

# Multicenter Assessment of Treatment Outcomes in a Historical Cohort of Patients with Relapsed or Refractory Acute Myeloid Leukemia (20180232) (Retrospective relapse/refractory AML outcomes)

**First published:** 13/11/2018

**Last updated:** 08/05/2024

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS26165

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### Study ID

49921

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### DARWIN EU® study

No

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### Study countries

Australia

Korea, Republic of

United States

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### Study description

Study activities on 20180232 were canceled December 31, 2023. As study activities were canceled during data analysis, no final study results are available and study report will not be authored.

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### Study status

Ongoing

## Research institutions and networks

### Institutions

Amgen

United States

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

**Last updated:** 27/03/2026

Institution

## Contact details

### Study institution contact

Global Development Leader Amgen Inc.

medinfo@amgen.com

Study contact

[medinfo@amgen.com](mailto:medinfo@amgen.com)

### **Primary lead investigator**

Global Development Leader Amgen Inc.

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Planned: 31/12/2018

Actual: 31/03/2019

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### **Study start date**

Planned: 30/04/2019

Actual: 04/04/2019

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### **Data analysis start date**

Planned: 01/07/2021

Actual: 14/11/2022

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### **Date of final study report**

Planned: 31/12/2022

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

## 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 type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

Other

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

Patient outcomes

**Main study objective:**

To estimate the proportion of patients achieving hematological complete remission (CR) following salvage treatment for relapsed or refractory (R/R) acute myeloid leukemia (AML).

## Study Design

## **Non-interventional study design**

Cohort

# Study drug and medical condition

## **Medical condition to be studied**

Acute myeloid leukaemia

# Population studied

## **Age groups**

- Adolescents (12 to < 18 years)
  - 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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## **Estimated number of subjects**

3000

# Study design details

## **Outcomes**

Complete remission after salvage therapy, Complete remission with incomplete hematologic recovery, best response, remission duration, stem cell transplant proportion, overall survival, event free survival

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## Data analysis plan

Descriptive analysis of complete remission proportions (N CR/N received therapy), duration of complete remission, event free survival, overall survival, stem cell transplant proportion.

## 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)

[Disease registry](#)

## 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**

No