

# Impact of the Adherence to Antiemetic Guidelines in Cancer Patients Undergoing Repeated Cycles of Either MEC or HEC Regimens in Eastern Europe (NERO - NAUSEA/EMESIS REGISTRY IN ONCOLOGY)

**First published:** 18/09/2018

**Last updated:** 18/09/2018

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS25577

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### Study ID

25578

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### DARWIN EU® study

No

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### Study countries

 Austria

 Bulgaria

 Czechia

 Poland

 Romania

 Slovakia

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## Study description

Multicentric non-interventional prospective study assessing antiemetic guidelines consistency in CINV prophylaxis and the impact of CINV on the quality of life on cancer patients receiving MEC or HEC.

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## Study status

Ongoing

# Research institutions and networks

## Institutions

### Institute of Biostatistics and Analyses (IBA)

 Czechia

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

**Last updated:** 06/06/2024

**Institution**

Other

ENCePP partner

## Contact details

### Study institution contact

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Study contact

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**Primary lead investigator**

Matti Aapro

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 14/12/2015

Actual: 14/12/2015

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**Study start date**

Actual: 28/09/2016

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**Date of final study report**

Planned: 30/09/2019

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Angelini Pharma Oesterreich, GmbH

## 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:**

Disease epidemiology

**Main study objective:**

Guideline consistent and guideline inconsistent CINV prophylaxis measured by Complete Response (CR: no emesis and no use of rescue medication) during 120 h after chemotherapy

### Study Design

**Non-interventional study design**

Other

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## **Non-interventional study design, other**

Non-interventional observational study

# 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**

1150

# Study design details

### **Data analysis plan**

Given the nature of the project descriptive statistics methods commonly used in epidemiological studies will be used. Part of the final report will be descriptive statistical evaluation of primary and secondary endpoints of the study, and all the monitored parameters in individual patients. Statistical analysis will respect the data types (continuous, ordinal and binary) and the distribution of values (normal and log-normal and other). Basic statistical parameters (mean, median, relative share) and reliability estimation indicators of the parameters in groups of patients (standard deviation (SD), confidence interval, and percentiles) will be calculated.

## 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

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### 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

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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