# A Prospective Observational Study to Estimate the Incidence of Febrile Neutropenia (FN) among Subjects with Non-myeloid Malignancies at High Risk for FN and receiving Neulasta® (pegfilgrastim) Onpro® kit or Other Physician Choice Options for Prophylaxis of FN (20170758)

**First published:** 25/06/2018

**Last updated:** 29/11/2021

Study Finalised

## Administrative details

**EU PAS number**

EUPAS24626

**Study ID**

44447

**DARWIN EU® study**

No

**Study countries**

United States

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Amgen

United States

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

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

**Institution**

### Multiple centres: 150 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**

Planned: 03/01/2018

Actual: 03/01/2018

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**Study start date**

Planned: 14/11/2018

Actual: 07/11/2018

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**Data analysis start date**

Planned: 03/10/2020

Actual: 01/12/2020

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**Date of final study report**

Planned: 04/06/2021

Actual: 25/11/2021

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

## Study protocol

EUPAS24626-25197.pdf (1.64 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:**

Human medicinal product

Disease /health condition

**Study type:**

Non-interventional study

**Scope of the study:**

Disease epidemiology

**Data collection methods:**

Primary data collection

**Main study objective:**

To estimate the incidence of FN among subjects treated with myelosuppressive chemotherapy for the treatment of non myeloid malignancies and receiving Neulasta Onpro kit, Neulasta Onpro kit with every administered chemotherapy cycle, or other physician choice options for FN prophylaxis

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name, other**

Neulasta Onpro kit

**Medical condition to be studied**

Febrile neutropenia

## Population studied

**Short description of the study population**

The study population will consist of subjects diagnosed with biopsy-proven confirmed breast cancer, lung cancer, NHL, or prostate cancer, who are receiving myelosuppressive chemotherapy and are at “high risk” for FN. Subjects at “high risk” for FN will be defined as subjects receiving high risk chemotherapy regimens with FN risk > 20%, or intermediate risk chemotherapy regimen with FN risk between 10% to 20% and 1 additional risk factor for FN.

Inclusion Criteria

1. Subject ≥ 18 years of age at the time of signing the informed consent form.
2. Subject with biopsy-proven breast cancer, lung cancer, NHL or prostate cancer starting myelosuppressive chemotherapy in the neoadjuvant/adjuvant or first line advanced/metastatic setting with at least 4 anticipated chemotherapy cycles.
3. Life expectancy > 6 months
4. Subject is starting or has recently (within the past 7 days) started myelosuppressive chemotherapy regimen with every 3 or 4-week cycle with a high FN risk > 20%, OR intermediate FN risk 10% to 20% risk (refer to Appendix E [only regimens listed within this appendix are allowed for enrollment]) and at least 1 risk factor for FN per Appendix F. Addition of non-cytotoxic targeted agents (eg, monoclonal antibodies, anti-angiogenic agents, and kinase inhibitors) to the listed chemotherapy regimens is permitted.
5. Subject who is starting adjuvant chemotherapy, neoadjuvant chemotherapy or first line chemotherapy in the metastatic setting and will be receiving at least 4 cycles of planned chemotherapy

Exclusion Criteria

1. Subject initiating chemotherapy regimen with < 14 days between cytotoxic and G-CSF drug dosing.
2. Planned chemotherapy dose reduction for cycle 1.
3. Known history of serious allergic reactions to pegfilgrastim or filgrastim.

4. Contraindication to short acting G-CSFs, Neulasta PFS, pegfilgrastim biosimilar PFS, or Neulasta Onpro kit.
5. Currently receiving treatment in another investigational device or drug study, or ≤ 28 days before screening/enrollment since ending treatment on another investigational device or drug study(ies).
6. Subject who started first line chemotherapy for metastatic disease who completed adjuvant/neoadjuvant chemotherapy < 6 months prior to study enrollment.
7. Subject who has received radiation < 2 weeks prior to study enrollment.
8. Any co-morbidity (refer to Appendix H) in the opinion of investigator will prevent the subject from receiving chemotherapy.
9. Subject has significant abnormalities on the most recent laboratory test prior to screening/enrollment per the Investigator including but not limited to the following: • white blood cell (WBC) < 4, ANC < lower limit of normal (LLN), hemoglobin < 10 g/dL, hematocrit < 30%, platelet count < 100,000, creatinine ≥ 1.5 or glomerular filtration rate < 30 (as calculated by Cockcroft-Gault Equation), total Bilirubin ≥ 2.0, aspartate aminotransferase/alanine aminotransferase (AST/ALT) ≥ 3 x upper limit of normal (ULN), and a subject without liver metastasis or AST/ALT ≥ 5 ULN in a subject with liver metastasis
10. Known human immunodeficiency virus (HIV) infection by history.
11. History of solid organ or stem cell transplant.
12. Concurrent primary cancers except non-melanoma skin cancer, or adequately treated carcinoma in situ (CIS)

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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)

**Special population of interest**

Other

**Special population of interest, other**

Febrile neutropenia patients

**Estimated number of subjects**

5.440

## Study design details

**Data analysis plan**

Estimation Analysis, Confidence Intervals

## Documents

**Study results**

20170758_ORSR_Abstract.pdf (262.81 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 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