# A PROSPECTIVE NON-INTERVENTIONAL SAFETY STUDY IN PATIENTS WITH CHRONIC MYELOID LEUKEMIA RECEIVING NILOTINIB IN DAILY PRACTICE ACCORDING TO UPDATED GUIDELINES

**First published:** 21/01/2013

**Last updated:** 02/07/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS3335

**Study ID**

16550

**DARWIN EU® study**

No

**Study countries**

Austria

Germany

**Study description**

This non-interventional, observational study will provide real-world safety data on CML CP patients exposed to nilotinib and therefore provide insights into disease management as well as the safety profile of nilotinib.

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Novartis Pharmaceuticals

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

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Institution

### Multiple centres: 15 centres are involved in the study

## Contact details

**Study institution contact**

Laura Hagan trialandresults.registries@novartis.com

**Study contact**

trialandresults.registries@novartis.com

**Primary lead investigator**

Novartis Clinical Disclosure Officer

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 10/02/2013

Actual: 10/02/2013

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**Study start date**

Planned: 26/08/2013

Actual: 10/10/2013

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**Data analysis start date**

Planned: 01/07/2020

Actual: 31/12/2015

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**Date of final study report**

Planned: 31/12/2016

Actual: 31/12/2015

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Novartis Pharmaceuticals

## Study protocol

CAMN107AAT01_Tasigna_PASS_Protocol_version01_Redacted.pdf (512.23 KB)

## Regulatory

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

No

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

Not applicable

## Other study registration identification numbers and links

CAMN107AAT01

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Disease /health condition

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

**Data collection methods:**

Primary data collection

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**Main study objective:**

This observational study will provide real-world safety data on CML patients exposed to nilotinib and therefore provide insights into disease management, efficacy as well as the safety profile of nilotinib and the adherence to current treatment recommendations (Baccarani et al. 2009, Valent et al. 2011, Rosti et al. 2011) in daily clinical practice.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

TASIGNA

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

NILOTINIB

**Anatomical Therapeutic Chemical (ATC) code**

(L01XE08) nilotinib

nilotinib

**Medical condition to be studied**

Chronic myeloid leukaemia

## Population studied

**Short description of the study population**

Patients with chronic myeloid leukemia receiving Nilotinib in daily practice.

**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)

**Special population of interest**

Other

**Special population of interest, other**

Chronic myeloid leukaemia patients

**Estimated number of subjects**

100

## Study design details

**Outcomes**

The main goal of this non-interventional study is to document the following parameters under specific conditions of daily clinical practice:• Safety and tolerability and all adverse events (AE, serious and non-serious) during treatment with nilotinib and adherence to current treatment recommendations in daily clinical practice, Clinical, cytogenetic, hematologic and molecular responses to nilotinib

**Data analysis plan**

There are no predefined hypotheses regarding the incidence of specific safety outcomes, the magnitude of effectiveness or treatment practices. Descriptive statistical methods will be used for all variables of evaluation. Efficacy and safety variables will be presented descriptive and will be interpreted in comparison to historic controls and published data.

## Documents

**Study results**

CAMN107AAT01_Redacted CSR.pdf (612.58 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**

Prospective patient-based data collection

## 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