

A non-interventional, multicentre, prospective study to estimate the incidence of invasive fungal infections and to monitor the diagnostic and therapeutic management of suspected fungal-related febrile episodes in patients affected with hematological neoplasm (Hema e-Chart II) (MK-0991-803) (Hema E-Chart II)

**First published:** 14/10/2014

**Last updated:** 27/02/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS7534

### Study ID

47228

### DARWIN EU® study

No

---

### **Study countries**

Italy

---

### **Study description**

This study will assess the incidence of invasive fungal diseases (IFDs) in patients with hematological malignancies (HMs, acute myeloid leukemia or acute lymphoid leukemia) admitted to Italian hematology wards. This study will also monitor the diagnostic and therapeutic management of suspected fungal-related febrile episodes in patients affected with HMs. Drug use in this study will be based on the investigators' daily clinical practice and data reported on the Summary of Product Characteristics.

---

### **Study status**

Finalised

## Research institutions and networks

### Institutions

#### [Merck Sharp & Dohme LLC](#)

United States

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

**Last updated:** 08/07/2025

**Institution**

**Pharmaceutical company**

# Azienda Ospedaliero-Universitaria Di Parma Parma, Italy

## Contact details

### **Study institution contact**

Clinical Trials Disclosure Merck Sharp & Dohme LLC  
ClinicalTrialsDisclosure@merck.com

**Study contact**

[ClinicalTrialsDisclosure@merck.com](mailto:ClinicalTrialsDisclosure@merck.com)

### **Primary lead investigator**

Clinical Trials Disclosure Merck Sharp & Dohme LLC

**Primary lead investigator**

## Study timelines

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

Actual: 05/07/2013

---

### **Study start date**

Planned: 02/03/2015

Actual: 17/02/2015

---

### **Data analysis start date**

Planned: 11/08/2016

Actual: 21/06/2016

---

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

Planned: 16/06/2017

Actual: 08/06/2017

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Merck Sharpe & Dohme LLC

## 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

---

**Study type:**

Non-interventional study

---

**Scope of the study:**

Disease epidemiology

Effectiveness study (incl. comparative)

**Data collection methods:**

Primary data collection

---

**Main study objective:**

To estimate the rate of occurrence of possible, probable, and proven IFDs in patients affected by newly diagnosed HMs (acute myeloid leukemia or acute lymphoid leukemia) admitted to hematology wards in Italy.

## Study Design

**Non-interventional study design**

Other

---

**Non-interventional study design, other**

Observational study, Review of electronic case report forms

## Study drug and medical condition

**Medical condition to be studied**

Fungal infection  
Acute myeloid leukaemia  
Acute lymphocytic leukaemia

## Population studied

### **Short description of the study population**

Patients with hematological malignancies (HMs, acute myeloid leukemia or acute lymphoid leukemia) admitted to Italian hematology wards.

---

### **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**

Hematological malignancies patients

---

### **Estimated number of subjects**

1000

## Study design details

## Outcomes

Rate of occurrence of possible, probable, and proved IFDs.

---

## Data analysis plan

No formal statistical hypotheses will be tested, only descriptive statistics will be calculated. The analysis to assess the outcomes of patients with suspected fungal-related febrile events will be performed using standard survival analysis methods, including Kaplan-Meier product-limit survival curve estimates and log-rank tests for comparison between groups.

## Documents

### Study results

[0991-803 ENCePP.pdf](#) (2.18 MB)

---

## 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