# An observational study - Evaluation of efficacy and safety of Bosulif® under real life conditions of use (BOSEVAL)

**First published:** 07/01/2015
**Last updated:** 05/06/2024

Study | Finalised

## Administrative details

**PURI**
https://redirect.ema.europa.eu/resource/8232

**EU PAS number**
EUPAS8231

**Study ID**
8232

**DARWIN EU® study**
No

**Study countries**
France

**Study description**
This trial is a national, observational, descriptive, prospective study conducted in France on adult patients treated for Philadelphia positive (Ph+) CML in the chronic, accelerated or blast phase, previously treated with one or more TKIs and for whom imatinib, dasatinib or nilotinib are not considered as appropriate treatments. CML is a rare disease, a minimum number of patients is not expected but a total of about one hundred (100) patients included in the study appears to be a reasonable objective. This non-interventional study is designed to evaluate the safety and efficacy, and the methods of use of Bosulif®, under real life conditions.

**Study status**
Finalised

# Research institution and networks

## Institutions

### Pfizer
**First published:** 01/02/2024
Last updated 01/02/2024
Institution

### Multiple centres: 23 centres are involved in the study

## Contact details

**Study institution contact**
Delphine BERZIN
Study contact

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**Primary lead investigator**
Philippe Rousselot
Primary lead investigator

## Study timelines

**Date when funding contract was signed**
Planned:
10/02/2015

**Study start date**
Planned:
01/04/2015
Actual:
24/10/2015

**Date of final study report**
Planned:
31/01/2024
Actual:
31/05/2024

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer

## Study protocol

B1871047_Protocole v1.1 _16032015-EN .pdf(4.12 MB)

B1871047_Protocole v2 _Amendment 1_ 15022019_Clean_English.pdf(1.03 MB)

## Regulatory

**Was the study required by a regulatory body?**
No

**Is the study required by a Risk Management Plan (RMP)?**
Not applicable

# Methodological aspects

## Study type

## Study type list

**Study type:**
Non-interventional study

**Scope of the study:**
Assessment of risk minimisation measure implementation or effectiveness
Drug utilisation
Effectiveness study (incl. comparative)

**Study design:**
Non-interventional observational multicentric prospective study not affecting the patient's medical care.

**Main study objective:**
To determine the percentage of patients with Ph+ CML in chronic, accelerated or blast phase presenting with AEs considering related to bosutinib by the investigator,

# Study Design

**Non-interventional study design**
Cohort

# Study drug and medical condition

**Name of medicine**
Bosulif

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

**Additional medical condition(s)**
Chronic Myeloid Leukemia (CML)

# Population studied

**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**
100

# Study design details

**Outcomes**
To evaluate the percentage of patients who permanently discontinued bosutinib following an AE considered as related to bosutinib by the investigator.
- Safety profile of bosutinib
- Evaluate patient compliance
- Evaluate quality of life
- Describe the methods of treatment of bosutinib under real-life conditions of use
- Evaluate the efficacy of treatment
- Describe the haematological, cytogenetic and molecular responses
- Describe the characteristics of patients
- Evaluate cross-intolerance between bosutinib and previously prescribe TKI

**Data analysis plan**
The descriptive analysis of qualitative and ordinal variables will consist of the sample size and frequency of each modality with its 95% confidence interval (CI), as well as the number of missing data. Quantitative variables will be described in terms of sample size, mean, median, standard deviation, confidence interval, as well as number of missing data. Data on overall survival and progression-free survival will be described with Kaplan Meier curves. Median survival will be estimated and presented with its 95% CI. The data will be evaluated separately for patients with Ph + CML in PC, PA or CB and depending on the processing line. Interim analyzes will be carried out once a year.

# Documents

**Study report**
B1871047_BOSEVAL_Study report_V1.0_30MAY2024.pdf(16.28 MB)
B1871047_BOSEVAL_Study report abstract_V1.0_30MAY2024.pdf(180.12 KB)
2024-48327 CIOMS_1.pdf(1.28 MB)
2024-48327 CIOMS_2.pdf(991.98 KB)
2024-48327 CIOMS_3.pdf(884.19 KB)
2024-48327 CIOMS_4.pdf(902.98 KB)
2024-48327 CIOMS_5.pdf(884.9 KB)
2024-48327 CIOMS_6.pdf(740.13 KB)

# Data management

# 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**
No