

# Use of Erythropoiesis Stimulating Agents (ESA) in Patients With Non-myeloid Malignancies Receiving Myelosuppressive Chemotherapy 2014 – 2021 (20170210)

**First published:** 25/05/2018

**Last updated:** 22/01/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS24079

### Study ID

28521

### DARWIN EU® study

No

### Study countries

United States

### Study description

The study utilizes data from the Truven MarketScan claims database and the US-based Oncology Services Comprehensive Electronic Records (OSCER) database. Both databases were used to evaluate the use of ESAs after the initiation of myelosuppressive chemotherapy among patients diagnosed with non-myeloid malignancy. Patients were further categorized into the following specific tumor types: breast cancer, breast cancer receiving adjuvant therapy, metastatic breast cancer, CRC, lymphoma, lung cancer, and NSCLC. The study aims are: 1) To estimate the proportion of patients with non myeloid malignancies receiving an ESA over a 180-day follow-up period after initiation of myelosuppressive chemotherapy by calendar year, overall and stratified by specific tumor types (described above); and 2) To describe the hemoglobin (Hb) levels and estimate the proportion of patients with Hb values greater than 10 g/dL immediately preceding ESA treatment initiation in patients with non-myeloid malignancies after initiation of myelosuppressive chemotherapy by calendar year, overall and stratified by specific tumor types described above.

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## Study status

Finalised

## Research institutions and networks

### Institutions

[Amgen](#)

United States

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[Institution](#)

# Contact details

## **Study institution contact**

Global Development Leader Amgen Inc.

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[Study contact](#)

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## **Primary lead investigator**

Global Development Leader Amgen Inc.

[Primary lead investigator](#)

# Study timelines

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

Planned: 02/01/2017

Actual: 02/01/2017

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## **Study start date**

Planned: 19/05/2017

Actual: 19/05/2017

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## **Data analysis start date**

Planned: 01/09/2023

Actual: 22/09/2023

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## **Date of interim report, if expected**

Planned: 31/03/2018

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## **Date of final study report**

Planned: 31/01/2024

Actual: 31/01/2024

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

## Study protocol

[01.02.06 Public Redacted Protocol Ver 1.0 English.pdf \(854.75 KB\)](#)

## Regulatory

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

Yes

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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:**

Other

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

To assess the utilization of Aranesp or EpoGen/Procrit for the treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy

**Main study objective:**

To assess the utilization of Aranesp or EpoGen/Procrit for the treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy stratified by calendar year and selected tumor types

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

ARANESP

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**Medicinal product name, other**

EpoGen/Procrit

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

DARBEPoETIN ALFA

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**Anatomical Therapeutic Chemical (ATC) code**

(B03XA02) darbepoetin alfa

darbepoetin alfa

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**Medical condition to be studied**

Microcytic anaemia

## 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)

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**Estimated number of subjects**

1100000

## Study design details

**Outcomes**

Estimate the proportion of patients with non-myeloid malignancies receiving an ESA over a 180 day follow-up period after initiation of myelosuppressive chemotherapy by calendar year, overall and stratified by specific tumor types

including patients with breast cancer, adjuvant breast cancer, metastatic breast cancer, CRC, lung cancer, NSCLC, and lymphoma. Describe the demographic and clinical characteristics of patients with non-myeloid malignancies after initiation of myelosuppressive chemotherapy by calendar year, overall and stratified by specific tumor types including patients with breast cancer, adjuvant breast cancer, metastatic breast cancer, CRC, lung cancer, NSCLC, and lymphoma.

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### **Data analysis plan**

The incidence proportion (%) and 95% CIs for ESA use during the 180-day follow-up period and the proportion of patients with Hb values > 10 g/dL at the time of ESA initiation were estimated for the population overall and by specific tumor type. The 95% CI surrounding the incidence estimate was based on the binomial distribution. The incidence proportion for ESA use was defined as the number of patients who received at least 1 ESA administration during follow-up divided by the number of patients at risk in the cohort at the beginning of follow-up. The incidence proportion for patients with Hb values > 10 g/dL was defined as the number of patients with Hb values > 10 g/dL divided by the number of patients with observed Hb values at the time ESA initiation. All analyses were conducted by calendar year cohort.

## Documents

### **Study report**

[ORSR Abstract 20170210.pdf](#) (56.86 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 source(s), other**

- Truven MarketScan claims database
- OSCER database

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### **Data sources (types)**

- Administrative healthcare records (e.g., claims)
- Drug dispensing/prescription data
- Electronic healthcare records (EHR)

## 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