

Cefiderocol RWE library

Guidance document

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SHIONOGI

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Purpose and function of the library



Purpose and function of the library

- This cefiderocol RWE library includes publications reporting real-world use of cefiderocol for the treatment of patients with Gram-negative infection
- The purpose of the library is to enable MSLs to identify publications of interest to aid HCP conversations or for personal use
- Specific publications can be identified using study or patient characteristics, allowing publications to be filtered down to those reporting RWE of interest. Key study information and data are displayed in the search results

Disclaimers

- The data shown in the library should not be relied upon for HCP discussions, as the nuance of data cannot always be fully captured in this format

For example:

A case series might show '*Acinetobacter* spp.', '*P. aeruginosa*' and 'COVID-19', but this does not indicate that all patients had all these characteristics (e.g., only one patient with *P. aeruginosa* infection had COVID-19, and no patients with *Acinetobacter* spp. infection had COVID-19)

- Supplementary data have not been included
- Data from the same patients may be reported across several studies, so data are not necessarily mutually exclusive

Searching for publications



Searching for publications

- All available publications appear in the library by default
- Filter categories include specific characteristics of the study or patient(s) that can be used to find relevant data and narrow down the results
- The numbers to the right of each filter indicate how many publications include patients with those characteristics – these numbers change depending on the characteristics selected

List of filters to find specific publications

Filter by:	
Countries	^
☐ France	10
☐ UK	9
☐ Germany	4
☐ Italy	43
☐ Spain	10
☐ US	36
☐ Other (EU)	4
☐ Other (GL)	4

Numbers of publications matching each filter

Filter by:

Countries

Pathogens

Infections

Characteristics

Resistance & safety

Use the filter to start your search

Order by:

Please select

Download Excel

Case Report: Successful Rescue Therapy of Extensively Drug Resistant *Acinetobacter baumannii* Osteomyelitis with Cefiderocol

First author
Dagher

Country	Date	Patients	AST method
US	2020	1	DD

Over 18

Off label

View publication

BJI

Acinetobacter spp.

Other comorbidities

Diabetes

Long Term Compassionate Use of Cefiderocol to Treat Chronic Osteomyelitis Caused by XDR-*Pseudomonas aeruginosa* and ESBL-producing *Klebsiella pneumoniae* in a Pediatric Patient

First author
Alamarat

Country	Date	Patients	AST method
US	2019	1	DD

Over 18

Off label

View publication

BJI

P. aeruginosa

Klebsiella spp.

Other comorbidities

MBL-producing pathogen



Searching for publications

For example:

A shows the numbers of overall publications, before characteristics are selected, e.g.:

- 10 publications include patients from France
- 53 publications that include patients with *Acinetobacter* spp.

B shows the selection of 'France' and '*Acinetobacter* spp.', and the publications matching the selected and unselected characteristics (to guide your additional searches), e.g.:

- 7 publications include patients from France **and** with *Acinetobacter* spp. infection (these publications are shown)
- 5 publications include patients from France **and** with *Acinetobacter* spp. **and** *P. aeruginosa* infection (only if '*P. aeruginosa*' were to be selected would the 7 publications from the above filter decrease to these 5 publications of interest)
- No publications include patients from France **and** with *Acinetobacter* spp. infection **and** from the UK

A

Filter by:

- Countries**
 - France 10
 - UK 9
 - Germany 4
 - Italy 43
 - Spain 10
 - US 36
 - Other (EU) 4
 - Other (GL) 4
- Pathogens**
 - Acinetobacter spp. 53
 - P. aeruginosa 63
 - Klebsiella spp. 38
 - E. coli 12
 - Enterobacter spp. 13
 - Other Enterobacterales 10
 - S. maltophilia 26
 - B. cepacia (complex) 5

Use the filter to start your search

Order by: Please select

Download Excel

Case Report: Successful Rescue Therapy of Extensively Drug Resistant Acinetobacter baumannii Osteomyelitis with Cefiderocol

First author: Dagher

Country: US, Date: 2020, Patients: 1, AST method: DD, Over 18: ✓, Off label: -

Long Term Compassionate Use of Cefiderocol to Treat Chronic Osteomyelitis Caused by XDR-Pseudomonas aeruginosa and ESBL-producing Klebsiella pneumoniae in a Pediatric Patient

First author: Alamarat

Country: US, Date: 2019, Patients: 1, AST method: DD, Over 18: X, Off label: ✓

B

Filter by: **Reset**

- Countries**
 - France 7
 - UK -
 - Germany 1
 - Italy 1
 - Spain 1
 - US -
 - Other (EU) -
 - Other (GL) -
- Pathogens**
 - Acinetobacter spp. 7
 - P. aeruginosa 5
 - Klebsiella spp. 2
 - E. coli -
 - Enterobacter spp. 3
 - Other Enterobacterales 1
 - S. maltophilia 3

7 publications found match your search

Order by: Please select

Download Excel

Susceptibility Testing is Key for the Success of Cefiderocol Treatment: A Retrospective Cohort Study

First author: Bleibtreu

Country: France, Date: 2021, Patients: 12, AST method: Multiple, Over 18: ✓, Off label: ✓



Searching for publications

Data and characteristics of each study are shown in this format in the results

Filter results can be reset here

The number of publications matching the filters are shown here

Results can be ordered by total number of patients or publication year

The screenshot shows a search results page. On the left, there is a 'Filter by:' section with two categories: 'Countries' and 'Pathogens'. Under 'Countries', 'France' is selected with a red checkmark, and the count is 7. Other countries listed are UK, Germany, Italy, Spain, US, Other (EU), and Other (GL). Under 'Pathogens', 'Acinetobacter spp.' is selected with a red checkmark, and the count is 7. Other pathogens listed are P. aeruginosa, Klebsiella spp., E. coli, Enterobacter spp., Other Enterobacterales, and S. maltophilia. At the top right of the filter section is a 'Reset' button. Below the filter section, it says '7 publications found match your search'. There is an 'Order by:' dropdown menu with 'Please select' as the current selection. To the right of the dropdown is a 'Download Excel' link. The main content area shows a publication titled 'Susceptibility Testing Is Key for the Success of Cefiderocol Treatment: A Retrospective Cohort Study'. Below the title, there is a list of characteristics: RTI, BSI, BJI, SSTI, IAI, UTI, Acinetobacter spp. (circled in red), P. aeruginosa, Klebsiella spp., Enterobacter spp., Severity of illness data reported, Renal impairment or renal disease, Immunosuppressed, Other comorbidities, MBL-producing pathogen, and MIC shift or treatment-emergent resistance. At the bottom, there is a table with columns: Country, Date, Patients, AST method, Over 18, and Off label. The first row shows France, 2021, 12, Multiple, Over 18, and Off label. To the right of the table is a 'View publication' link.

Click to download an Excel spreadsheet of the studies and key data or characteristics matching your filters

Characteristics and data relevant to patients who received cefiderocol are shown here. Terms that were selected when filtering papers are circled in red

The full publication pdf (in Box) can be accessed here. **N.B.** these pdfs are for internal use only. Online links or citations for external use can be found in the downloadable Excel spreadsheet

General information and data from the publication are shown here, most of which are not included in the filter criteria

Guidance on the data format



Guidance on the data format

- With the exception of the number of patients (the total patient population from the study), all data in the library are specific to patients treated with cefiderocol, and not any comparator(s)
- Data apply to all patients treated with cefiderocol, no matter how many patients have a characteristic or outcome. So, individual patients cannot be identified from the library (with the exception of a case report), but may be derived from the publication if individual patient data are reported

For example:

If a study reported 50 patients treated with cefiderocol (including COVID-19: n=1; diabetes: n=10; and cancer: n=0) and 50 with non-cefiderocol therapy (including COVID-19: n=0; diabetes: n=4; and cancer: n=5), the number of patients would be listed as '100' and the comorbidities appearing in the filters would be 'COVID-19' and 'diabetes', but not 'cancer'

- Supplementary data have not been included, nor have any data assumptions been made. If specific data in patients treated with cefiderocol cannot be differentiated from patients treated with a comparator, no data are included for that characteristic

Please see the following slides for more guidance on the data in specific categories and filters



Guidance on the data format

General data or terms not included in the filter criteria

Data or term	Additional guidance
Title	-
Author	Last name of the first author
Country	See next slide
Date	Publication year on PubMed (or on the journal website if unavailable) or the congress year, if relevant
Patients	Total number of patients (includes those treated with cefiderocol and comparator[s])
AST method	Describes the testing method used for cefiderocol, not comparator(s) • BMD: includes the reference method and commercially available kits • DD: includes disk diffusion and zone of inhibition data reported • E test: includes MTS Strip • Other: e.g. automated AST • Multiple: reports ≥ 1 method of cefiderocol AST • Unknown: AST was performed and susceptibility/resistance results or MIC data are reported, but the method is unknown • Not reported: AST was not mentioned in the methodology and/or no results were reported
Over 18	-
Off label (EU)	• Y: a study that reports ≥ 1 patients treated with off-label cefiderocol (at least one of the following criteria: <18 years of age; received a dosing regimen not stated in the EMA SmPC; or received CRRT or CVVH/CVVHDF), even if the study includes other patients who received on-label cefiderocol. Patients treated in the US who still received cefiderocol treatment in line with the EU label were not indicated as having received off label (EU) treatment • Blank (-): all patients in the study definitely received on-label cefiderocol (≥ 18 years of age; received a dosing regimen in line with the EMA SmPC; no mention of receiving CRRT or CVVH/CVVHDF) • Unknown: there is insufficient data to determine on- or off-label use



Guidance on the data format

Countries

- Each country or region from which there is ≥ 1 patient reported in a study will be indicated for that publication
- If no country is specified, but the authors are from the same institution/country and/or refer to 'our' patient/institution/hospital/centre etc. or mention their institution's review board for ethics approval, the relevant country has been included

Data or term	Additional guidance
France	-
Germany	-
Italy	-
Spain	-
UK	-
US	-
Other (EU)	Includes any country in Europe other than Italy, France, Spain, Germany and the UK
Other (GL)	Includes any country outside of Europe other than the US



Guidance on the data format

Pathogens

Includes the causative pathogen(s) of the primary infection for which cefiderocol treatment was used

Data or term or example	Additional guidance
<i>Achromobacter</i> spp.	-
<i>Acinetobacter</i> spp.	-
<i>B. cepacia</i> (complex)	-
<i>E. coli</i>	-
<i>Enterobacter</i> spp.	-
<i>Klebsiella</i> spp.	-
<i>P. aeruginosa</i>	-
<i>S. maltophilia</i>	-
Other Enterobacterales	Includes any Enterobacterales other than <i>Klebsiella</i> spp., <i>E. coli</i> and <i>Enterobacter</i> spp.
Other GNB	Includes any GNB other than those listed here, e.g. <i>P. putida</i>
Gram-positive pathogens	No data included



Guidance on the data format

Infections

Data or term or example	Additional guidance
BJI	-
BSI	-
CNS infection or meningitis	-
IAI	-
RTI	Includes patients in whom RTI is specified, and any with VAP, HAP and V-HAP (even if RTI is not mentioned in the publication[s])
Sepsis due to X (e.g. due to IAI)	Indicated as only 'sepsis' and not the cause (e.g. 'IAI'), unless the publication refers to treatment of the causative infection
SSTI	Includes SSTI, and acute bacterial skin and skin structure infections
UTI	-
VAP, HAP, V-HAP	Includes VAP, HAP and V-HAP (as relevant), only if these are specified in the publication(s) • HAP: includes nosocomial pneumonia
Other	Includes wound infection, prosthetic joint infection, and any other specified infections not listed in the filter criteria (if no infection site is specified, then no data are included [see guidance below])
Unknown infection type (e.g. 'patients with Gram-negative infection' or 'nosocomial infection')	No data included



Guidance on the data format

Characteristics

Data or term or example	Additional guidance
Cancer	Includes any specific cancer, tumour(s) or malignancies (e.g. malignant neoplasms or haematological malignancy)
COVID-19	Includes COVID-19 and SARS-CoV-2
CVD	-
Cystic fibrosis	-
Diabetes	-
ECMO	-
Immunosuppressed	Includes patients with immunosuppression (e.g. autoimmune disease or specific immunosuppressive illness) or who have had transplants (solid organ or cell), but does not include cancer patients unless immunosuppression is specified
Mechanical ventilation	-
Organ support	Includes patients with any form of organ support (e.g. mechanical ventilation, ECMO, CRRT and CVVH/CVVHDF)
Renal impairment or renal disease	Includes specified renal impairment, renal disease or CKD
Severity of illness data reported	Includes studies that report SOFA, APACHE or CCI scores
TDM	-
Other comorbidities	Includes unspecified comorbidities, hypertension, hepatic impairment, COPD, CLD, CRD, haemodialysis, septic shock, burns, vascular disease, IBD, hypotonia, dementia, encephalopathy, HIV, obesity, polytrauma, prematurity, pancreatitis, etc.



Guidance on the data format

Resistance & safety results

Data or term or example	Additional guidance
MBL-producing pathogen	-
MIC shift or treatment-emergent resistance	Includes publications reporting the development of resistance to cefiderocol in patients treated with cefiderocol during the study period. This does not include cases where AST was performed on an initial sample after cefiderocol treatment was initiated and resistance was then identified
Special or drug-related adverse events	-



Guidance on the data format

Publication links or references

Link or reference	Additional guidance
Shionogi Box link	Internal use only – links to the full pdf of the publication on Box
External link or citation	Internal or external use – links to the online version of the publication (or provides a reference for the publication if no online link is available)

Abbreviations

Abbreviations

APACHE, Acute Physiology and Chronic Health Evaluation

AST, antimicrobial susceptibility testing

BJI, bone and joint infection

BMD, broth microdilution

BSI, bloodstream infection

CCI, Charlson Comorbidity Index

CKD, chronic kidney disease

CLD, chronic liver disease

CNS, central nervous system

COPD, chronic obstructive pulmonary disease

CRD, chronic respiratory disease

CRRT, continuous renal replacement therapy

CVD, cardiovascular disease

CVVH, continuous venovenous haemofiltration

CVVHDF, continuous venovenous haemodiafiltration

DD, disk diffusion

ECMO, extracorporeal membrane oxygenation

EU, European Union

GL, global

GNB, Gram-negative bacteria

HCP, healthcare professional

HIV, human immunodeficiency virus

IAI, intra-abdominal infection

IBD, inflammatory bowel disease

MIC, minimum inhibitory concentration

MSL, medical science liaison

RTI, respiratory tract infection

RWE, real-world evidence

SOFA, Sequential Organ Failure Assessment

SSTI, skin and soft tissue infection

TDM, therapeutic drug monitoring

UK, United Kingdom

US, United States

UTI, urinary tract infection

VAP, ventilator-associated pneumonia

V-HAP, ventilated hospital-acquired pneumonia