

# Evaluation of the effectiveness of additional risk minimisation measures (aRMMs) that aim to reduce the risks of phototoxicity, squamous cell carcinoma (SCC) of the skin and hepatic toxicity in patients receiving voriconazole in the European Union (EU)

**First published:** 29/07/2015

**Last updated:** 22/02/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS10428

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### Study ID

14677

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### DARWIN EU® study

No

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### Study countries

-  Austria
  -  Denmark
  -  France
  -  Germany
  -  Hungary
  -  Ireland
  -  Italy
  -  Netherlands
  -  Spain
  -  United Kingdom
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## **Study description**

The study is a survey of healthcare professionals (HCPs) to evaluate the effectiveness of the additional risk minimisation measures (aRMMs) being implemented across Europe to mitigate the risks associated with voriconazole (Vfend®) (i.e. phototoxicity, SCC of the skin and hepatic toxicity in patients using voriconazole). The evaluation is being conducted in 10 of the 33 countries in the EU where RM tools are being implemented. Specifically, the goals of the study are to: 1) Assess HCPs' awareness of the RM tools, 2) Assess HCPs' utilization of the RM tools, 3) Assess HCPs' knowledge of the risks, 4) Assess whether HCPs' self reported behaviour/practices with respect to minimizing the risks of phototoxicity, SCC of the skin and hepatic toxicity are in accordance with the voriconazole SmPC. The study objectives will be accomplished by means of a cross-sectional survey of all targeted HCPs who received the aRMMs and self-report as prescribers of voriconazole in 10 EU countries. Voriconazole is mainly prescribed by select specialty care physicians (i.e., infectious disease physicians, oncologists, haematologists, solid organ transplant physicians--- however the speciality that actually prescribes voriconazole can vary by country). These speciality care physicians in the 10 EU countries will constitute the study population for the survey. A structured self-administered

questionnaire comprised of closed-ended questions or statements with multiple response choices will be used to collect the survey data. The questionnaire will collect data on HCP characteristics in addition to their responses pertaining to the effectiveness of the aRMMs. A sample size of 750 completed surveys is being targeted across 10 countries.

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## Study status

Finalised

## Research institutions and networks

### Institutions

#### United BioSource Corporation (UBC)

 Switzerland

**First published:** 25/04/2013

**Last updated:** 06/03/2024

**Institution**

**Non-Pharmaceutical company**

**ENCePP partner**

## Contact details

### Study institution contact

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**Study contact**

[joannaasia.lem@pfizer.com](mailto:joannaasia.lem@pfizer.com)

### Primary lead investigator

Joanna Lem

Primary lead investigator

## Study timelines

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

Planned: 05/08/2013

Actual: 05/08/2013

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### **Study start date**

Planned: 01/09/2015

Actual: 02/09/2015

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### **Data analysis start date**

Planned: 02/03/2016

Actual: 02/03/2016

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

Planned: 31/05/2016

Actual: 17/05/2016

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer

# Study protocol

[A1501102\\_VFEND aRMM evaluation survey PROTOCOL\\_FINAL REDACTED\\_7\\_28\\_2015\\_B.pdf](#) (341.59 KB)

[A1501102\\_PROTOCOL AND APPROVAL\\_NIS\\_08JULY2015\\_FINAL\\_part1.pdf](#) (637.76 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)?**

EU RMP category 3 (required)

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Main study objective:**

The overall objective is to evaluate the effectiveness of the additional RMMs being implemented across Europe to mitigate the risks of phototoxicity, SCC of the skin and hepatic toxicity with the use of voriconazole.

## Study Design

**Non-interventional study design**

Cross-sectional

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(J02AC03) voriconazole

voriconazole

## Population studied

**Short description of the study population**

Healthcare professionals that prescribe voriconazole and received the RM tools in the following countries: UK, France, Austria, Ireland, Denmark, Germany, Spain, Italy, Netherlands, and Hungary.

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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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## Estimated number of subjects

332

# Study design details

## Data analysis plan

Data collected from the survey will be reported as descriptive statistics. Frequency distributions with 95% CIs will be calculated for HCPs' responses to all questions that address the survey objectives. Depending on the sample size, survey data will be stratified by country and medical specialty. In the final analysis of all specialists there will be weighted analysis completed based on HCP speciality.

# Documents

## Study results

[a1501102-report-body\\_1.pdf](#) (1.41 MB)

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## Study report

[a1501102-abstract.pdf](#) (1.9 MB)

## Study, other information

[A1501102\\_PROTOCOL AND APPROVAL\\_NIS\\_08JULY2015\\_FINAL\\_part2.pdf](#) (1.68 MB)

[A1501102\\_PROTOCOL AND APPROVAL\\_NIS\\_08JULY2015\\_FINAL\\_part3.pdf](#) (1.16 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](#)

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### Data sources (types), other

Cross-sectional survey

## 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