

# Retrospective chart review study of cefiderocol real world outcomes and safety in the treatment of patients with Gram-negative bacterial infections (GNBI) in the US and Europe (PROVE)

**First published:** 12/04/2021

**Last updated:** 23/04/2024

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS40551

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### Study ID

41381

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### DARWIN EU® study

No

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### Study countries

 France

 Germany

 Italy

 Spain

 United Kingdom

 United States

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## Study description

Characterize the use of cefiderocol in the treatment of Gram-negative bacterial infections (GNBI) by describing the patients that have been prescribed this antibiotic as well as the hospital course of such patients. This will include risk factors for carbapenem resistant disease, baseline comorbidities, and the pattern of other antibiotics used for the same infection. Outcomes such as inpatient mortality, safety events, and length of stay will be assessed.

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## Study status

Ongoing

## Research institutions and networks

### Institutions

**Shionogi**

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

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

**Institution**

Shionogi BV (SBV), Hoburn, UK Shionogi, Inc.  
Florham Park, NJ, USA

## Contact details

### Study institution contact

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Study contact

[stephen.marcella@shionogi.com](mailto:stephen.marcella@shionogi.com)

### Primary lead investigator

Bin Cai

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 01/04/2020

Actual: 16/10/2020

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### Study start date

Planned: 01/05/2021

Actual: 29/04/2021

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### Data analysis start date

Planned: 01/03/2023

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**Date of interim report, if expected**

Planned: 01/06/2021

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**Date of final study report**

Planned: 01/06/2023

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Shionogi, Inc

## Regulatory

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

No

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Other study registration identification numbers and links

Non-interventional study protocol 2020-266-1

## Methodological aspects

### Study type

### Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

**Main study objective:**

Describe how cefiderocol is used in patients with documented gram-negative bacterial infections

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name, other**

Fetroja

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**Medical condition to be studied**

Bacterial infection

## Population studied

## **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**

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

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## **Estimated number of subjects**

1000

# Study design details

## **Outcomes**

Characteristics of patients placed on cefiderocol, description of types of infections: sites, severity, pathogen, and resistance patterns, how cefiderocol is used (dose, frequency, and how used with other antibiotics. Clinical resolution including all-cause mortality, length of stay. Adverse events associated with cefiderocol use. Above primary outcomes stratified by carbapenem resistance status, specific pathogens, and infection sites, potential risk factors for carbapenem resistance, time to clinical cure, pattern of overall antibiotic treatments before, after, during the use of cefiderocol, hospital resource use after infection onset.

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## Data analysis plan

This is a descriptive study and most measurements will be summary measures of central tendency with confidence intervals and/or quartile measurement where appropriate. Where trends are seen among ordered categories, tests of trends will be used. For predictors of carbapenem resistance, logistic regression will be used with the odds ratio as the primary measure of association. For linear predictors, linear regression may be employed.

## 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

Retrospective hospital chart review

## 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