

# Pattern of Use and Safety/Effectiveness of Nivolumab in Routine Oncology Practice (CA209234)

**First published:** 10/10/2016

**Last updated:** 08/02/2021

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS14071

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### Study ID

39427

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### DARWIN EU® study

No

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### Study countries

 Australia

 Austria

 Belgium

 Czechia

-  France
  -  Germany
  -  Hungary
  -  Italy
  -  Poland
  -  Spain
  -  Switzerland
  -  United Kingdom
  -  United States
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## **Study description**

This is an observational, single-arm, multicenter, prospective cohort study in patients treated with nivolumab for the approved indications of melanoma and lung cancer in Australia, the EU, Switzerland, and the United States (US).

Targeted countries in the EU for study participation include Austria, Belgium, France, Germany, Italy, Spain, and the United Kingdom (UK). Study objectives are to assess the safety experience, survival, adverse event management, and outcomes of adverse events associated with nivolumab in routine oncology care facilities. The study population includes 400 adults treated with nivolumab for histologically or cytologically confirmed melanoma and 800 adults treated with nivolumab for histologically or cytologically confirmed lung cancer. The study will be started in 2016, and data collection will be continued until March 2024.

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## **Study status**

Ongoing

## Contact details

## **Study institution contact**

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Study contact

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**Primary lead investigator**

Scotto Julie

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 17/07/2015

Actual: 17/07/2015

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**Study start date**

Planned: 31/07/2016

Actual: 29/07/2016

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**Data analysis start date**

Planned: 30/08/2016

Actual: 29/07/2016

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**Date of interim report, if expected**

Planned: 11/09/2018

Actual: 10/09/2018

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**Date of final study report**

Planned: 31/12/2024

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Bristol Myers Squibb

## Regulatory

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

No

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

EU RMP category 3 (required)

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

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

Assessment of risk minimisation measure implementation or effectiveness

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

As additional pharmacovigilance measure in the post-approval EU RMP for nivolumab, the study will assess the use pattern and safety/effectiveness profile

of nivolumab and the management strategies and outcomes of identified risks associated with nivolumab treatment for melanoma and lung cancer in routine oncology practice. This study will generate data to inform future risk minimization efforts.

## Study Design

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

Cohort

Other

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### **Non-interventional study design, other**

Observational, multicenter, single-arm study

## Study drug and medical condition

### **Anatomical Therapeutic Chemical (ATC) code**

(L01XC17) nivolumab

nivolumab

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### **Medical condition to be studied**

Metastatic malignant melanoma

Non-small cell lung cancer metastatic

## 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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### **Special population of interest**

Immunocompromised

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### **Estimated number of subjects**

1200

## **Study design details**

### **Outcomes**

Primary Endpoints: Immune-related pneumonitis, Immune-related colitis, Immune-related hepatitis, Immune-related nephritis/renal dysfunction, Immune-related endocrinopathies, Immune-related skin reactions, Other immune-related, adverse reactions, Severe infusion reactions, Secondary Endpoints: Other nivolumab treatment-related AEs, Management of Immune-related AEs, Outcomes of Immune-related AEs, Overall Survival, Nivolumab treatment pattern

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### **Data analysis plan**

Incidence rates of immune-related AEs as in primary objective calculated separately for melanoma and lung cancer. Other immune-related AEs analyzed as combined endpoint. # and % of patients whose immune-related AEs are managed according to recommended strategies will be summarized.

Approaches to diagnose AEs are summarized by # and % for immune-related AEs. Doses/duration of systemic corticosteroids, of non-corticosteroid treatment, hormone therapies/other treatment modalities will be summarized.

AE Outcomes to present with # and % of patients experiencing outcomes presented separately for those managed with recommended algorithms and those not. Data on deaths to summarize as follows: # and % of all deaths, of deaths  $\leq$  30d of last dose received, of deaths  $\leq$  1 to 5 yrs after initiation of nivolumab. Analyze survival with Kaplan-Meier plots. Calculate survival rates & the corresponding 95% CIs, median survival and 95% CIs.

## 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