

# A Retrospective Cohort Study of the Risk of Severe Hepatotoxicity in Hospitalized patients Treated with Echinocandins

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Study

Finalised

## Administrative details

### EU PAS number

EUPAS14665

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### Study ID

14666

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### DARWIN EU® study

No

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### Study countries

 United States

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### Study status

Finalised

## Contact details

### Study institution contact

Weiss Lisa [lisa.weiss@pfizer.com](mailto:lisa.weiss@pfizer.com)

Study contact

[lisa.weiss@pfizer.com](mailto:lisa.weiss@pfizer.com)

### Primary lead investigator

Weiss Lisa

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 11/12/2013

Actual: 12/03/2014

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### Study start date

Planned: 15/12/2013

Actual: 24/04/2014

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### Date of final study report

Planned: 06/04/2015

Actual: 20/04/2015

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer

## Study protocol

[Pfizer\\_Antifungal\\_Protocol\\_Oct\\_09\\_2013\\_final.pdf](#) (461.53 KB)

## Regulatory

### **Was the study required by a regulatory body?**

Yes

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### **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

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#### **Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Secondary use of data

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**Main study objective:**

The primary objective of the study was to estimate the risk of severe hepatotoxicity associated with exposure to echinocandins, and to compare the risk of severe hepatotoxicity in hospitalized patients treated with anidulafungin to that of hospitalized patients treated with other echinocandins (caspofungin and micafungin) in a real-world setting.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

[ECALTA](#)

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**Medical condition to be studied**

Hepatotoxicity

## Population studied

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

Patients admitted to a hospital, with  $\geq$  1 dose of echinocandin antifungal medicines, and aged 18 and above at hospitalization admission.

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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)
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## **Special population of interest**

Hepatic impaired

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## **Estimated number of subjects**

12678

# Study design details

## **Outcomes**

First severe hepatotoxicity event in the observation period. Severe hepatotoxicity was ascertained based on the first LFT of Grades 3, 4, or 5 in the observation period. For this study, the definition of the LFT grades was adapted from the CIT-TCAE, Version 5.0, modified standards from National Cancer Institute, Common Terminology Criteria for Adverse Events.

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## **Data analysis plan**

The risks were evaluated in the forms of absolute risk (i.e. cumulative incidence) and incidence rate. The risk ratios were evaluated in the forms of

relative risk and incidence rate ratio. The null hypotheses tested were that the risk of severe hepatotoxicity in hospitalized patients treated with anidulafungin was not statistically different from that in hospitalized patients treated with caspofungin or micafungin.

## Documents

### Study results

[Pfizer Antifungal Safety Study Abstract- April 20, 2016\\_FINAL.pdf](#) (122.62 KB)

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### Study report

[Pfizer Antifungal Safety Study Report - April 20, 2016\\_FINAL.pdf](#) (581.09 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)

[Administrative healthcare records \(e.g., claims\)](#)

[Drug dispensing/prescription data](#)

## 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