Program to evaluate the Tasigna (nilotinib) educational materials: survey to patients and physicians in five EU countries

First published: 13/03/2014

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS6073

Study ID

28196

DARWIN EU® study

No

Study countries

- ☐ France
- ☐ Germany
- ☐ Italy
- ☐ Spain

United Kingdom

Study description

The objective of the proposed survey is to evaluate the effectiveness of the educational material for healthcare professionals and patients/caregivers used as part of the Tasigna® risk management plan. Specifically:•to evaluate physician’s receipt and review as well as their understanding of the educational material •to evaluate the physician’s assessment of the effectiveness of the educational materials, as tools to convey important safety information to physicians who prescribe Tasigna.•to assess patients' understanding of the patient educational material, to confirm that patients have received and reviewed as well as comprehended the material.

Study status

Finalised

Research institutions and networks

Institutions

Novartis Pharmaceuticals

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Institution

Contact details

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Study contact

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Primary lead investigator

Clinical Disclosure Officer Novartis

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/11/2013

Actual: 09/01/2014

Study start date

Planned: 09/10/2014

Actual: 08/12/2014

Data analysis start date

Planned: 31/12/2015

Actual: 31/12/2015

Date of final study report

Planned: 31/12/2015

Actual: 27/04/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis Pharmaceuticals

Study protocol

AMN107A2001--protocol_Redacted.pdf(1.46 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Other study registration identification numbers and links

CAMN107A2001

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Primary data collection

Main study objective:

The objective of the proposed survey is to evaluate the effectiveness of the educational material for healthcare professionals and patients/caregivers used as part of the Tasigna® risk management plan.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

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

NILOTINIB

Population studied

Short description of the study population

Patients and physicians in five largest European countries (France, Germany, Italy, Spain and the United Kingdom).

Participating physicians must meet the following criteria at the study start:

1. Oncology-haematology specialist.

2. Have prescribed Tasigna in the preceding 12 months at the time of survey.

Included patients must meet the following criteria:

1. CML patient who has been prescribed Tasigna within 12 months of the date the patient starts the survey.

2. Provides informed consent in accordance with local national requirements (where required).

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

150

Study design details

Data analysis plan

The following metrics will be reported as part of this analysis. All data will be reported by country and for all countries in aggregate:• Number of patients and HCPs receiving survey invitations • Number of patients and HCPs who met eligibility criteria• Number of completed patient and HCP surveys by internet•

Description of survey participants’ characteristics o Patients• Gender, Age• Length of CML treatment(s)o HCPs• Medical specialty (if other than hematologists attend CML patients)• Type of institution• Gender, Age• Prescribing level• Frequency distribution of responses to each question in each survey• Percent of respondents indicating correct response to each key risk message and 95% confidence intervals of the estimates

Documents

Study results

CAMN107A2001 CSR EuPAS6073_Redacted.pdf(2.95 MB)

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

Physicians 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

Unknown