

# A Non-Interventional Study of Bosutinib in Patients With Previously Treated Chronic Phase Chronic Myelogenous Leukemia (CML)

**First published:** 23/12/2013

**Last updated:** 30/03/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS5461

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### Study ID

18483

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### DARWIN EU® study

No

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### Study countries

 United States

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### Study description

# A Non-Interventional Study of Bosutinib in Patients With Previously Treated Chronic Phase Chronic Myelogenous Leukemia (CML)

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## Study status

Finalised

## Research institutions and networks

### Institutions

**Pfizer**

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

**Last updated:** 01/02/2024

**Institution**

**Multiple centres:** 30 centers are involved in the study

## Contact details

### Study institution contact

Graciela Mabel Woloj [mabel.woloj@pfizer.com](mailto:mabel.woloj@pfizer.com)

**Study contact**

[mabel.woloj@pfizer.com](mailto:mabel.woloj@pfizer.com)

## Primary lead investigator

Jorge Cortes

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 01/04/2014

Actual: 28/10/2013

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### Study start date

Planned: 01/05/2014

Actual: 08/01/2014

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### Date of final study report

Planned: 23/06/2015

Actual: 23/06/2015

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer

## Study protocol

[FAP B1871042 Protocol 28 October 2013.pdf](#) (996.13 KB)

## Regulatory

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

No

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

Not applicable

**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:**

Drug utilisation

Effectiveness study (incl. comparative)

Other

**If 'other', further details on the scope of the study**

This Non-Interventional Study (NIS) will aim to capture real-world treatment related adverse events (AEs) and discontinuation rates and evaluate effective dosing strategies employed in clinical practice when managing these AEs.

**Data collection methods:**

Primary data collection

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**Main study objective:**

This Non-Interventional Study (NIS) will aim to capture real-world treatment related adverse events (AEs) and discontinuation rates and evaluate effective dosing strategies employed in clinical practice when managing these AEs.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Prospective Non-Interventional

## Study drug and medical condition

**Medicinal product name**

BOSULIF

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**Medical condition to be studied**

Chronic myeloid leukaemia

## Population studied

**Short description of the study population**

Previously treated patients from US with chronic phase chronic myelogenous leukemia (CML) who were prescribed or started with bosutinib.

Patients meeting the following criteria were included:

1. Evidence of a personally signed and dated informed consent document indicating that the patient (or a legally acceptable representative) has been informed of all pertinent aspects of the study
  2. Age 18 years or older
  3. Philadelphia chromosome positive or BCR-ABL positive CP ML
  4. Resistant or intolerant to previous therapy for CP CML
  5. Has been prescribed bosutinib for the treatment of previously treated CP CML, who has either not started treatment or has not taken bosutinib for more than 7 days at the time of baseline visit
  6. Prior history of malignancy is permitted
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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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### **Special population of interest**

Hepatic impaired

Immunocompromised

Renal impaired

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### **Estimated number of subjects**

170

## Study design details

## Outcomes

The primary objectives of this NIS are to:

1. Determine the rate of treatment related AEs in CP CML patients treated with bosutinib.
2. Observe the discontinuation (DC) rate due to treatment related AEs and compare with the DC rate in patients with chronic phase CML resistant or intolerant to previous treatment(s) observed in the clinical trials.

Safety dosing, treatment duration, adherence, reasons for dose reductions/ delay/ discontinuations, timing and tests performed during treatment, concomitant medications). Patient self reported adherence information and quality of life Responses (results of hematological, cytogenetic and/or molecular testing) Baseline information to describe the patient population treated with bosutinib

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## Data analysis plan

Analysis will be based on the safety population, which includes all enrolled patients who received at least one dose of bosutinib. Patients who signed informed consent but who were not treated will be reported with a reason(s) why treatment was not received. Analysis will be based on observed data. Incomplete data will be imputed and details will be included in the SAP.

## Documents

### Study report

[B1871042 CSR Final 20150623.pdf](#) (7.41 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

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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**

Unknown