# A Multi-country, Non-interventional, Retrospective Drug Utilization Study in Haematological Malignancy Patients Treated for Probable or Proven Invasive Aspergillosis (AmBiVor)

**First published:** 17/05/2023

**Last updated:** 22/04/2025

Study | Finalised

## Administrative details

**EU PAS number**

EUPAS104818

**Study ID**

105892

**DARWIN EU® study**

No

**Study countries**

Belgium

France

Germany

Spain

United Kingdom

**Study description**

GS-EU-131-6385: This was a real-world, non-interventional, multi-country, retrospective chart review study using patient medical record data collected from 15 hospitals in 5 European countries (Belgium, France, Germany, Spain, and the United Kingdom (UK)). This was a study of Haematological malignancy patients (patients who have undergone Haematopoietic stem-cell transplantation HSCT, acute myeloid leukemia AML, myelodysplastic syndromes MDS and acute lymphoblastic leukaemia ALL) with a diagnosis of documented probable or proven IA (Invasive Aspergillosis) and who received at least 1 dose of AmBisome or voriconazole as primary treatment from 01 January 2014 to 31 December 2019. The primary objective of this study was to describe demographic, clinical and treatment patterns/sequences in haematologic malignancy patients treated either with AmBisome or voriconazole as primary treatment for the index proven or probable IA.

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Gilead Sciences

**First published:** 12/02/2024

**Last updated:** 12/02/2024

Institution | Pharmaceutical company

## Contact details

**Study institution contact**

Gilead Study Director ClinicalTrialDisclosure@gilead.com

Study contact

ClinicalTrialDisclosure@gilead.com

**Primary lead investigator**

Gilead Study Director

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Actual: 22/12/2022

**Study start date**

Planned: 22/05/2023

Actual: 27/06/2023

**Date of final study report**

Planned: 28/02/2025

Actual: 11/02/2025

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Gilead Sciences

## Study protocol

GS-EU-131-6385 - appendix-16.1.-protocol_f-redact_reduced.pdf (5.25 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

**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

**Main study objective:**

The primary objective of the study was to describe demographic, clinical, and treatment patterns/sequences in haematologic malignancy patients treated either with AmBisome or voriconazole as primary treatment for the index proven or probable IA.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

VORICONAZOLE

AMBISOME

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**Medical condition to be studied**

Aspergillus infection

## Population studied

**Age groups**

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Elderly (≥ 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**

400

## Study design details

**Outcomes**

Demographic, clinical, and treatment patterns, 42-day overall survival (OS) in haematological malignancy patients with IA treated with either AmBisome or voriconazole as primary treatment, percentage AmBisome- and voriconazole-treated patients that experience adverse events of special interests and any AEs leading to treatment discontinuation or modification, and time to first nephrotoxicy and/or hepatotoxicity during the follow-up period.

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**Data analysis plan**

Descriptive statistics were tabulated for the demographic and clinical characteristics and outcome variables. In all cases, point estimates as well as the corresponding two-sided 95% confidence intervals (CIs) were presented.
No missing value imputation was performed.
Treatment sequence was visualized through Sankey diagrams.
The secondary objective was to estimate the 42-day OS of patients treated with AmBisome and of patients treated with voriconazole. OS and time to first

nephrotoxicity and hepatotoxicity were described using Kaplan-Meier methods and reported using descriptive statistics with 95% CIs and survival curves.

## Documents

**Study report**

GS-EU-131-6385-CSR abstract_f-redact.pdf (577.61 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)**

Electronic healthcare records (EHR)

## Use of a Common Data Model (CDM)

**CDM mapping**

No

## Data quality specifications

**Check conformance**

Yes

**Check completeness**

Yes

**Check stability**

Yes

**Check logical consistency**

Yes

## Data characterisation

**Data characterisation conducted**

No