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

Study ID

38849

DARWIN EU® study

No

Study countries

- ☐ Austria
- ☐ Germany
- ☐ Netherlands

United Kingdom

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.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

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

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

Study start date

Planned: 14/01/2020

Actual: 14/01/2020

Data analysis start date

Planned: 30/10/2020

Actual: 07/10/2020

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

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

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

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

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)

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.

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% (± 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)

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

Data sources (types), other

Physician Survey

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No