effectiveness study (PAES) to characterize the real world effectiveness of pembrolizumab for the treatment of non-small cell lung cancer (NSCLC) among United States (US) patients across races, ethnicities, and age groups to address part of an FDA post-marketing commitment (PMC) for KEYNOTE-671 (4531-2).

The primary objectives are as follows:

(1) To evaluate the real-world effectiveness of pembrolizumab monotherapy in US NSCLC patients by estimating real-world overall survival (rwOS) among the following subgroups: Race (racial minorities [e.g., Black or African American, Asian, American Indian/Alaska Native, Native Hawaiian/Other Pacific Islander, and Other Race] and white patients), Hispanic/Latino ethnicity (Hispanic/Latino patients and not Hispanic/Latino patients), and Age (elderly patients  $\geq 75$  years and younger patients  $< 75$  years).

(2) To evaluate the real-world effectiveness of pembrolizumab in combination with platinum-based chemotherapy in US NSCLC patients by estimating rwOS among the following subgroups: Race, Hispanic/Latino ethnicity, and Age.

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## **Study status**

Planned

## Research institutions and networks

### Institutions

Merck Sharp & Dohme LLC

Flatiron Health, Inc.

## Contact details

### Study institution contact

Clinical Trials Disclosure Merck Sharp & Dohme LLC

ClinicalTrialsDisclosure@msd.com

Study contact

[ClinicalTrialsDisclosure@msd.com](mailto:ClinicalTrialsDisclosure@msd.com)

### Primary lead investigator

Clinical Trials Disclosure Merck Sharp & Dohme LLC

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 22/07/2024

Actual: 22/07/2024

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### Study start date

Planned: 04/01/2026

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### Data analysis start date

Planned: 31/12/2027

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### Date of final study report

Planned: 15/11/2028

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Merck Sharp & Dohme LLC

## Regulatory

### **Was the study required by a regulatory body?**

Yes

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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:**

Human medicinal product

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#### **Study type:**

Non-interventional study

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

Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Study design:**

This retrospective cohort study will be conducted using the Flatiron Health US-based deidentified electronic health record databases to characterize the real-world effectiveness of pembrolizumab for the treatment of non-small cell lung cancer (NSCLC) across races, ethnicities, and age groups.

**Main study objective:**

The main objective of this study is to evaluate the real-world effectiveness of pembrolizumab monotherapy and pembrolizumab in combination with platinum-based chemotherapy (PBC) in United States (US)-based NSCLC patients by estimating real-world overall survival (rwOS) among the following subgroups: Race (racial minorities [e.g., Black or African American, Asian, American Indian/Alaska Native, Native Hawaiian/Other Pacific Islander, and Other Race] and white patients), Hispanic/Latino ethnicity (Hispanic/Latino patients and not Hispanic/Latino patients), and Age (elderly patients  $\geq 75$  years and younger patients  $< 75$  years).

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

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

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**Anatomical Therapeutic Chemical (ATC) code**  
(L01FF02) pembrolizumab  
pembrolizumab

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**Medical condition to be studied**  
Non-small cell lung cancer

## Population studied

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

Adult patients diagnosed with non-small cell lung cancer (NSCLC) and treated with pembrolizumab (monotherapy or in combination with platinum-based chemotherapy [PBC]) between the eligibility October 2, 2015 and June 30, 2025 in the US will be eligible for inclusion in this study.

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### **Age groups**

- **Adult and elderly population ( $\geq 18$  years)**
    - Adults (18 to < 65 years)
      - Adults (18 to < 46 years)
      - Adults (46 to < 65 years)
    - Elderly ( $\geq 65$  years)
      - Adults (65 to < 75 years)
      - Adults (75 to < 85 years)
      - Adults (85 years and over)
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## **Estimated number of subjects**

10000

## **Study design details**

### **Setting**

This retrospective cohort study will be conducted using the Flatiron Health US-based deidentified electronic health record (EHR)-derived databases: early non-small cell lung cancer (eNSCLC) Flatiron Health Research Database (FHRD), and advanced non-small cell lung cancer (aNSCLC) FHRD.

The study will include adult patients diagnosed with NSCLC and treated with pembrolizumab (monotherapy or in combination with PBC) between October 2, 2015 and June 30, 2025.

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### **Outcomes**

The primary outcome of interest for the current study will be death, as measured by rwOS, defined as the time from pembrolizumab treatment start to date of death.

Patients without a date of death will be censored on the date of the last follow-up or data cutoff date, whichever occurs first.

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### **Data analysis plan**

Real-world overall survival will be estimated using Kaplan-Meier methods for each of the following subgroups: race (racial minorities, white), ethnicity (Hispanic/Latino, not Hispanic/Latino), and age group (elderly, younger).

Median survival times and the probabilities of survival at key milestones of interest (e.g., 1-year, 2-year) and corresponding 95% confidence intervals will be calculated.

These methods will be used to describe estimates of real-world overall survival for each subgroup.

## **Data management**

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 data source

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### Data source(s), other

Flatiron Health: early non-small cell lung cancer (eNSCLC) Flatiron Health Research Database (FHRD), and advanced non-small cell lung cancer (aNSCLC) FHRD.

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### Data sources (types)

[Electronic healthcare records \(EHR\)](#)

[Non-interventional study](#)

## 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