

# A Cross-sectional Survey to Evaluate Physician Knowledge of Safety Messages Included in the Physician Education Booklet (PEB) for IMLYGIC®

**First published:** 10/12/2019

**Last updated:** 05/01/2021

Study

Finalised

## Administrative details

### EU PAS number

EUPAS31188

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### Study ID

38849

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### DARWIN EU® study

No

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### Study countries

 Austria

 Germany

 Netherlands

### Study description

The overall objective of this study is to evaluate awareness of the IMLYGIC PEB and knowledge of the key messages included in the IMLYGIC PEB among physicians who completed the required IMLYGIC training.

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### Study status

Finalised

## Research institutions and networks

### Institutions

Amgen

 United States

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

**Last updated:** 27/03/2026

Institution

Multiple centres: 50 centres are involved in the study

### Contact details

**Study institution contact**

Global Development Leader Amgen Inc.  
medinfo@amgen.com

Study contact

[medinfo@amgen.com](mailto:medinfo@amgen.com)

**Primary lead investigator**

Global Development Leader Amgen Inc.

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 11/07/2018

Actual: 11/07/2018

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**Study start date**

Planned: 14/01/2020

Actual: 14/01/2020

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**Data analysis start date**

Planned: 30/10/2020

Actual: 07/10/2020

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**Date of final study report**

Planned: 28/02/2021

Actual: 05/01/2021

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

## Study protocol

[20180099\\_01.02.06 Public Redacted Protocol Ver 1.0 2019-10-14 English\\_2.pdf](#)

(6.05 MB)

## 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 topic:**

Human medicinal product

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Main study objective:**

The primary objective is to evaluate physicians' knowledge levels of the key messages included in the IMLYGIC PEB among physicians who completed the required IMLYGIC training.

## Study Design

**Non-interventional study design**

Cross-sectional

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(L01XX51) talimogene laherparepvec

talimogene laherparepvec

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**Medical condition to be studied**

Malignant melanoma stage III

## Population studied

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

The target population is physicians who completed the required IMLYGIC training in the 4 participating European countries.

Physicians eligible for study inclusion are those who:

1. completed the controlled distribution programme training, and
2. provided permission to share their responses in aggregate with the EMA or national competent authorities, if requested.

Physicians will be excluded if they have:

1. participated in the cognitive pre-testing of the survey questionnaire to be used for this study, or
  2. have been direct employees of Amgen, ICON, or the EMA within the year prior to completing the survey
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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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## **Estimated number of subjects**

50

## **Study design details**

## **Outcomes**

Percentages of physicians with correct responses to the knowledge-related questions about the key messages included in the IMLYGIC PEB. Success criteria are at least 80% of HCPs provide a correct response to each individual knowledge-related question that has a minimum n = 30. The secondary endpoints are the percentages of physicians that recall receiving and reading the IMLYGIC PEB and distributing the patient-directed materials to their patients.

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### **Data analysis plan**

Primary analysis population will include all physicians who completed at least 1 endpoint question in the survey. Frequencies, percentages and corresponding 95% confidence intervals will be used to summarise the endpoints for the primary analysis set overall, by country, and by subgroups (practice setting, primary medical speciality, and last time prescribed IMLYGIC). For each question, the percentage of HCPs who answer each question correctly will be estimated and assessed against the 80% ( $\pm$  95% CI) target. For secondary endpoints of receipt and reading of the PEB, and distribution of patient directed materials, percentages and 95% CI will be estimated. The primary analysis will be performed by having read vs. not read the IMLYGIC PEB and also by prescribing status. An analysis to evaluate the impact of recall bias will be performed by repeating the primary analysis stratified by tertiles of time since physicians completed the required IMLYGIC controlled distribution training.

## Documents

### **Study results**

[EUPAS31188-38847.pdf](#) (100.5 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 sources (types)

Other

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### Data sources (types), other

Physician Survey

## 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