

# 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 Saudi Arabia

**First published:** 30/10/2024

**Last updated:** 30/10/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS1000000266

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### Study ID

1000000266

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### DARWIN EU® study

No

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### Study countries

## Study description

Pfizer Saudi Limited will conduct a non-interventional, cross-sectional survey of healthcare professionals (HCPs) to evaluate the effectiveness of the aRMMs being implemented across Saudi Arabia to mitigate the risks of phototoxicity, SCC of the skin and hepatic toxicity in patients prescribed voriconazole (Vfend®).

To ensure that the risks are adequately managed, aRMMs in Saudi Arabia have been implemented since Feb 2023. The aRMM material distribution has been started on 05-Feb-2023 and continued until 05-Feb-2024 to the relevant HCPs who may initiate or manage patients on Vfend®.

The RM tools are the HCP Checklist, HCP Question & Answer (Q&A) Brochure and Patient Alert Card. HCPs who the materials are targeting will be invited to participate in the survey.

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## Study status

Finalised

# Research institutions and networks

## Institutions

**Pfizer**

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

**Last updated:** 01/02/2024

**Institution**

**IQVIA**

 United Kingdom

**First published:** 12/11/2021

**Last updated:** 22/04/2024

**Institution**

**Non-Pharmaceutical company**

**ENCePP partner**

## Contact details

### Study institution contact

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**Study contact**

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### Primary lead investigator

Hala Sayed

**Primary lead investigator**

## Study timelines

### Date when funding contract was signed

Actual: 29/04/2024

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### Study start date

Planned: 15/11/2024

Actual: 11/11/2024

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## Date of final study report

Planned: 30/06/2025

Actual: 26/06/2025

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer Saudi Limited 100% Funding

## Study protocol

[A1501110\\_Non Interventional Study Protocol](#)

[\(Combined\)\\_V1\\_16AUG2024\\_Redacted.pdf](#) (558.23 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)?

Non-EU RMP only

## 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:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Primary data collection

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**Study design:**

The data from the HCPs will be collected using a structured self-administered questionnaire to gather evaluation metrics related to the utilization and understanding of RM tool content and messages. In addition, the survey will assess behaviors, including a set of hypothetical scenarios for HCPs.

**Main study objective:**

The overall objective of the study is to evaluate the effectiveness of the aRMMs being implemented across Saudi Arabia 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

**Medicinal product name**

VFEND

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**Study drug International non-proprietary name (INN) or common name**

VORICONAZOLE

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**Anatomical Therapeutic Chemical (ATC) code**

(J02AC03) voriconazole

voriconazole

## Population studied

**Short description of the study population**

The target population will include all HCPs who were targeted to receive Vfend® aRMM materials within 12 months preceding the survey in Saudi Arabia (Central, East and North regions). It is important to note that the final survey sample size will depend on HCPs' willingness to participate in the survey.

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**Estimated number of subjects**

10

## Study design details

**Setting**

Given this relatively small pool of HCPs, an empirical sample size of 10 HCPs is proposed.

Participants/ HCPs must meet all of the following criteria to be eligible for inclusion in the survey:

1. Willing/consent to participate in this self-administered survey.
2. Involved in the treatment of at least one patient with voriconazole within the last 12 months.

Participants/ HCPs meeting any of the following criteria will not be included in the survey:

1. Employed in full-time research or hospital administration (i.e., non practicing physicians).
  2. Employment by Pfizer Inc or any research organization/vendor contracted by Pfizer to administer the survey.
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### **Outcomes**

1. Estimate the proportion of targeted HCPs who acknowledge receiving the tools.
  2. Estimate the proportion of targeted HCPs who acknowledge reading and utilizing the tools.
  3. Estimate the proportion of targeted HCPs who responds correctly to questions about the risks of phototoxicity, SCC of the skin, and hepatic toxicity.
  4. Estimate the proportion of targeted HCPs who provided desirable responses to the practice-related questions and self-declared behavior with regard to strategies to mitigate the risks.
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### **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.

## **Documents**

## Study report

[A1501110\\_Non-Interventional Study Report\\_V1\\_20JUN2025\\_Redacted.pdf](#)

(627.65 KB)

## Study, other information

[A1501110\\_Non-Interventional Study Report\\_V2\\_03OCT2025\\_Redacted.pdf](#)

(376.25 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 source(s), other

A structured self-administered questionnaire comprised of closed-ended questions or statements with multiple response choices (ie, questions or statements asking the HCPs to choose from a defined list of responses) will be used to collect the survey data.

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### Data sources (types)

[Non-interventional study](#)

## 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**

Not applicable