# Granulocyte Colony-Stimulating Factor ("G-CSF"): Patient profiles, Scheduling Patterns and Clinical Outcomes

First published: 20/01/2021

**Last updated:** 21/02/2025





# Administrative details

EU PAS number EUPAS38906	
EUFASS6900	
Study ID	
45192	
DARWIN EU® study	
No	
Study countries	
United States	

**Study description** 

This study is a retrospective cohort study assessing patient characteristics, scheduling patterns and clinical outcomes among patients with a diagnosis of breast cancer, colorectal cancer, non-Hodgkin's lymphoma (NHL), non-small cell lung cancer (NSCLC), or ovarian cancer, treated with pegfilgrastim in the US Oncology network (USON) between January 1, 2018 and October 31, 2019, with follow-up until December 31, 2019. This study proposes to describe real-world patient profiles, treatment patterns and clinical outcomes with use of the different G-CSF products in USON clinics. All study data will originate from the electronic healthcare record (EHR) of the USON. There are 2 phases in this study. The objective of the Phase 1 analysis will be to describe treatment scheduling patterns with pegfilgrastim among the study population. The objective of Phase 2 will be to describe clinical outcomes and resource utilization by conducting a chart review.

### **Study status**

Finalised

# Research institutions and networks

# Institutions

Amgen
United States
First published: 01/02/2024
Last updated: 21/02/2024
Institution

# Multiple centres: 400 centres are involved in the study

# Contact details

# **Study institution contact**

Global Development Leader Amgen Inc. medinfo@amgen.com

Study contact

medinfo@amgen.com

# **Primary lead investigator**

Global Development Leader Amgen Inc.

**Primary lead investigator** 

# Study timelines

# Date when funding contract was signed

Actual: 02/06/2020

# **Study start date**

Planned: 31/10/2020

Actual: 31/10/2020

Data analysis start date

Planned: 15/01/2021

Actual: 15/01/2021

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

Planned: 31/12/2021 Actual: 14/01/2022

# Sources of funding

• Pharmaceutical company and other private sector

# More details on funding

**Amgen** 

# Study protocol

Protocol-Published Original pegfilgrastim 20200230 .pdf (3.31 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 topic:**

Disease /health condition

Human medicinal product

## Study type:

Non-interventional study

### **Scope of the study:**

Drug utilisation

Effectiveness study (incl. comparative)

### **Data collection methods:**

Secondary use of data

# Main study objective:

The aim of this study is to understand the patient profiles, scheduling patterns and clinical outcomes among patients with breast cancer, colorectal cancer, ovarian cancer, NHL or NSCLC treated with pegfilgrastim in the US community setting.

# Study Design

# Non-interventional study design

Cohort

# Study drug and medical condition

Name of medicine, other

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

**PEGFILGRASTIM** 

### **Anatomical Therapeutic Chemical (ATC) code**

(L03AA13) pegfilgrastim pegfilgrastim

### Medical condition to be studied

Breast cancer

Colorectal cancer

Ovarian cancer

Non-Hodgkin's lymphoma

Non-small cell lung cancer

# Population studied

### Short description of the study population

Adult patients with a diagnosis of breast cancer, colorectal cancer, NHL, NSCLC, or ovarian cancer, treated with pegfilgrastim within US Oncology Network (USON) clinics during January 1, 2018 and October 31, 2019, with follow-up until December 31, 2019.

# **Age groups**

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

# **Special population of interest**

Other

### Special population of interest, other

Breast cancer, colorectal cancer, non-Hodgkin's lymphoma, non-small cell lung cancer, or ovarian cancer patients

### **Estimated number of subjects**

15443

# Study design details

### **Outcomes**

Phase 1: • Patient demographics and clinical disease characteristics • Scheduling patterns with pegfilgrastim Phase 2 • Scheduling patterns with pegfilgrastim • Clinical outcomes among patients initiating pegfilgrastim • Recourse utilization (hospitalization and ER visits) among patients initiating pegfilgrastim

### Data analysis plan

Descriptive analyses will be conducted to evaluate the demographic, clinical and treatment characteristics of the overall study population. Descriptive statistics will be used to summarize clinical outcomes and resource utilization among patients selected for chart review in Phase 2. No multivariable statistical analyses will be conducted (e.g. multivariable logistic regression). Results will be reported in aggregate using SAS® 9.4 (SAS Institute Inc. Cary, NC, US). All results will be reported at patient-level (stratified by optimal, sub-optimal or missed appointments for pegfilgrastim) and cycle-level (stratified by

chemotherapy cycle 1-6). Data from all sources and any derived variables will be merged into one master dataset for analysis. Data will be handled in compliance with the Health Insurance Portability and Accountability Act (HIPAA) and Health Information Technology for Economic and Clinical Health (HITECH).

# **Documents**

### **Study results**

20200230 - GCSF Scheduling Patterns - ORSR Abstract v011222 (003)\_Redacted.pdf (512.47 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

Electronic healthcare record (EHR) of the USON, iKM and Limited Access Death Master File (LADMF) and the Social Security Death Index

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

Electronic healthcare records (EHR)

# 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