Fetroja® – PROVE (Real-World Evidence) Study

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Summary

Background[1–5]

The PROVE Study (Retrospective Cefiderocol Chart Review Study) was a multicenter, retrospective, medical chart review study in patients treated with cefiderocol in the US and European hospitals. The main objectives of PROVE were to describe the patient characteristics and clinical outcomes in patients treated for the first time with cefiderocol for GNBIs in real-world settings between November 2020 and February 2024.

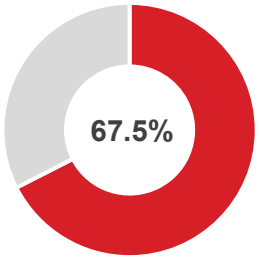
- This study included patients with a documented GNBI (including data regarding infection sites and pathogens) and who were required to receive cefiderocol treatment both for the first time and continuously for ≥72 hours

Analysis of Global Cohort[1]

This global analysis **(Clancy et al 2024)** describes results for 1075 patients enrolled from US and European medical centers between November 2020 and February 2024.

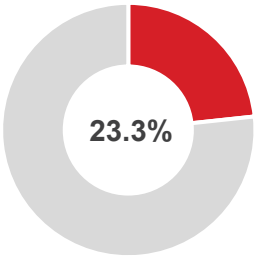
- A total of 88.7% of patients had ≥1 risk factor for CR infections
- The most frequent infection sites were the respiratory tract, skin and skin structure, urinary tract, and the bloodstream
- The most frequent species in monomicrobial infections was *Pseudomonas aeruginosa* (35.9%), followed by *Acinetobacter baumannii* (18.1%), while polymicrobial infections occurred in 25.2% of cases

Clinical Cure



- Overall, **75.1%** of patients responded to cefiderocol treatment at EOT and **67.5%** had clinical cure
- In monomicrobial infections the clinical cure rate was **67.8%**, while in polymicrobial infections it was **66.1%**

Mortality



- The overall **30-Day ACM** rate was **23.3%**
- In monomicrobial infections the 30-Day ACM rate was **23.5%**, while in polymicrobial infections it was **22.9%**

Safety



- A total of **29 ADRs** were experienced by **25 patients**, of which 3 were classed as serious ADRs (interstitial nephritis and acute kidney injury, elevation of liver enzymes, and hepatic cytolysis)
- Cefiderocol treatment was discontinued for 16 events (in 13 patients)

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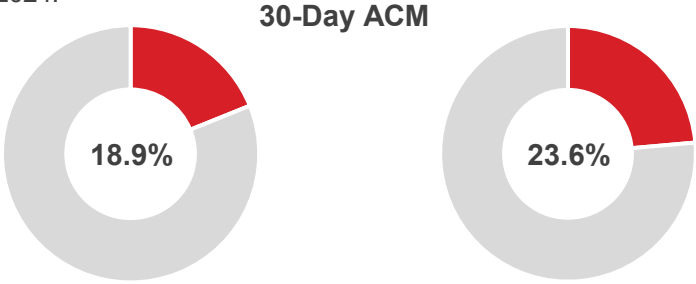
Summary (Cont.)

Subgroup Analyses (Global Cohort)

Treatment with Cefiderocol for Infections Caused By BL–BLI-NS Bacteria[2]

A separate subgroup analysis **(Shields et al 2025)** describes the outcomes in 504 patients enrolled from US and European medical centers with infections caused by BL–BLI-S (n=122) and BL–BLI-NS (n=382) bacteria between November 2020 and July 2024.

30-Day ACM



BL–BLI-S **BL–BLI-NS**

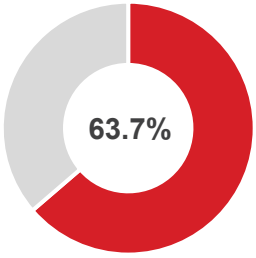
- Both **clinical cure and clinical response at EOT rates were similar** in patients with BL-BLI-S and BL-BLI-NS bacteria (70.5% vs 70.2% and 77.9% vs 76.7%, respectively)
- **30-day ACM was lower for patients with BL-BLI-S** than BL-BLI-NS bacteria (18.9% vs 23.6%, respectively)

- **Lower clinical cure rates were observed among patients who received cefiderocol as salvage treatment** compared with those with documented infection or empiric use irrespective of BL-BLI susceptibility status
- Patients infected with BL-BLI-NS bacteria had lower clinical cure rates when cefiderocol was initiated either 5–7 days or >7 days after culture collection compared with earlier cefiderocol treatment initiation

Treatment with Cefiderocol for BSIs[3]

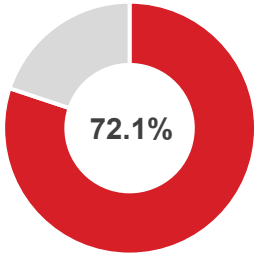
- A separate subgroup analysis **(Drwiega et al 2025)** describes results for a total of 226 patients with a documented BSI enrolled from US and European medical centers between 2020 and 2024
- Lower rates of clinical cure and clinical response at EOT and higher 30-day ACM rates were observed when cefiderocol treatment was initiated ≥5 days following culture collection compared to earlier treatment initiation

Clinical Cure



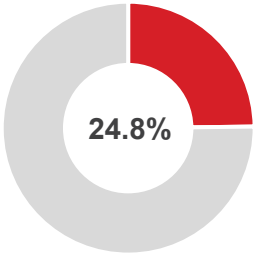
- Overall, the clinical cure rate was **63.7%** (primary BSIs: 68.5%; secondary BSIs: 59.3%)

Clinical Response at EOT



- Overall, clinical response at EOT was **72.1%** (primary BSIs: 74.1%; secondary BSIs: 70.3%)

Mortality



- Overall, 30-day ACM was **24.8%** (primary BSIs: 19.4%; secondary BSIs: 29.7%)

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Summary (Cont.)

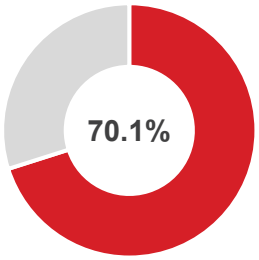
Subgroup Analyses (US Cohort)

Early Treatment with Cefiderocol[4]

This subgroup analysis **(Clancy et al 2025)** describes the outcomes of early treatment with cefiderocol in 508 hospitalized patients from the US (November 2020 to July 2024).

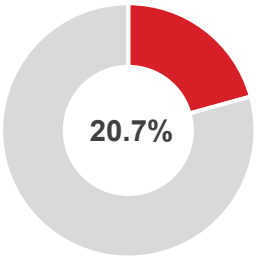
- Cefiderocol was used as a result of:
  - Documented infections (n=375; 73.8%)
  - Empiric treatment (n=57; 11.2%)
  - Salvage treatment (n=70; 13.8%)
  - Other/unknown (n=6; 1.2%)

Clinical Cure



- Overall, **77.8%** of patients responded to cefiderocol treatment at EOT and **70.1%** had clinical cure
- Among patients with RTIs, clinical response at EOT was **76.5%**, while clinical cure was **64.7%**

Mortality



- The overall 30-Day ACM rate was **20.7%**
- Among patients with RTIs, the 30-Day ACM rate was **25.7%**

- Clinical cure rates for patients with documented *Pseudomonas aeruginosa*, *Acinetobacter baumannii*, and Enterobacterales infections were 70.4%, 68.2%, and 79.3%, respectively, while the 30-day ACM rates were 20.4%, 22.7%, and 17.2%, respectively
- **Rates of clinical cure and clinical response at EOT were lower, and 30-day ACM was higher**, when cefiderocol was used as salvage therapy compared with either documented infections or empiric use

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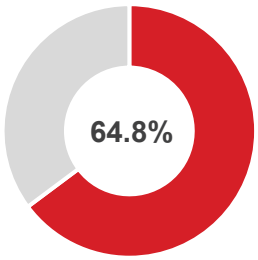
Summary (Cont.)

Interim Analysis (US Cohort)[5]

This interim analysis **(Clancy et al 2024)** describes results for 244 patients enrolled from US medical centers (November 2020–March 2023).

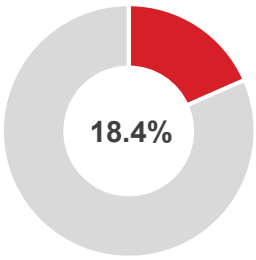
- At least 1 comorbid condition was present in 96% of patients
- The most frequent infection sites were the respiratory tract, skin and skin structure, bloodstream, urinary tract, and bone/joint
- Most infections were monomicrobial (69.3%), most frequently with *P. aeruginosa* (82 [33.6%]) *or A. baumannii* (43 [17.6%])
- Susceptibility test results for cefiderocol were available for 142 patients, of which 124 (87.3%) were susceptible
- A total of 152 patients (62.3%) stayed in the ICU while receiving treatment with cefiderocol, while the median length of stay in the ICU was 39 days
- Cefiderocol was administered for a median duration of 12 days, 110 patients (45.1%) received cefiderocol for ≥14 days, and 171 patients (70.1%) received concomitant antibiotic treatment

Clinical Cure



- Clinical cure was achieved by 158 (64.8%) patients
- **In the CR population**, clinical cure was achieved by 135 (**64.6%**) patients

Mortality



- Overall, 23 (9.4%) patients died by **Day 14**, and 45 (18.4%) died by **Day 30**
- In the **CR population**, Day 14 and Day 30 mortality was **10%** and **19.6%**, respectively

Safety



A total of **6 ADRs** were experienced by **5 patients**

- 1 of the 5 patients experienced a serious ADR (interstitial nephritis, acute kidney injury)

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Study Background and Methodology

The PROVE Study (Retrospective Cefiderocol Chart Review Study) was a multicenter, retrospective, medical chart review study in patients treated with cefiderocol in US and European hospitals. The main objectives of PROVE were to describe the patient characteristics and clinical outcomes in patients treated for the first time with cefiderocol for GNBIs in real-world settings between November 2020 and July 2024.[1–5]

Methods

Study Population[5]

- The PROVE Study included patients with a documented GNBI (including data on infection sites and pathogens)
- Patients in the study population were required to receive cefiderocol treatment for the first time and continuously for ≥72 hours. In addition, patients with the following treatment information were included:
  - Cefiderocol start/end dates, daily dose, treatment duration
  - Known outcomes at the end of cefiderocol treatment
  - Discharge status at the end of hospitalization
- Documented ADRs that were associated with cefiderocol were evaluated

Outcome Measures[5]

- Patient characteristics
- Infection type (Gram-negative pathogen, susceptibility, infection site, monomicrobial or polymicrobial)
- Cefiderocol treatment course: time from culture collection to first dose of cefiderocol, daily dose, treatment duration
  - Positive culture: defined as the sample collected prior to starting cefiderocol that resulted in cefiderocol prescription. The index culture may have been collected and tested in the outpatient setting prior to hospitalization
- Efficacy endpoints: clinical response, clinical cure, ACM at Day 14, ACM at Day 30, and in-hospital mortality
  - Clinical response was defined as resolution or improvement of signs/symptoms at EOT as judged by the physician, excluding patients who died during therapy
  - Clinical cure was defined as resolution or improvement in infection signs and symptoms at EOT, without evidence of a later relapse or death

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Analysis of Global Cohort

Clancy et al (2024) presented data from 1075 patients enrolled from US and European medical centers between November 2020 and February 2024.[1]

Results

Patient Characteristics[1]

- Participating countries included the US (47.3%), Spain (14.8%), France (11.9%), Italy (11.3%), United Kingdom (7.5%), and Germany (7.3%)
- 65.6% of patients were male, the median (IQR) age was 60 (46–69) years, and the median (IQR) CCI was 2 (1–4)
- The most common reported comorbidities included chronic pulmonary disease (20.4%), uncomplicated diabetes (18.5%), COVID-19 (17%), moderate-severe renal disease (16.9%), and CHF (14%)
- 88.7% of patients had ≥1 risk factor for CR infections

Infection Characteristics[1]

- Overall, 56.6% of patients were in the ICU, 44.3% received organ support, and 33.9% of patients received combination therapy
  - Information regarding cefiderocol utilization is shown in **Figure 1**
- The median (IQR) duration of treatment was 11 (7–16) days
- The most frequent infection sites were the respiratory tract (53.1%), followed by skin and skin structure (12.6%), urinary tract (10.6%), and the bloodstream (10%) – see **Figure 2**
- The most frequent species in monomicrobial infections was *P. aeruginosa* (35.9%), followed by *A. baumannii* (18.1%), while polymicrobial infections occurred in 25.2% of cases – see **Figure 3**

Figure 1. Reason for Cefiderocol Use[1,a]

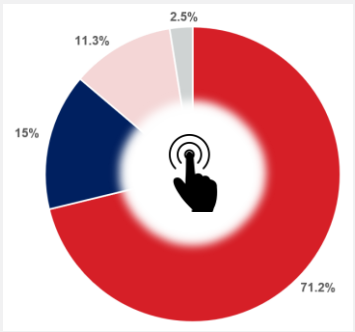


Figure 2. Distribution of Primary Infection Sites[1]

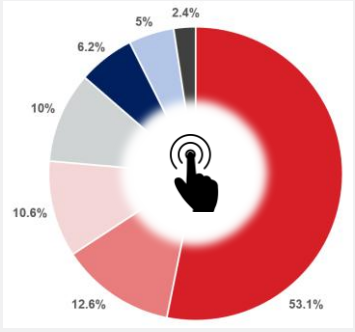
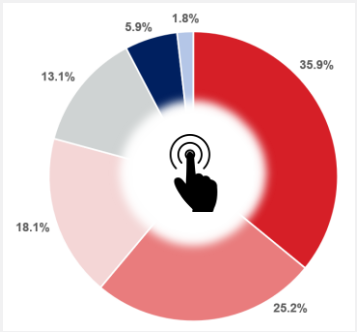


Figure 3. Distribution of Baseline Gram-Negative Pathogens[1]



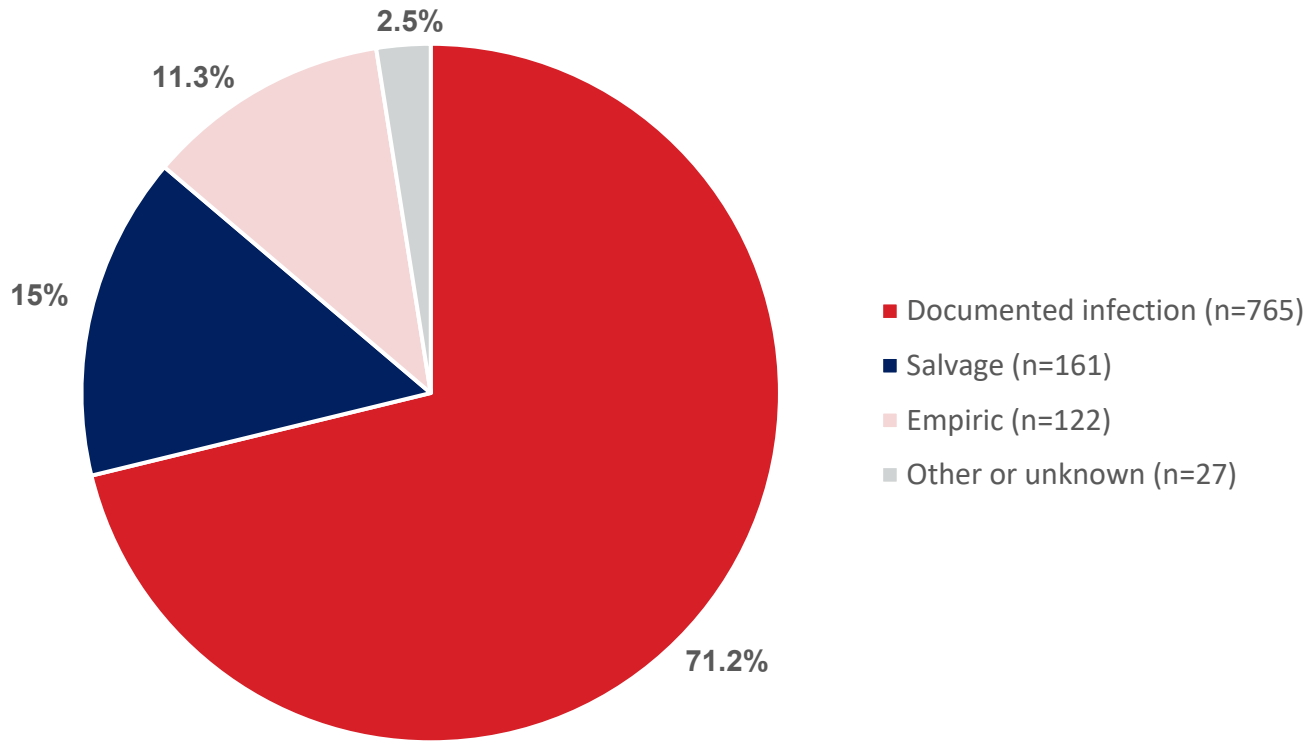
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Analysis of Global Cohort

Figure 1. Reason for Cefiderocol Use[1a]



[a]Reported by the investigator. *Documented infection*: the pathogen and susceptibilities were known, and cefiderocol use was not due to failure of a prior antibiotic regimen. *Empiric use*: cefiderocol use started before the pathogen and/or susceptibilities were available to help guide the choice. *Salvage therapy*: cefiderocol was used after a prior antibiotic regimen had failed; patients usually received at least 3 days of prior antibiotic therapy to see if there was an adequate response before the next course of antibiotic would be considered salvage. *Other, including unknown*: any other reason provided by the physician.
Figure adapted from Clancy et al. IDWeek. 2024.

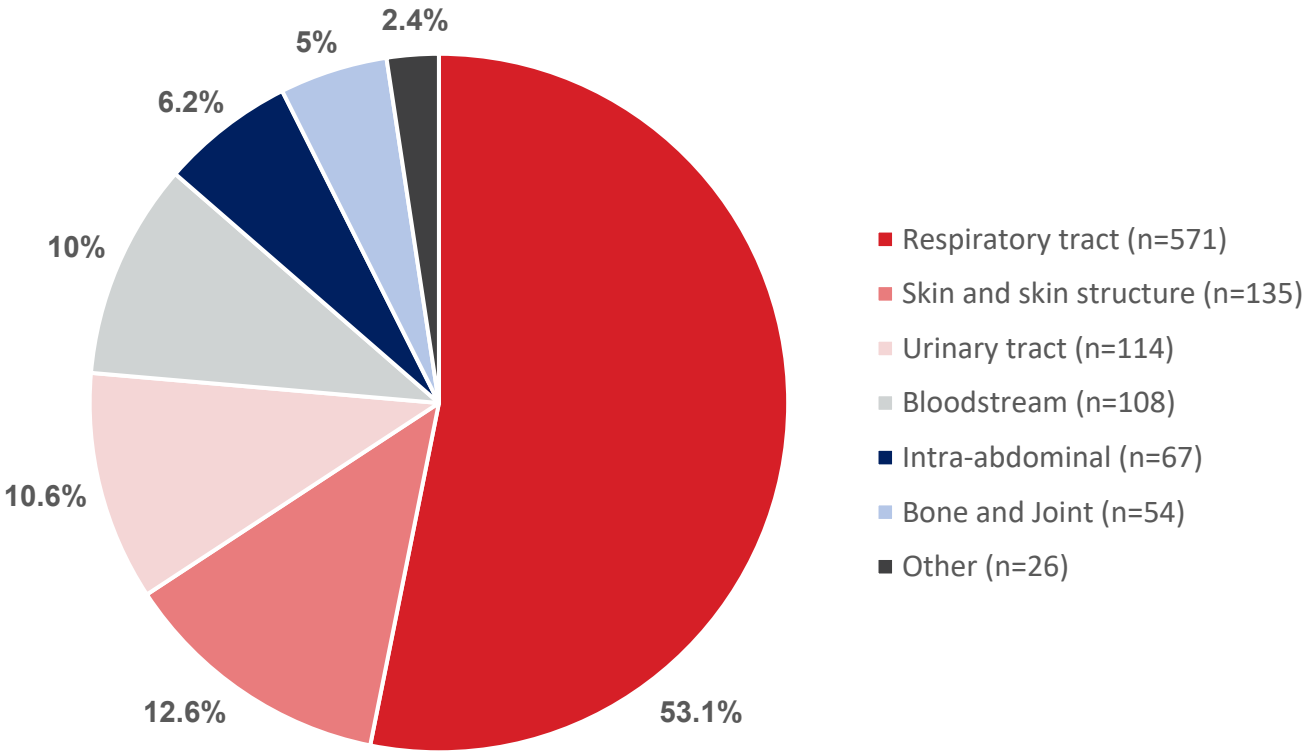
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Analysis of Global Cohort

Figure 2. Distribution of Primary Infection Sites[1]



Other: bone and joint, skin and skin structure, intra-abdominal, and other sites.
Figure adapted from Clancy et al. IDWeek. 2024.

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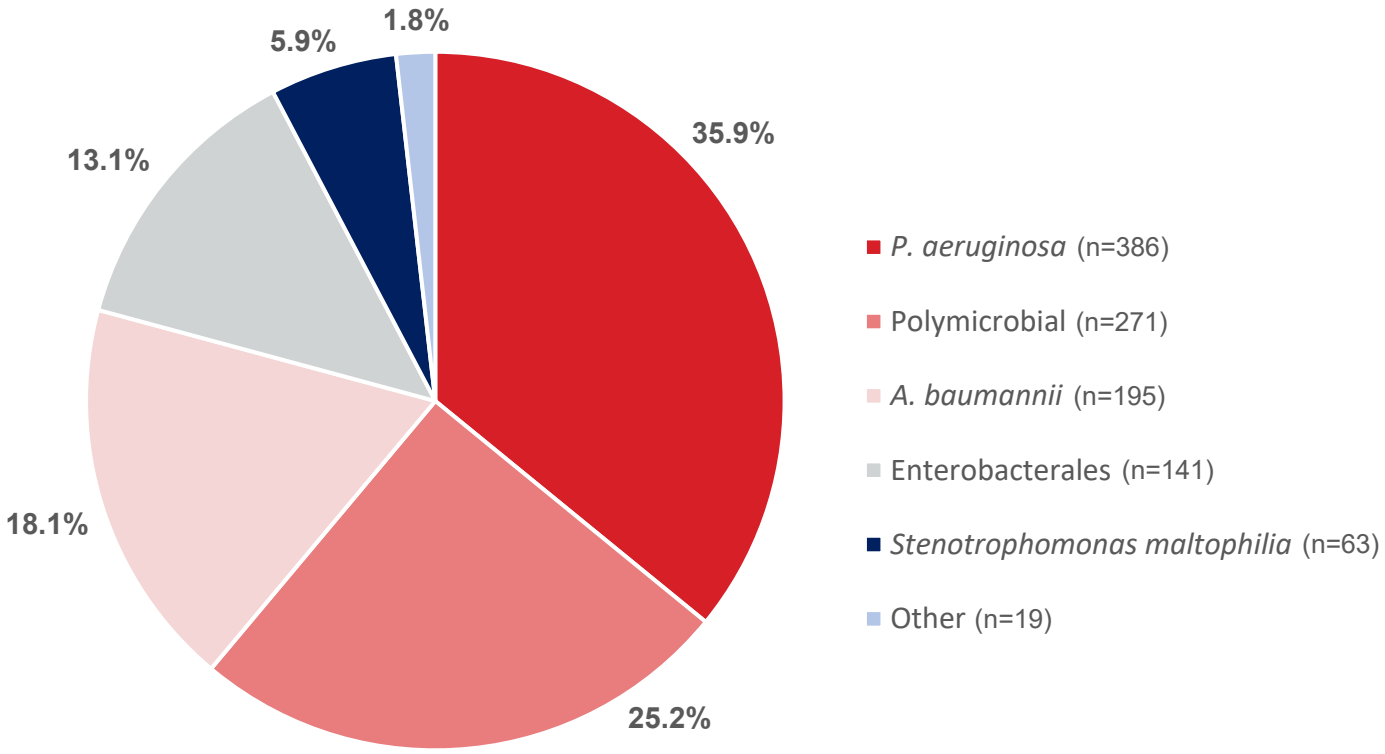


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Analysis of Global Cohort

Outcomes[1]

- Overall, 75.1% of patients responded to cefiderocol treatment at EOT and 67.5% had clinical cure. Clinical response at EOT and clinical cure rates by infection site are shown in **Table 1**
- Among patients with a RTI or BSI, 29.2% and 19.4%, respectively, had died by Day 30
- The overall 30-Day ACM rate was 23.3%. Clinical cure and 30-Day ACM rates by pathogen are shown in **Table 2**
- In monomicrobial infections, the clinical cure rate was 67.8%, while the 30-Day ACM rate was 23.5%

Table 1. Clinical Response at EOT and Clinical Cure by Infection Site[1]

Infection Site	Clinical Response at EOT (% of patients)	Clinical Cure (% of patients)
Overall (n=1075)	**75.1**	**67.5**
Respiratory tract (n=571)	71.6	61.8
Bloodstream (n=108)		68.5
Urinary tract (n=114)		88.6
Intra-abdominal (n=67)		59.7
Bone and joint (n=54)		83.3
Skin and skin structure (n=135)	77	71.1
Other (n=26)	69.2	65.4

Table 2. Clinical Cure and 30-Day ACM by Pathogen[1]

Pathogen	Clinical Cure (% of patients)	30-Day ACM (% of patients)
Overall (n=1075)	**67.5**	**23.3**
A. baumannii (n=195)	60.5	28.2
P. aeruginosa (n=386)		19.9
Enterobacterales (n=141)		22
S. maltophilia (n=63)		36.5
Other (n=19)	52.6	15.8
Polymicrobial (n=271)	66.1	22.9

Safety[1]

- 25 patients had a total of 29 ADRs, of which 3 were classed as a serious ADR (interstitial nephritis and AKI, elevation of liver enzymes, and hepatic cytolysis)
- Cefiderocol treatment was discontinued for 16 events (in 13 patients)

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Bloodstream (n=108)	74.1	68.5
Urinary tract (n=114)	91.2	88.6
Intra-abdominal (n=67)	65.7	59.7
Bone and joint (n=54)	88.9	83.3
Skin and skin structure (n=135)	77	71.1
Other (n=26)	69.2	65.4

Abbreviation: EOT, end of treatment.
Table adapted from Clancy et al. IDWeek. 2024.

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A. baumannii (n=195)	60.5	28.2
P. aeruginosa (n=386)	72	19.9
Enterobacterales (n=141)	70.2	22
S. maltophilia (n=63)	66.7	36.5
Other (n=19)	52.6	15.8
Polymicrobial (n=271)	66.1	22.9

Abbreviation: ACM, all-cause mortality.
Table adapted from Clancy et al. IDWeek. 2024.

- Cefiderocol treatment was discontinued for 16 events (in 13 patients)

Subgroup Analyses (Global Cohort): Infections Caused by BL–BLI-NS Bacteria

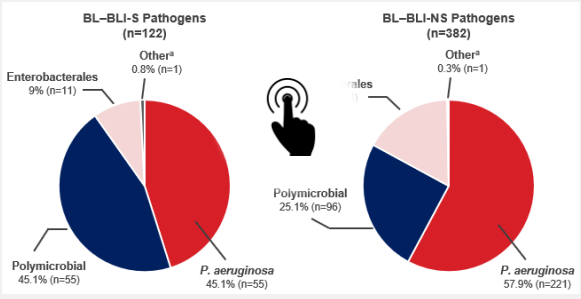
Shields et al (2025) conducted a subgroup analysis of 504 patients (from the US and Europe) with infections caused by BL–BLI (ceftazidime–avibactam, ceftolozane–tazobactam, and imipenem–relebactam)-NS bacteria between November 2020 and July 2024.[2]

- Susceptibility data for the BL–BLI combination products were reported via medical charts and interpreted based on locally applicable breakpoints
  - Susceptible (S) bacteria were pathogens that were susceptible to all BL–BLIs tested (n=122)
  - Non-susceptible (NS) bacteria were resistant (or intermediate) to ≥1 BL–BLIs tested (n=382)
- Infections due to *S. maltophilia* and *Acinetobacter* spp. were excluded

Results[2]

- Among the subpopulation of 504 patients, susceptibility data were available for:
  - Ceftazidime–avibactam (n=464)
  - Ceftolozane–tazobactam (n=368)
  - Imipenem–relebactam (n=104)
- Compared to patients with BL–BLI-NS infections, there were a higher proportion of patients with BL–BLI S infections with:
  - Indicators of more severe disease at time of cefiderocol initiation:
    - ICU stay: 67.2 % vs 52.6%
    - Organ support: 51.6% vs 39.8%
  - Polymicrobial infections: 45.1% vs 25.1% – see **Figure 4**
  - ≥2 risk factors for acquired CR-GNB: 66.4% vs 58.9%

Figure 4. Pathogen Distribution among Patients (US and Europe) with BL–BLI-S and BL–BLI-NS Gram-Negative Pathogens[2]

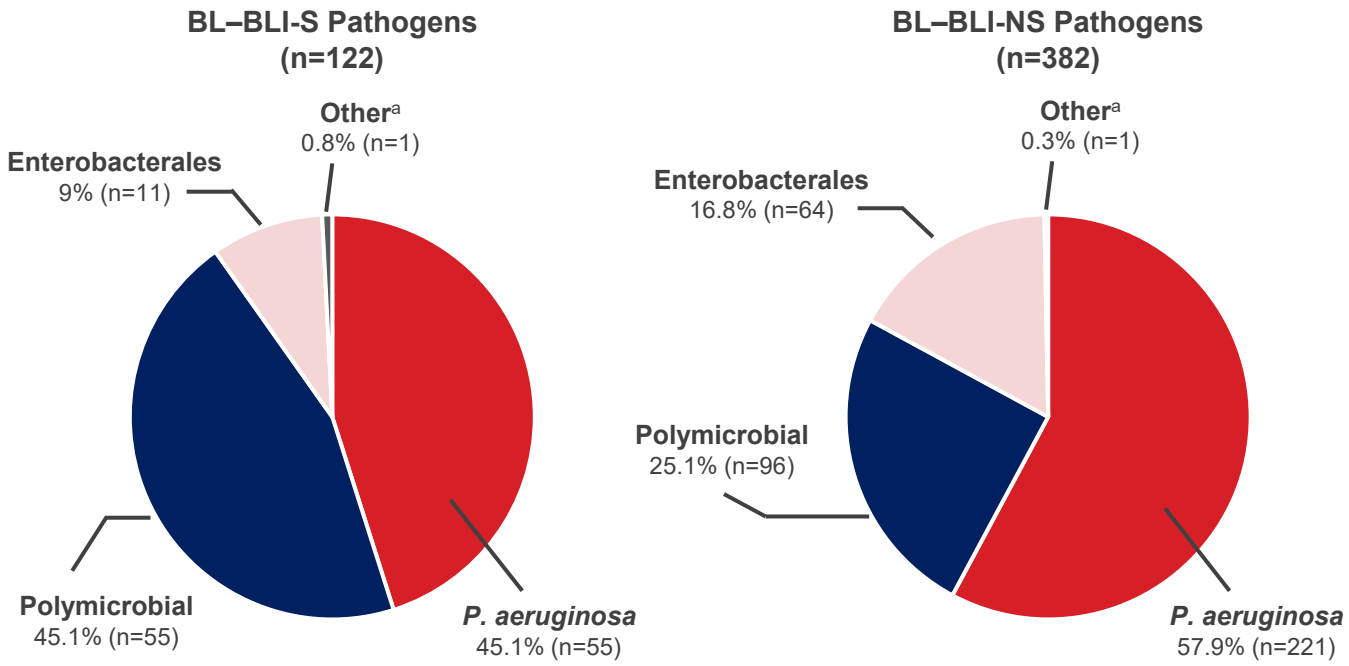


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Figure 4. Pathogen Distribution among Patients (US and Europe) with BL–BLI-S and BL–BLI-NS Gram-Negative Pathogens[2]



Abbreviations: BL–BLI, β-lactam–β-lactamase inhibitor; NS, non-susceptible; S, susceptible.
[a]*Burkholderia* spp. n=1 in both subgroups.
Figure adapted from Shields et al. IDWeek. 2025.

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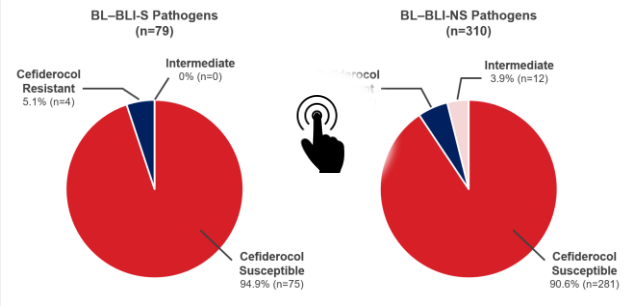
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Subgroup Analyses (Global Cohort): Infections Caused by BL–BLI-NS Bacteria

Results (Cont.)[2]

- Of the pathogens with known cefiderocol susceptibility data, 75 of 79 (94.9%) BL-BLI-S and 281 of 310 (90.6%) BL-BLI-NS isolates were susceptible to cefiderocol – see **Figure 5**

Figure 5. Cefiderocol Susceptibility Status among Patients (US and Europe) with BL–BLI-S and BL–BLI-NS Gram-Negative Pathogens[2,a,b]



- Both clinical cure rates (70.5% vs 70.2%) and clinical response at EOT rates (77.9% vs 76.7%) were similar in patients with BL-BLI-S and BL-BLI-NS bacteria, respectively – see **Figure 6**
- 30-day ACM was lower for patients with BL-BLI-S compared to BL-BLI-NS bacteria (18.9% vs 23.6%, respectively)
- For the patients infected with BL-BLI-NS bacteria, clinical cure rates were lower when cefiderocol treatment was initiated ≥5–7 days following culture collection compared with earlier treatment initiation – see **Figure 7**

Figure 6. Overall Outcomes in Patients (US and Europe) with BL–BLI-S and BL–BLI-NS Gram-Negative Pathogens[2]

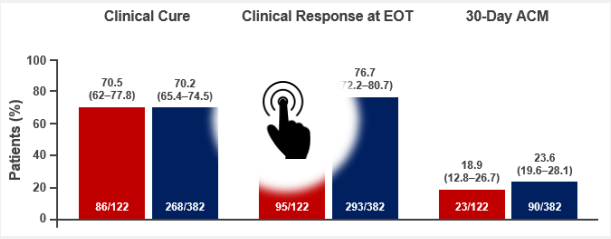


Figure 7. Clinical Cure Rates Stratified by Time from Culture Collection to Initiation of Cefiderocol in Patients with BL–BLI-S and BL–BLI-NS Gram-Negative Pathogens[2]

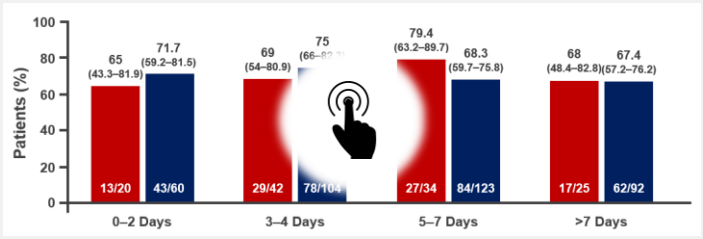
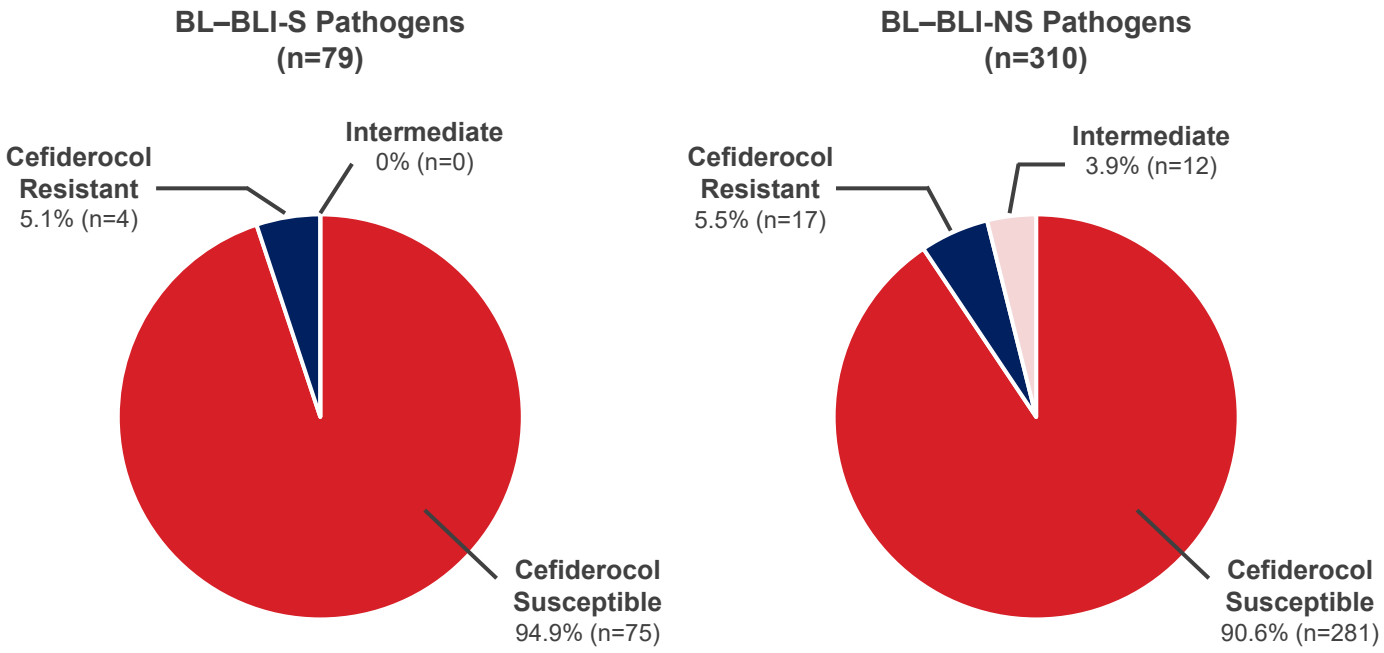


Figure 5. Cefiderocol Susceptibility Status among Patients (US and Europe) with BL–BLI-S and BL–BLI-NS Gram-Negative Pathogens[2,a,b]



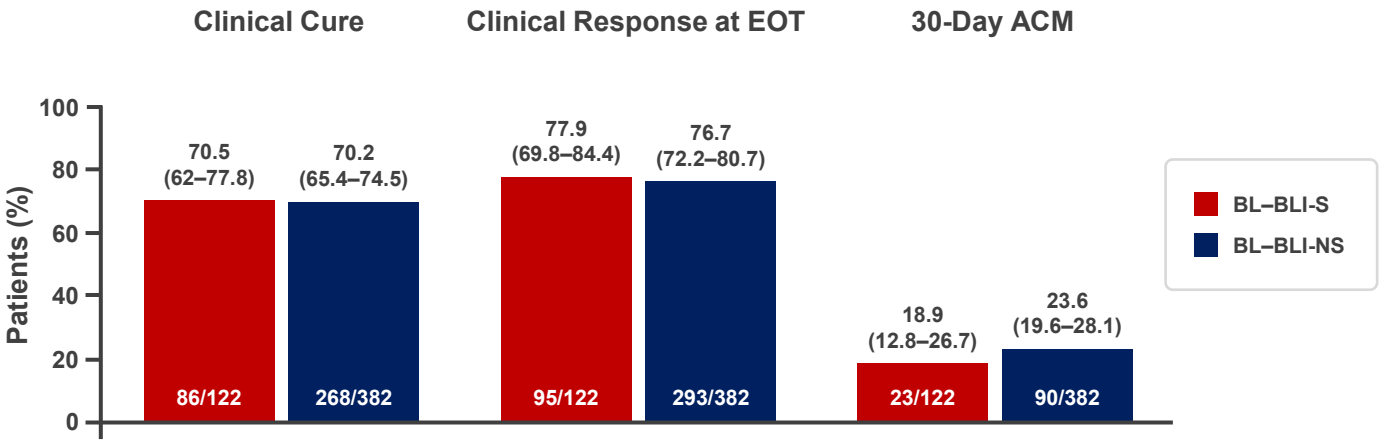
Abbreviations: BL–BLI, β-lactam–β-lactamase inhibitor; NS, non-susceptible; S, susceptible.
[a]Unknown susceptibility: S isolates: n=43; NS isolates: n=72.
[b]Susceptibility status was reported; all cefiderocol susceptibilities were obtained from each site's local microbiology laboratory. The test result may have been collected in the local laboratory or in a reference laboratory. Susceptibility was interpreted according to local criteria in each country.
Figure adapted from Shields et al. IDWeek. 2025.

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Subgroup Analyses (Global Cohort): Infections Caused by BL–BLI-NS Bacteria

Results (Cont.)[2]

Figure 6. Overall Outcomes in Patients (US and Europe) with BL–BLI-S and BL–BLI-NS Gram-Negative Pathogens[2]



Data are expressed as % (95% CI).
Abbreviations: ACM, all-cause mortality; BL–BLI, β-lactam–β-lactamase inhibitor; CI, confidence interval; EOT, end of treatment; NS, non-susceptible; S, susceptible.
Figure adapted from Shields et al. IDWeek. 2025.

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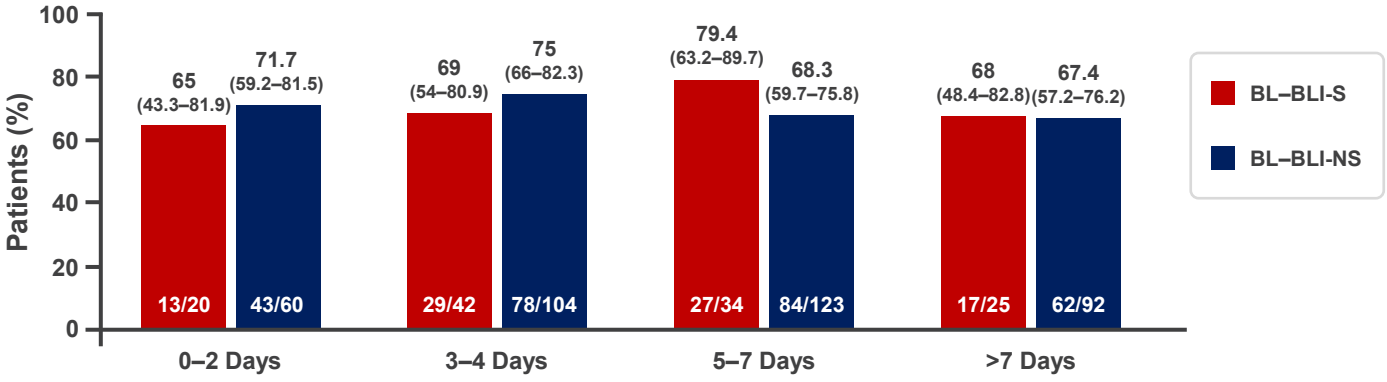
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Subgroup Analyses (Global Cohort): Infections Caused by BL–BLI-NS Bacteria

Results (Cont.)[2]

Figure 7. Clinical Cure Rates Stratified by Time from Culture Collection to Initiation of Cefiderocol in Patients with BL–BLI-S and BL–BLI-NS Gram-Negative Pathogens[2]



Data are expressed as % (95% CI).
Abbreviations: BL–BLI, β-lactam–β-lactamase inhibitor; CI, confidence interval; NS, non-susceptible; S, susceptible.
Figure adapted from Shields et al. IDWeek. 2025.

- For the patients infected with BL–BLI-NS bacteria, clinical cure rates were lower when cefiderocol treatment was initiated ≥5–7 days following culture collection compared with earlier treatment initiation – see Figure 7

Figure 6. Overall Outcomes in Patients (US and Europe) with BL–BLI-S and BL–BLI-NS Gram-Negative Pathogens[2]

Figure 7. Clinical Cure Rates Stratified by Time from Culture Collection to Initiation of Cefiderocol in Patients with BL–BLI-S and BL–BLI-NS Gram-Negative Pathogens[2]

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Subgroup Analyses (Global Cohort): Treatment of BSIs Caused by GNBs

Drwiega et al (2025) described the clinical outcomes in a subgroup analysis of patients (N=226) treated with cefiderocol (2020–2024) for BSIs (primary or secondary).[3]

- A primary BSI was defined as a confirmed Gram-negative pathogen in the bloodstream prompting treatment with cefiderocol
- A secondary BSI had a documented GNBI in the bloodstream, but with a different primary infection site which prompted treatment with cefiderocol

Results[3]

- Of the 226 patients with documented BSIs, 108 (47.8%) were primary BSIs, and 118 (52.2%) were secondary BSIs
- During the initiation of cefiderocol treatment, 125 (55.3%) patients were in the ICU, and 104 (46%) patients were receiving organ support
- *P. aeruginosa* was the most common pathogen observed (35.8%), followed by *A. baumannii* and Enterobacterales (both 20.8%), while polymicrobial BSIs were detected in 35 (15.5%) patients – see **Figure 8**
- Of 199 bacterial isolates with known carbapenem susceptibility data, 179 (89.9%) isolates were Carb-NS, while 20 (10.1%) isolates were susceptible to carbapenems
- Overall, clinical cure was achieved by 68.5% of patients with primary BSIs and 59.3% in those with secondary BSIs – see **Figure 9**
- Clinical response at EOT occurred in 74.1% in patients with primary and 70.3% in those with secondary BSIs, respectively
- The 30-day ACM rate was 19.4% in patients with primary and 29.7% in those with secondary BSIs, respectively

Figure 8. Pathogen Distribution among Patients with BSIs (N=226)[3]

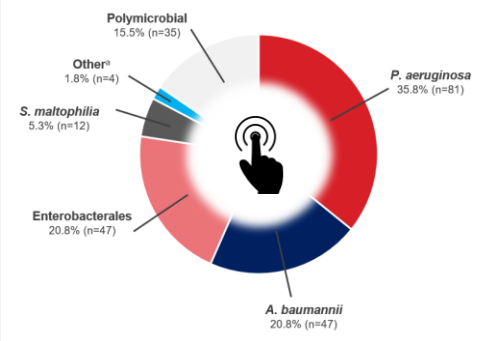
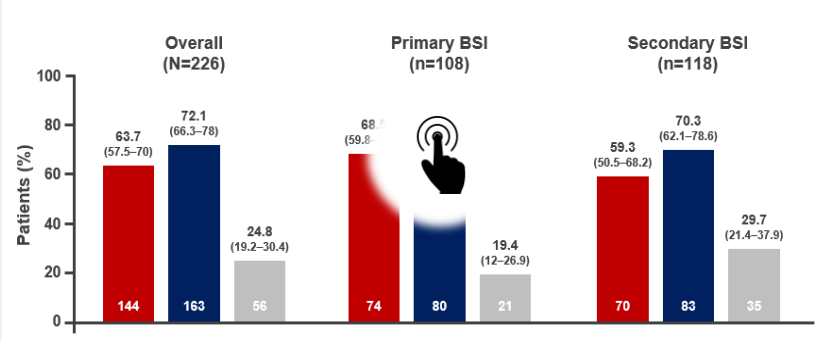
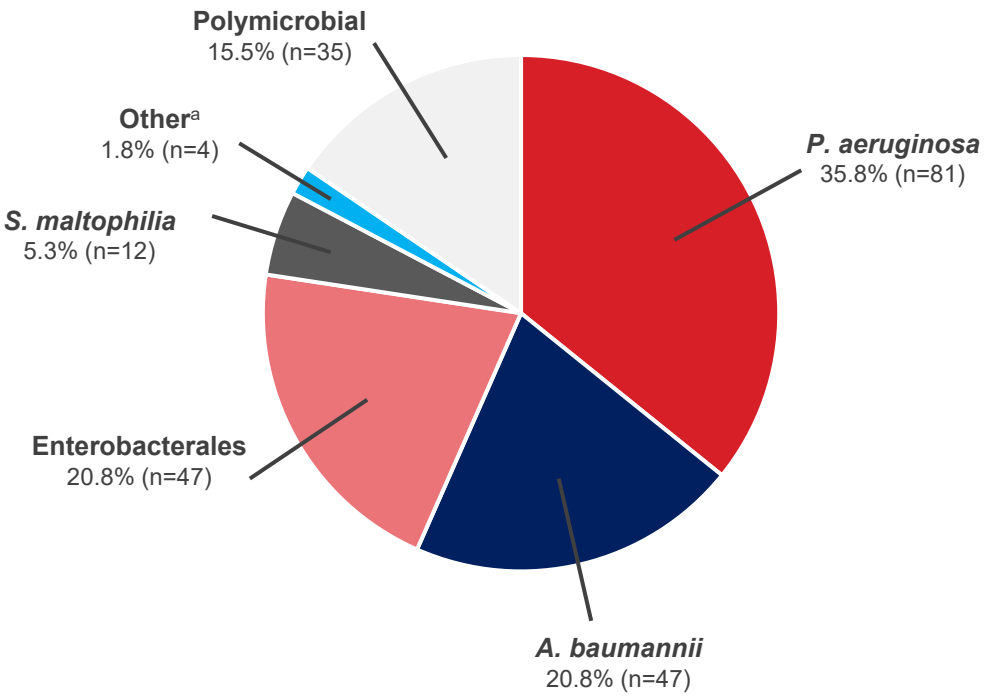


Figure 9. Overall Clinical Cure, Clinical Response Rates, and 30-Day ACM in Patients with BSIs[3]



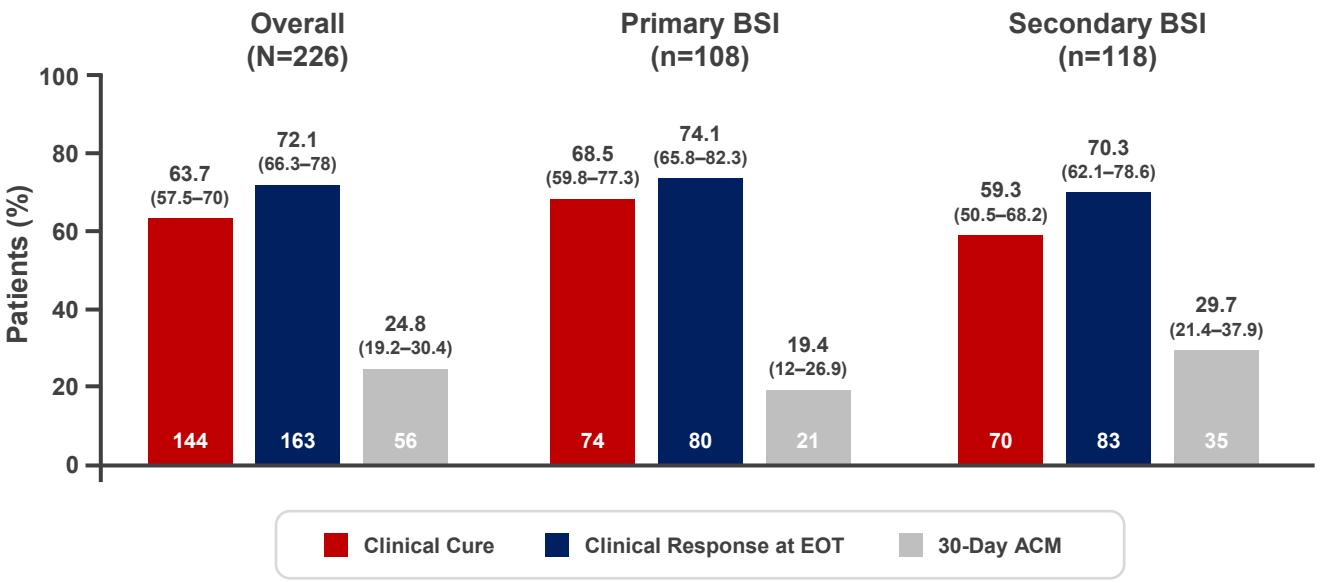
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Figure 8. Pathogen Distribution Among Patients with BSIs (N=226)[3]



Abbreviation: BSI, bloodstream infection.
[a]Other monomicrobial infections include *Achromobacter* spp., *Achromobacter xylosoxidans*, *Burkholderia cepacia* complex, and *Haemophilus influenzae*.
Figure adapted from Drwiega et al. IDWeek. 2025.

Figure 9. Overall Clinical Cure, Clinical Response Rates, and 30-Day ACM in Patients with BSIs[3]



Data are expressed as % (95% CI).
Abbreviations: ACM, all-cause mortality; BSI, bloodstream infection; CI, confidence interval; EOT, end of treatment.
Figure adapted from Drwiega et al. IDWeek. 2025.

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Subgroup Analyses (Global Cohort): Treatment of BSIs Caused by GNBs

Results (Cont.)[3]

- The clinical cure rate in patients with BSIs caused by P. aeruginosa was 72.8% – see **Figure 10**
- The clinical cure rates in patients with BSIs caused by Enterobacterales, *A. baumannii*, *S. maltophilia*, and polymicrobial infections were 57.4%, 55.3%, 83.3%, and 60%, respectively
- Clinical response at EOT in patients with BSIs caused by *P. aeruginosa* was 77.8%
- Clinical response rates at EOT in BSIs caused by Enterobacterales, *A. baumannii*, *S. maltophilia*, and polymicrobial infections were 66%, 66%, 83.3%, and 74.3%, respectively
- 30-day ACM rates for BSIs caused by *P. aeruginosa*, Enterobacterales, *A. baumannii*, *S. maltophilia*, and polymicrobial infections were 21%, 21.3%, 34%, 41.7%, and 22.9%, respectively
- Empiric use with cefiderocol was shown to have higher clinical cure rate and a lower 30-day ACM compared to patients that received cefiderocol as salvage therapy – see **Figure 11**
  - Most patients in this cohort, however, were treated with cefiderocol for a documented infection
- Lower rates of clinical cure and clinical response at EOT and higher 30-day ACM rates were observed when cefiderocol treatment was initiated ≥5 days following culture collection compared to earlier treatment initiation – see **Figure 12**

Figure 10. Clinical Cure, Clinical Response Rates, and 30-Day ACM by Pathogen in Patients with BSIs (N=226)[3]

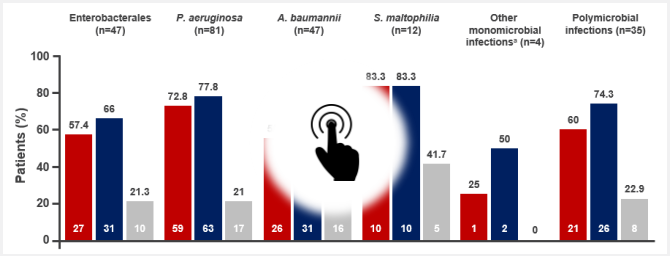


Figure 11. Clinical Outcomes by Reason for Cefiderocol Use[a] in Patients with BSIs (N=226)[3]

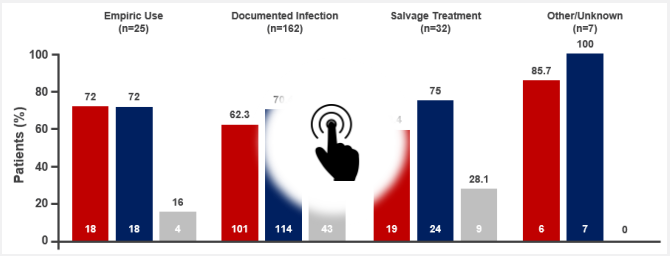


Figure 12. Clinical Cure Outcomes by Time from Culture Collection to Cefiderocol Initiation in Patients with BSIs (N=226)[3]

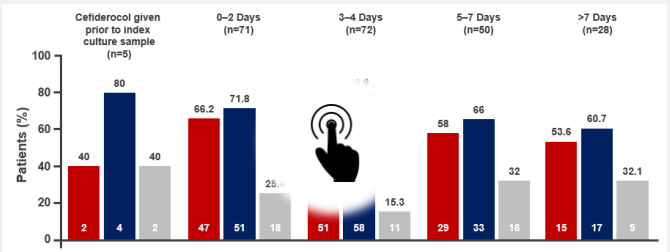
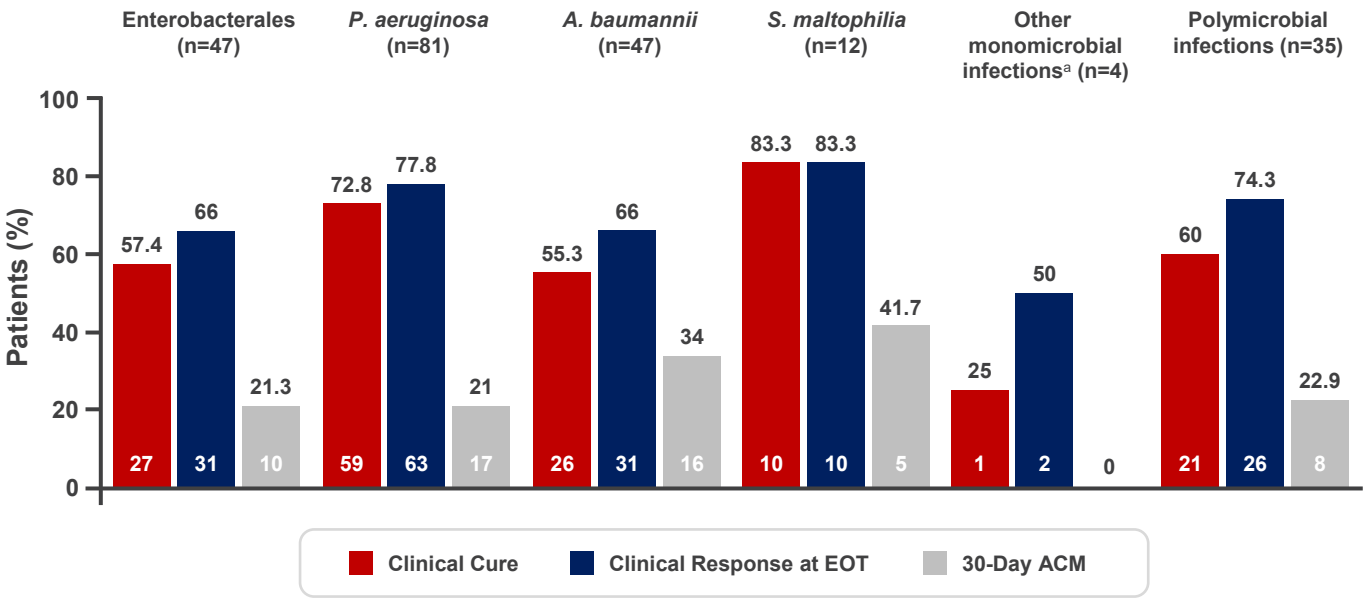


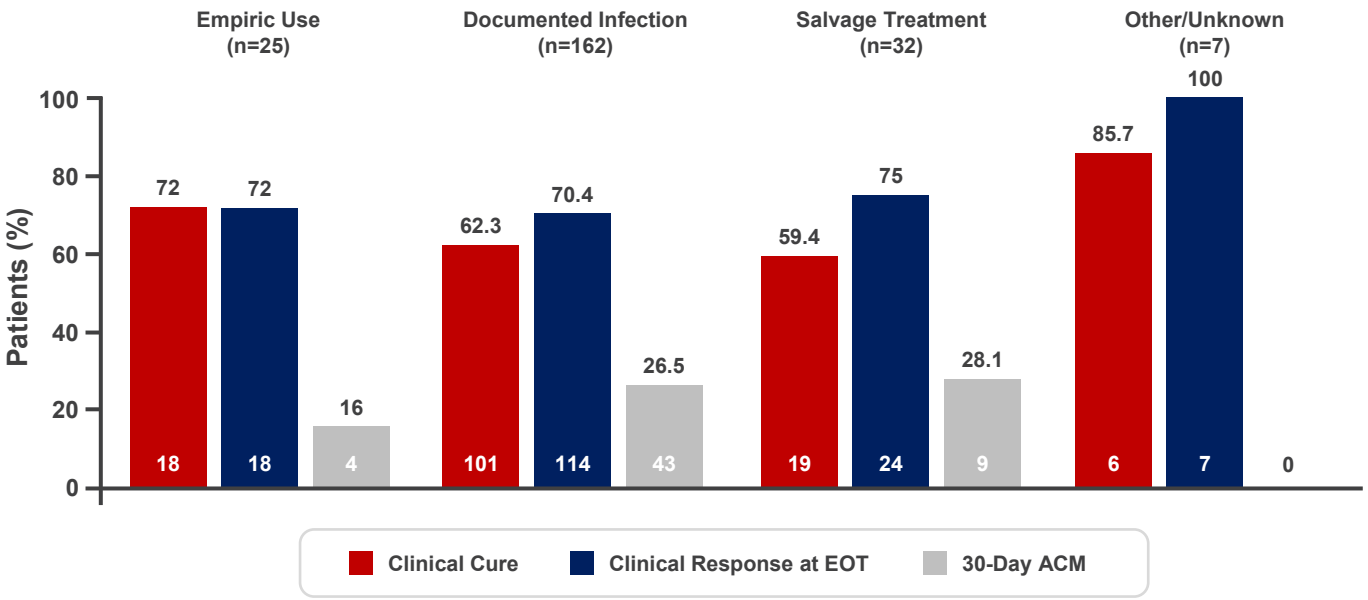
Figure 10. Clinical Cure, Clinical Response Rates, and 30-Day ACM by Pathogen in Patients with BSIs (N=226)[3]



Abbreviations: ACM, all-cause mortality; BSI, bloodstream infection; EOT, end of treatment.
[a]Other monomicrobial infections include *Achromobacter* spp., *A. xylosoxidans*, *B. cepacia* complex, and *H. influenzae*.
Figure adapted from Drwiega et al. IDWeek. 2025.

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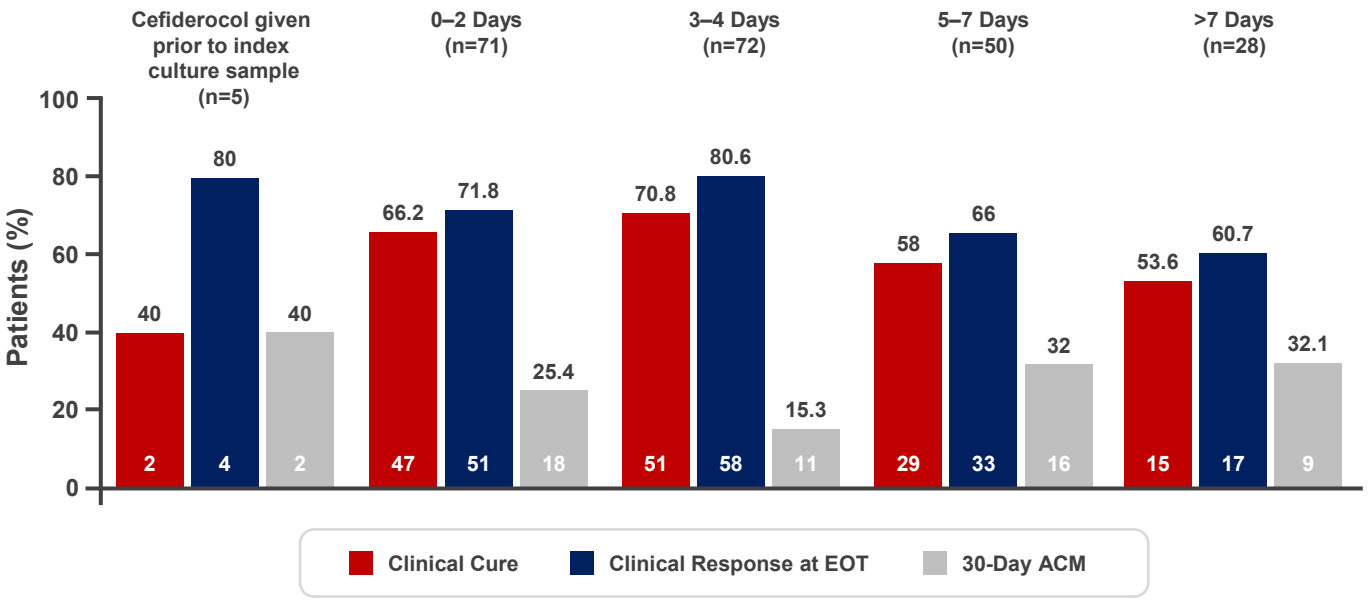
Abbreviations: ACM, all-cause mortality; BSI, bloodstream infection; EOT, end of treatment.
[a]Reported by the investigator. Documented infection: the pathogen and susceptibilities were known, and cefiderocol use was not due to failure of a prior antibiotic regimen. Empiric use: cefiderocol use started before the pathogen and/or susceptibilities were available to help guide the choice. Salvage therapy: cefiderocol was used after a prior antibiotic regimen had failed; patients usually received at least 3 days of prior antibiotic therapy to see whether there was an adequate response before the next course of antibiotic would be considered salvage. Other, including unknown: any other reason provided by the physician.
Figure adapted from Drwiega et al. IDWeek. 2025.

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Figure 12. Clinical Cure Outcomes by Time from Culture to Cefiderocol Initiation in Patients with BSIs (N=226)[3]



Abbreviations: ACM, all-cause mortality; BSI, bloodstream infection; EOT, end of treatment.
Figure adapted from Drwiega et al. IDWeek. 2025.

Subgroup Analyses (US Cohort): Early Treatment

Clancy et al (2025) conducted a subgroup analysis to describe the cohort of 508 patients from US hospitals, with data collated between November 2020 and July 2024.[4]

Results[4]

- Cefiderocol was used for the following:
  - Documented infections, 375 (73.8%)
  - Empiric treatment, 57 (11.2%)
  - Salvage treatment, 70 (13.8%)
  - Other/unknown, 6 (1.2%)
- At the time of cefiderocol initiation:
  - 291 (57.3%) patients were in the ICU
  - 242 (47.6%) were receiving organ support (ECMO, mechanical ventilation, renal replacement therapy, use of vasopressor medication)
  - Diabetes mellitus (n=183; 36%) was the most frequent comorbidity, while sepsis or septic shock was present in 118 (23.2%) patients
  - The majority of patients (n=474; 93.3%) had ≥1 risk factor for acquiring a CR-GNBI
- RTIs were the most common type of infection (n=272; 53.5%), while the most frequent causative pathogens were polymicrobial infections and monomicrobial *P. aeruginosa* infections (both 29.9%) – see **Figure 13**

Figure 13. Primary Infection Site and Baseline Pathogen in US Patients (N=508)[4]

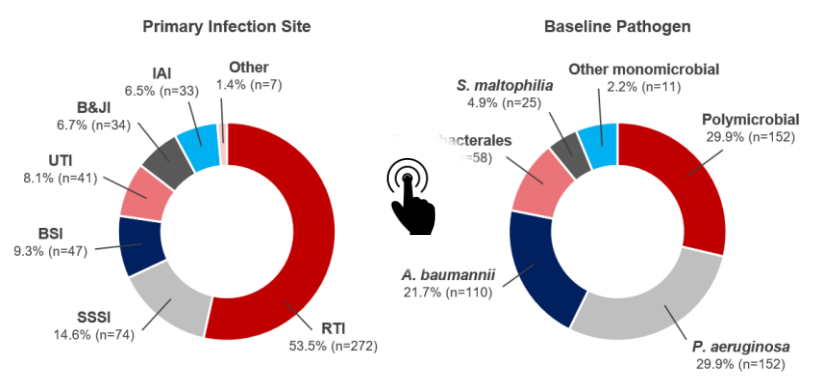
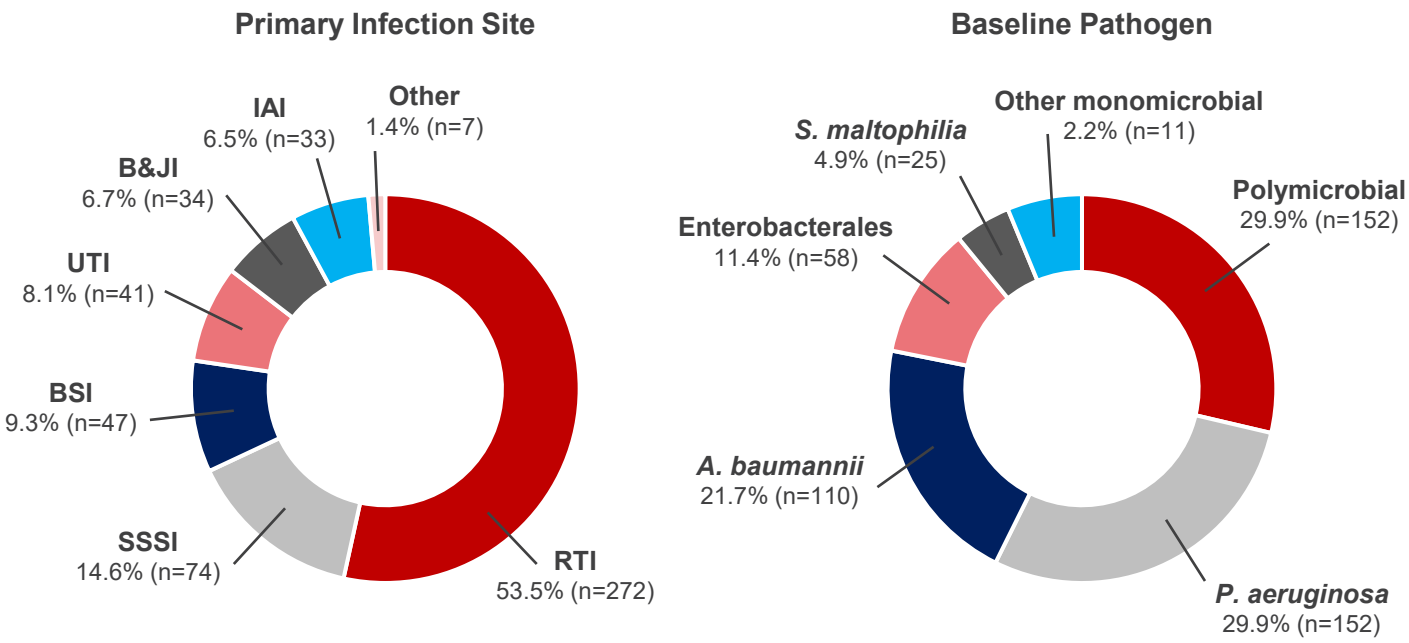


Figure 13. Primary Infection Site and Baseline Pathogen in US Patients (N=508)[4]



Abbreviations: B&JI, bone and joint infection; BSI, bloodstream infection; IAI, intra-abdominal infection; RTI, respiratory tract infection; SSSI, skin and skin structure infection; US, United States; UTI, urinary tract infection.
Figure adapted from Clancy et al. IDWeek. 2025.

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Subgroup Analyses (US Cohort): Early Treatment

Results (Cont.)[4]

- Overall, the clinical cure rate was 70.1%, clinical response at EOT was 77.8%, and the 30-day ACM was 20.7% – see **Table 3** for outcomes for the various infection sites
- The clinical cure rates for patients with documented *P. aeruginosa*, *A. baumannii*, and Enterobacterales infections were 70.4%, 68.2%, and 79.3%, respectively, while the respective 30-day ACM rates were 20.4%, 22.7%, and 17.2% – see **Figure 14**
- Rates of clinical cure and clinical response at EOT were lower, and 30-day ACM was higher, when cefiderocol was used as salvage treatment compared with either documented infections or empiric use – see **Figure 15**

Table 3. Clinical Outcomes in US Patients Treated with Cefiderocol by Infection Site[4]

Site of Infection	Clinical Cure	Clinical Response at EOT	30-Day ACM
	n (%) (95% CI)		
Overall (N=508)	356 (70.1) (66.1–74.1)	395 (77.8) (74.1–81.4)	105 (20.7) (17.2–24.2)
Respiratory tract (N=272)	176 (64.7) (59–70.4)	208 (76.5) (71.4–81.5)	70 (25.7) (20.5–30.9)
Bloodstream (N=47)	37 (78.7) (67–90.4)	38 (80.9) (69.6–92.1)	8 (17) (6.3–27.8)
Urinary tract (N=41)	35 (85 (74.6–	5 (85.4) 6–96.2)	6 (14.6) (3.8–25.5)
Skin and skin structure (N=74)	57 ((67.4–	(79.7) .6–88.9)	8 (10.8) (3.7–17.9)
Intra-abdominal (N=33)	18 (54.5) (37.6–71.5)	19 (57.6) (40.7–74.4)	6 (18.2) (5–31.3)
Bone and joint (N=34)	27 (79.4) (65.8–93)	30 (88.2) (77.4–99.1)	6 (17.6) (4.8–30.5)
Other (N=7)	6 (85.7) (59.8–100)	6 (85.7) (59.8–100)	1 (14.3) (0–40.2)

Figure 14. Clinical Outcomes by Causative Pathogen among US Patients[4]

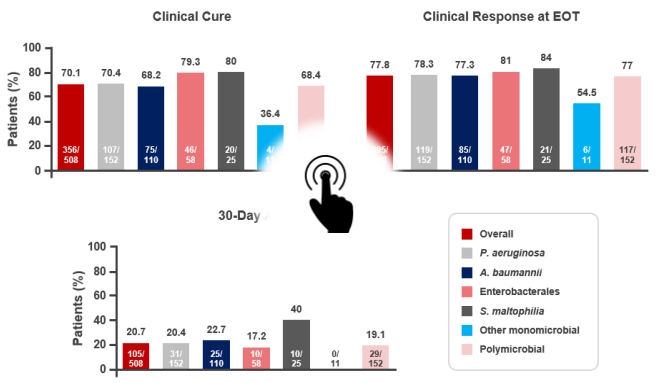
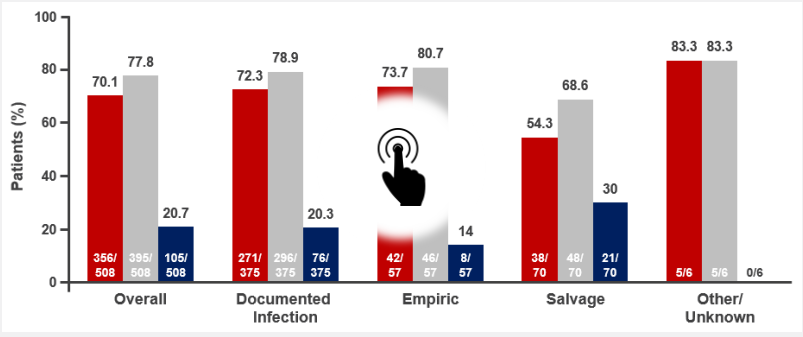


Figure 15. Clinical Outcomes by Reason for Cefiderocol Utilization among US Patients[4]



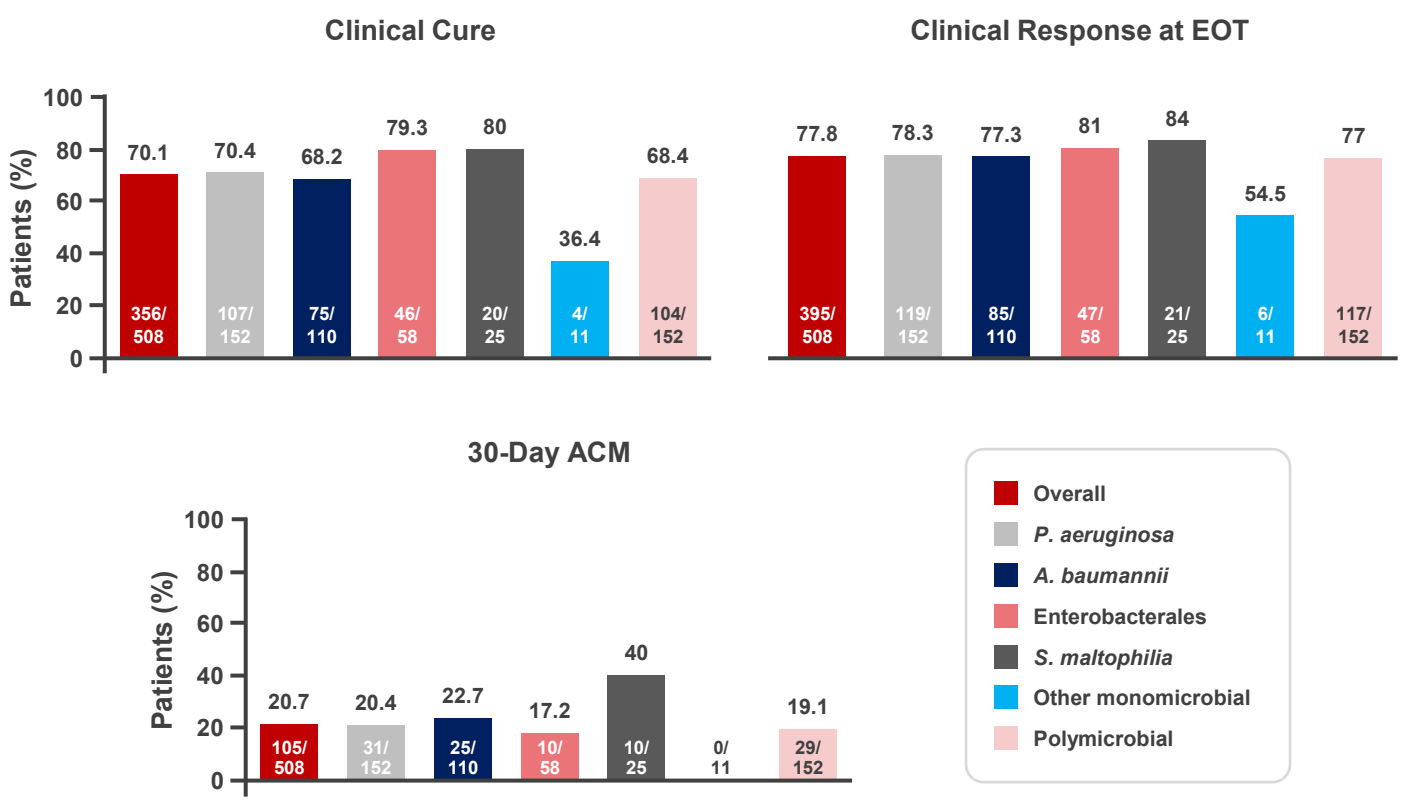
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Urinary tract (N=41)	35 (85.4) (74.6–96.2)	35 (85.4) (74.6–96.2)	6 (14.6) (3.8–25.5)
Skin and skin structure (N=74)	57 (77) (67.4–86.6)	59 (79.7) (70.6–88.9)	8 (10.8) (3.7–17.9)
Intra-abdominal (N=33)	18 (54.5) (37.6–71.5)	19 (57.6) (40.7–74.4)	6 (18.2) (5–31.3)
Bone and joint (N=34)	27 (79.4) (65.8–93)	30 (88.2) (77.4–99.1)	6 (17.6) (4.8–30.5)
Other (N=7)	6 (85.7) (59.8–100)	6 (85.7) (59.8–100)	1 (14.3) (0–40.2)

Abbreviations: ACM, all-cause mortality; EOT, end of treatment.
Table adapted from Clancy et al. IDWeek. 2025.

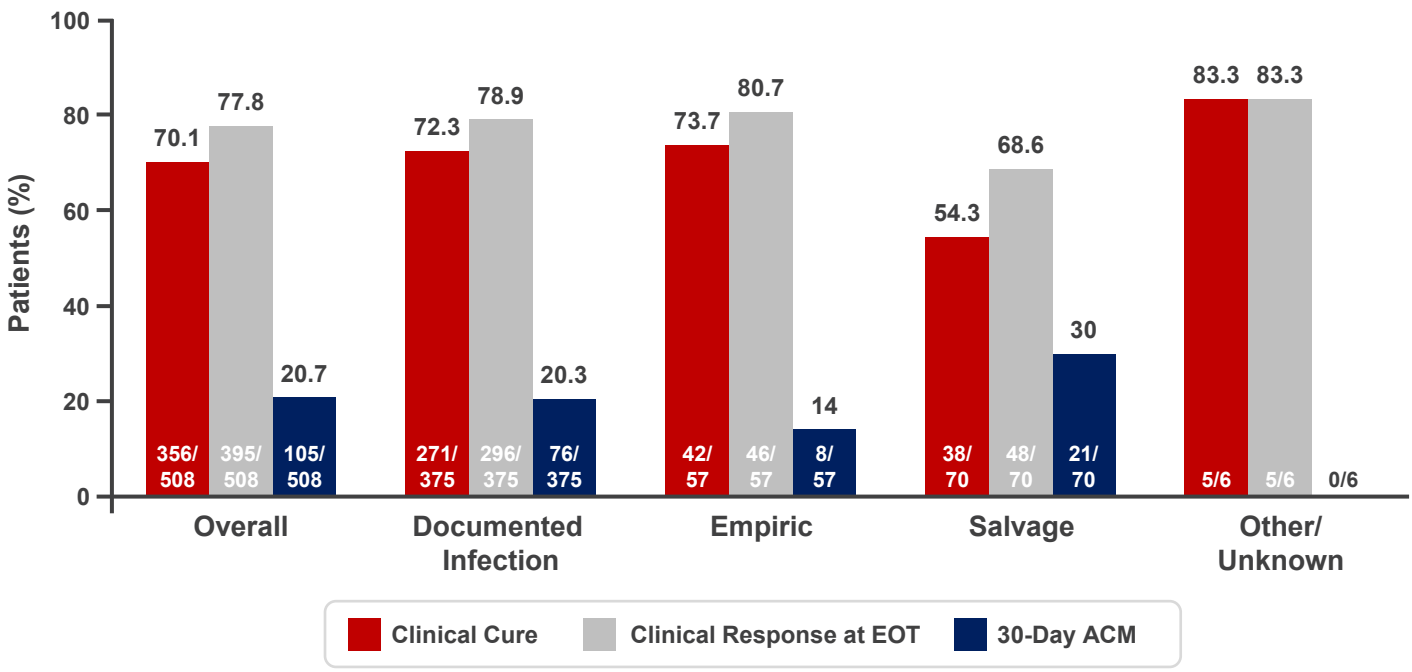
Figure 14. Clinical Outcomes by Causative Pathogen among US Patients[4]



Abbreviations: ACM, all-cause mortality; EOT, end of treatment; US, United States.
Figure adapted from Clancy et al. IDWeek. 2025.

Subgroup Analyses (US Cohort): Early Treatment

Figure 15. Clinical Outcomes by Reason for Cefiderocol Use among US Patients[4]



Abbreviations: ACM, all-cause mortality; EOT, end of treatment; GNBI, Gram-negative bacterial infection; US, United States.
Figure adapted from Clancy et al. IDWeek. 2025.

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Interim Analysis (US Cohort)

Clancy et al (2024) presented data from 244 patients enrolled from US medical centers between November 2020 and March 2023.[5,6]

Results

Patient Characteristics[5,6]

- The median (IQR) age of patients was 56 (43.5–65) years
- Patients ≥65 years old comprised 27% of the study population, and 61.5% were male
- Two-thirds of patients were admitted from an urgent or emergency unit
- The median (IQR) CCI was 2 (1–4)
- At least 1 comorbid condition was present in 95.9% of patients, the most common being moderate or severe kidney disease (21.7%), chronic pulmonary disease (19.7%), diabetes mellitus with no complications (19.3%), diabetes mellitus with end-organ damage (18.4%), CVD or TIA (12.3%), COVID-19 (12.3%), and CHF (11.5%)

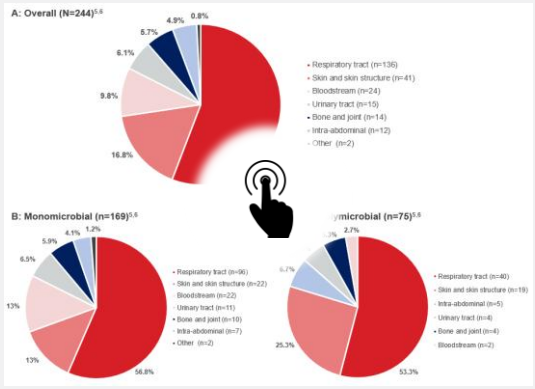
Infection Type[5,6]

- Of the 244 patients, 169 (69.3%) were treated with cefiderocol for monomicrobial infections, while 75 (30.7%) had polymicrobial infections. See **Table 4** for the distribution of pathogens
- Overall, the top 5 infection sites were the respiratory tract (55.7%), skin and skin structure (16.8%), bloodstream (9.8%), urinary tract (6.1%) and bone/joint (5.7%) – see **Figure 16**

Table 4. Pathogen Distribution[5,6]

Overall Population (N=244)			
Monomicrobial infections	**n=169 n (%)**	**Polymicrobial infections[a]**	**n=75 n (%)**
P. aeruginosa	82 (33.6)	*P. aeruginosa* + Enterobacterales	20 (8.2)
A. baumannii	43 (17.6)	*A. baumannii* + Enterobacterales	10 (4.1)
Enterobacterales	26 (10.7)	Enterobacterales + *P. aeruginosa*	7 (2.9)
S. maltophilia	10 (4.1)	Enterobacterales + *S. maltophilia*	8 (3.3)
Other	8 (3.3)	*A. baumannii* + *S. maltophilia*	2 (0.8)
		Other combinations of 2 pathogens	11 (4.5)
		Other combinations of ≥3 pathogens	17 (7)

Figure 16. Infection Sites[5,6]



- The pathogen distribution by infection site for monomicrobial and polymicrobial infections are provided in **Appendix Table 1**

Table 4. Pathogen Distribution[5,6]

Overall Population (N=244)			
Monomicrobial infections	**n=169 n (%)**	**Polymicrobial infections[a]**	**n=75 n (%)**
P. aeruginosa	82 (33.6)	*P. aeruginosa* + Enterobacterales	20 (8.2)
A. baumannii	43 (17.6)	*A. baumannii* + Enterobacterales	10 (4.1)
Enterobacterales	26 (10.7)	*A. baumannii* + *P. aeruginosa*	7 (2.9)
S. maltophilia	10 (4.1)	*P. aeruginosa* + *S. maltophilia*	8 (3.3)
Other	8 (3.3)	*A. baumannii* + *S. maltophilia*	2 (0.8)
		Other combinations of 2 pathogens	11 (4.5)
		Other combinations of ≥3 pathogens	17 (7)

[a]Polymicrobial infections defined as ≥2 different Gram-negative pathogens from the index culture of the same site.
Table adapted from Clancy et al. *Infect Drug Resist*. 2024.

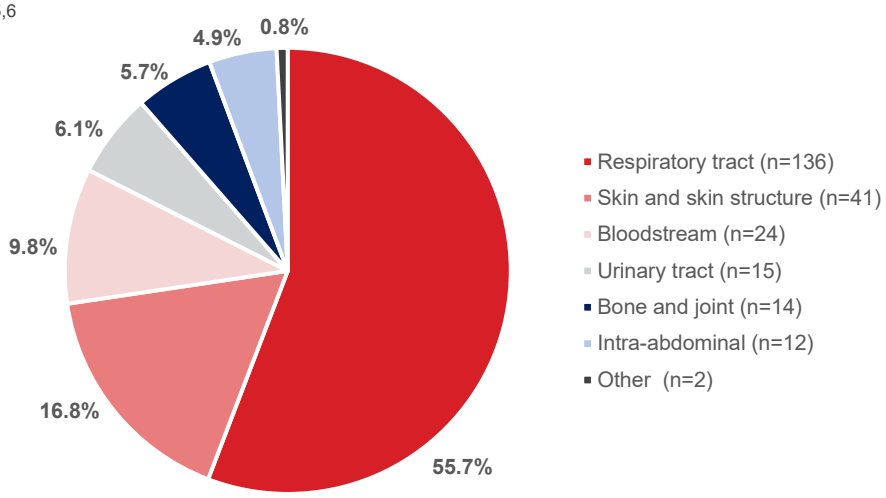
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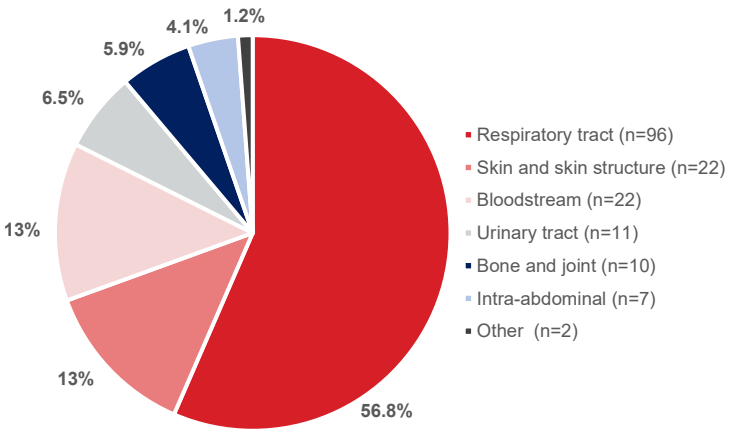
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Figure 16. Infection Sites[5,6]

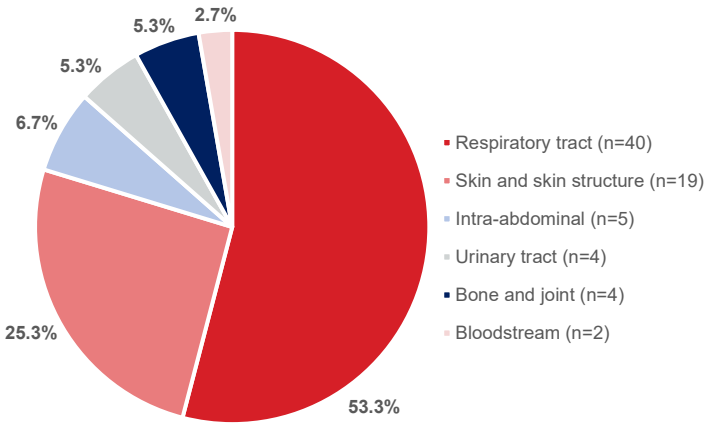
A: Overall (N=244)[5,6]



B: Monomicrobial (n=169)[5,6]



C: Polymicrobial (n=75)[5,6]



Other: Single site that is not included in any of the above categories.
Figure adapted from Clancy et al. *Infect Drug Resist*. 2024 (plus Supplementary Material).

Interim Analysis (US Cohort)

Results (Cont.)

Infection Type (Cont.)[5,6]

- Susceptibility test results were available for 229 patients, of which 209 (91.3%) were CR
  - The most common risk factors for CR included:
    - Hospitalization in the previous 6 months (66.8%)
    - Mechanical ventilation prior to the index culture symptom (57.8%)
    - Previous administration of a carbapenem or did not respond to a carbapenem within 30 days (33.2%)
    - History of a bacterial infection due to a CR Gram-negative pathogen or colonization within the previous 6 months (32.4%)
- Susceptibility test results for cefiderocol were available for 142 patients, of which 124 (87.3%) were shown to be susceptible

Resource Utilization[5,6]

- A total of 152 patients (62.3%) stayed in the ICU while receiving treatment with cefiderocol. The median (IQR) length of stay in the ICU was 39 (16–78) days
- Organ support modality (not mutually exclusive) was commonly received (51.6% of patients), including:
  - Mechanical ventilation (45.5%)
  - Vasopressor use (26.2%)
  - CRRT (13.5%)
  - ECMO (4.1%)
  - Dialysis (2.9%)
- A total of 102 patients (41.8%) were transferred to a different healthcare facility, 52 patients (21.3%) were discharged home, while 10 patients (4.1%) went to hospice care
- At the time of transfer or discharge, 48 patients (19.7%) were receiving antibiotics with Gram-negative activity

Interim Analysis (US Cohort)

Results (Cont.)

Cefiderocol Usage Pattern[5,6]

- For the 244 patients, cefiderocol was used for a documented infection (74.2%), as salvage therapy (12.7%), or used empirically (11.1%)
  - There were 115 (47.1%) patients that received previous antimicrobials within 14 days of initiating cefiderocol treatment
- Cefiderocol was administered for a median (IQR) duration of 12 (8–18.5) days. See **Figure 17** for the cefiderocol treatment duration among the study population
  - There were 110 patients (45.1%) that received cefiderocol treatment for at least 14 days
- There were 171 (70.1%) patients that received concomitant antibiotics during cefiderocol treatment
  - The concomitant antibiotics most commonly used included aminoglycosides, polymyxins, and tetracyclines (see **Appendix Table 2**)
- In 34 (13.9%) patients, additional antibiotics were initiated at the end of the treatment with cefiderocol and up to 2 days afterwards (3 calendar days)

Figure 17. Cefiderocol Treatment Duration (Days)[5,6]

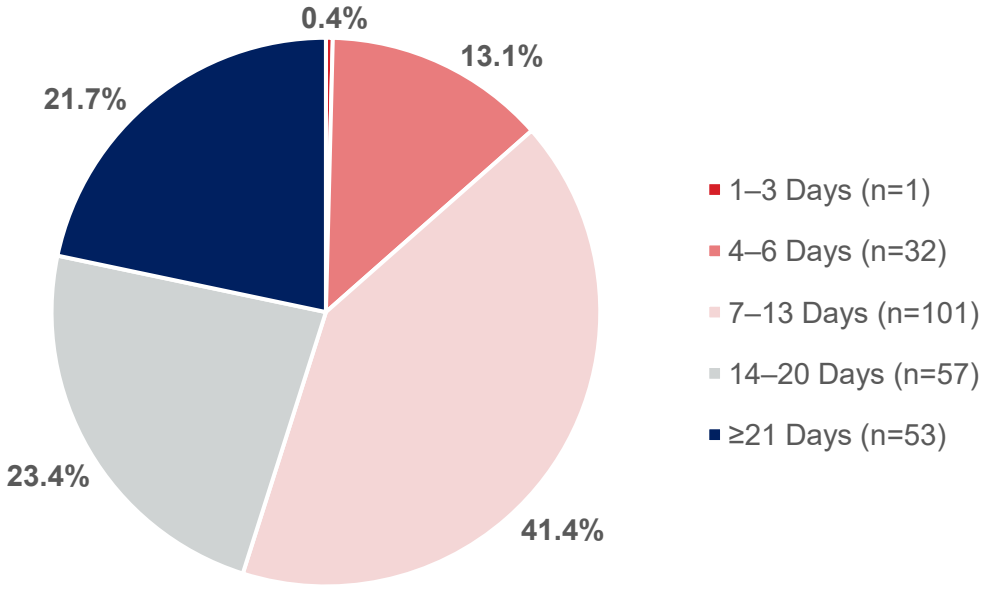


Figure adapted from Clancy et al. *Infect Drug Resist*. 2024.

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Interim Analysis (US Cohort)

Results (Cont.)

Outcomes[5,6]

Clinical Cure

- Clinical cure was achieved by 158 (64.8%) patients in the overall study population
  - Clinical cure rates were higher in patients that did not receive organ support, as well as in patients that did not receive cefiderocol while in the ICU – see **Table 5**
  - In addition, clinical cure rates were higher in patients that received cefiderocol as empiric therapy compared to patients that were administered cefiderocol as salvage treatment or for a documented infection
  - Overall, the clinical cure rate was 93.3% for patients with UTIs. For patients with RTIs or BSIs, clinical cure rates were 59.6% and 58.3%, respectively
    - See **Appendix Table 3** for outcomes at the various infection sites (in both monomicrobial and polymicrobial infections)
  - Clinical cure rates were similar for patients with monomicrobial (63.3%) or polymicrobial infections (68%)
    - Depending on the pathogen, clinical cure rates for monomicrobial infections were 60.5–73.1% – see **Table 5**
    - Polymicrobial infections involving *P. aeruginosa* had a 42.9–75% clinical cure rate
    - Polymicrobial infections involving *A. baumannii* had a clinical cure rate of 42.9–100%
  - For patients with pathogens that were CR (or non-susceptible), clinical cure was achieved in 135/209 (64.6%) patients

Table 5. Clinical Outcomes[5,6]

	n	Clinical Response at EOT[a] n (%)	Clinical Cure[b] n (%)	14-Day ACM n (%)	30-Day ACM n (%)
Overall	244	181 (74.2)	158 (64.8)	23 (9.4)	45 (18.4)
Infection site					
Respiratory	136	97 (71.3)	81 (59.6)	15 (11)	31 (22.8)
Bloodstream	24	17 (70.8)	14 (58.3)	3 (12.5)	5 (20.8)
Urinary	15	14 (93.3)	14 (93.3)	1 (6.7)	1 (6.7)
Intra-abdominal	12	6 (50)	5 (41.7)	2 (16.7)	3 (25)
Bone and joint	14	12 (85.7)	10 (71.4)	0 (0)	2 (14.3)
Skin and skin structure	41	33 (80.5)	32 (78)	2 (4.9)	3 (7.3)
Other[c]	2	2 (100)	2 (100)	0 (0)	0 (0)
ICU stay when cefiderocol was initiated or within 2 days after initiation					
Yes	152	102 (67.1)	83 (54.6)	19 (12.5)	36 (23.7)
No	92		75 (81.5)	4 (4.3)	9 (9.8)
Received organ support when cefiderocol was initiated[d]					
Yes	126		62 (49.2)	18 (14.3)	34 (27)
Mechanical ventilation	111		54 (48.6)	16 (14.4)	31 (27.9)
Chronic renal replacement therapy	33		9 (27.3)	7 (21.2)	16 (48.5)
Extracorporeal membrane oxygenation	10		4 (40)	2 (20)	4 (40)
Vasopressors	64		23 (35.9)	10 (15.6)	21 (32.8)
Dialysis	7		5 (71.4)	1 (14.3)	1 (4.3)
No	118		96 (81.4)	5 (4.2)	11 (9.3)
Reason for initiating cefiderocol					
Documented infection	181	133 (73.5)	117 (64.6)	17 (9.4)	37 (20.4)
Empiric for suspected CR Gram-negative infection	27	24 (88.9)	21 (77.8)	0 (0)	1 (3.7)
Salvage treatment (not previously treated or prior antibiotic failure)	31	20 (64.5)	16 (51.6)	6 (19.4)	7 (22.6)
Other reasons including unknown	5	4 (80)	4 (80)	0 (0)	0 (0)
Time from positive culture to first cefiderocol dose					
≤2 days	33	28 (84.8)	24 (72.7)	2 (6.1)	2 (6.1)
3–4 days	64	50 (78.1)	43 (67.2)	4 (6.3)	12 (18.8)
5–7 days	78	51 (65.4)	46 (59)	10 (12.8)	17 (21.8)
>7 days	59	46 (78)	42 (71.2)	7 (11.9)	10 (16.9)
Cefiderocol administered prior to index culture	10	6 (60)	3 (30)	0 (0)	4 (40)

Interim Analysis (US Cohort)

Table 5. Clinical Outcomes[5,6]

	n	Clinical Response at EOT[a] n (%)	Clinical Cure[b] n (%)	14-Day ACM n (%)	30-Day ACM n (%)
Overall	244	181 (74.2)	158 (64.8)	23 (9.4)	45 (18.4)
Infection site					
Respiratory	136	97 (71.3)	81 (59.6)	15 (11)	31 (22.8)
Bloodstream	24	17 (70.8)	14 (58.3)	3 (12.5)	5 (20.8)
Urinary	15	14 (93.3)	14 (93.3)	1 (6.7)	1 (6.7)
Intra-abdominal	12	6 (50)	5 (41.7)	2 (16.7)	3 (25)
Bone and joint	14	12 (85.7)	10 (71.4)	0 (0)	2 (14.3)
Skin and skin structure	41	33 (80.5)	32 (78)	2 (4.9)	3 (7.3)
Other[c]	2	2 (100)	2 (100)	0 (0)	0 (0)
ICU stay when cefiderocol was initiated or within 2 days after initiation					
Yes	152	102 (67.1)	83 (54.6)	19 (12.5)	36 (23.7)
No	92	79 (85.9)	75 (81.5)	4 (4.3)	9 (9.8)
Received organ support when cefiderocol was initiated or within 2 days after initiation					
Yes	126	79 (62.7)	62 (49.2)	18 (14.3)	34 (27)
Mechanical ventilation	111	68 (61.3)	54 (48.6)	16 (14.4)	31 (27.9)
Chronic renal replacement therapy	33	13 (39.4)	9 (27.3)	7 (21.2)	16 (48.5)
Extracorporeal membrane oxygenation	10	7 (70)	4 (40)	2 (20)	4 (40)
Vasopressors	64	33 (51.6)	23 (35.9)	10 (15.6)	21 (32.8)
Dialysis	7	5 (71.4)	5 (71.4)	1 (14.3)	1 (4.3)
No	118	102 (86.4)	96 (81.4)	5 (4.2)	11 (9.3)
Reason for initiating cefiderocol					
Documented infection	181	133 (73.5)	117 (64.6)	17 (9.4)	37 (20.4)
Empiric for suspected CR Gram-negative infection	27	24 (88.9)	21 (77.8)	0 (0)	1 (3.7)
Salvage treatment (not previously treated or prior antibiotic failure)	31	20 (64.5)	16 (51.6)	6 (19.4)	7 (22.6)
Other reasons including unknown	5	4 (80)	4 (80)	0 (0)	0 (0)
Time from positive culture to first cefiderocol dose					
≤2 days	33	28 (84.8)	24 (72.7)	2 (6.1)	2 (6.1)
3–4 days	64	50 (78.1)	43 (67.2)	4 (6.3)	12 (18.8)
5–7 days	78	51 (65.4)	46 (59)	10 (12.8)	17 (21.8)
>7 days	59	46 (78)	42 (71.2)	7 (11.9)	10 (16.9)
Cefiderocol administered prior to index culture	10	6 (60)	3 (30)	0 (0)	4 (40)

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Interim Analysis (US Cohort)

Table 5 (Cont.). Clinical Outcomes[5,6]

	n	Clinical Response at EOT[a] n (%)	Clinical Cure[b] n (%)	14-Day ACM n (%)	30-Day ACM n (%)
Monomicrobial infections by pathogen	169	125 (74)	107 (63.3)	20 (11.8)	35 (20.7)
P. aeruginosa	82	61 (74.4)	53 (64.6)	11 (13.4)	21 (25.6)
A. baumannii	43	32 (74.4)	26 (60.5)	4 (9.3)	8 (18.6)
Enterobacterales	26	20 (76.9)	19 (73.1)	4 (15.4)	4 (15.4)
S. maltophilia	10	8 (80)	7 (70)	1 (10)	2 (20)
Other	8	4 (50)	2 (25)	0 (0)	0 (0)
Polymicrobial infections by pathogen	75	56 (74.7)	51 (68)	3 (4)	10 (13.3)
A. baumannii + *P. aeruginosa*	7	4 (57.1)	3 (42.9)	2 (28.6)	2 (28.6)
A. baumannii + Enterobacterales	10	8 (80)	8 (80)	1 (10)	3 (30)
A. baumannii + *S. maltophilia*	2	2 (100)	2 (100)	0 (0)	0 (0)
P. aeruginosa + Enterobacterales	20	15 (75)	13 (65)	0 (0)	2 (10)
P. aeruginosa + *S. maltophilia*	8	7 (87.5)	6 (75)	0 (0)	0 (0)
Other combinations of 2 pathogens	11	10 (90.9)	9 (81.8)	0 (0)	1 (9.1)
Other combinations of ≥3 pathogens	17	10 (58.8)	10 (58.8)	0 (0)	2 (11.8)
CR status					
Resistant (or non-susceptible)	209	155 (74.2)	135 (64.6)	21 (10)	41 (19.6)
Susceptible	20	15 (75)	13 (65)	1 (5)	2 (10)
Unknown or not tested	15	11 (73.3)	10 (66.7)	1 (6.7)	2 (13.3)

Positive culture: defined as the sample collected prior to starting cefiderocol that resulted in cefiderocol prescription.
The index culture may have been collected and tested in the outpatient setting prior to hospitalization.
Abbreviations: ACM, all-cause mortality; CR, carbapenem-resistant; EOT, end of treatment; ICU, intensive care unit.
[a]Clinical response: signs/symptoms improved or resolved at EOT (patients who died at EOT were categorized as failures regardless of reasons).
[b]Clinical cure: signs/symptoms improved or resolved at EOT without a relapse or reinfection after EOT.
[c]Other: single infection site not included in any of the categories above.
Table adapted from Clancy et al. *Infect Drug Resist*. 2024 (plus Supplementary Material).

Interim Analysis (US Cohort)

Results (Cont.)

Outcomes[5,6]

Mortality

- In the overall study population (N=244), a total of 23 (9.4%) patients had died by Day 14
  - The overall ACM at Day 14 for patients with the following infections was 12.5% in BSIs, 11% in RTIs, and 6.7% in UTIs
- By Day 30, 45 (18.4%) patients had died
  - The ACM at Day 30 for patients with the following infections was 20.8% in BSIs, 22.8% in RTIs, and 6.7% in UTIs
- Overall, the ACM at Day 14 and Day 30 was 11.8% and 20.7%, respectively, for monomicrobial infections, and 4% and 13.3%, respectively, for polymicrobial infections
  - For patients with pathogens that were CR (or NS), the ACM at Day 14 and Day 30 was 10% and 19.6%, respectively. The ACM at Day 14 and Day 30 for patients with carbapenem-susceptible pathogens was 5% and 10%, respectively

Safety

- Cefiderocol was well tolerated
- There were 5 (2%) patients that experienced a total of 6 ADRs – see **Table 6**
  - 1 of the 5 patients experienced a serious ADR (interstitial nephritis, AKI)
- Cefiderocol treatment was discontinued in 2 patients due to ADRs

Table 6. Safety[6]

AEs	N=244 n (%)
Patients with ≥1 ADR (including serious ADRs)	5 (2)
Total ADRs (by event)	6 (2.5)
Interstitial nephritis, AKI (serious ADR)	1 (0.4)
Diarrhea (suspected *Clostridium difficile* but not confirmed)	1 (0.4)
Diarrhea (possibly due to cefiderocol or daptomycin)	1 (0.4)
Elevated liver enzymes	1 (0.4)
Rash	1 (0.4)
Urticarial rash	1 (0.4)

Abbreviations: ADR, adverse drug reaction; AE, adverse event; AKI, acute kidney injury.
Table adapted from Clancy et al. *Infect Drug Resist*. 2024 (Supplementary Material).

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Relevant Prescribing Information

Fetroja® is indicated in patients 18 years of age or older for the treatment of:[7]

- Complicated urinary tract infections (cUTIs), including pyelonephritis caused by the following susceptible Gram-negative microorganisms:
  - *Escherichia coli*
  - *Klebsiella pneumoniae*
  - *Proteus mirabilis*
  - *Pseudomonas aeruginosa*
  - *Enterobacter cloacae* complex
- Hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP), caused by the following susceptible Gram-negative microorganisms:
  - *Acinetobacter baumannii* complex
  - *Escherichia coli*
  - *Enterobacter cloacae* complex
  - *Klebsiella pneumoniae*
  - *Pseudomonas aeruginosa*
  - *Serratia marcescens*

Fetroja is contraindicated in:[7]

- Patients with a known history of severe hypersensitivity to cefiderocol or other beta-lactam antibacterial drugs, or any other component of **Fetroja**

Please read the attached **Fetroja Full Prescribing Information**

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Abbreviations

ACM	all-cause mortality	ECMO	extracorporeal membrane oxygenation
ADR	adverse drug reaction	EOT	end of treatment
AE	adverse event	FDA	US Food and Drug Administration
AKI	acute kidney injury	GNB	Gram-negative bacteria
B&JI	bone and joint infection	GNBI	Gram-negative bacterial infection
BL–BLI	β-lactam–β-lactamase inhibitor	HABP	hospital-acquired bacterial pneumonia
BSI	bloodstream infection	IAI	intra-abdominal infection
Carb-NS	carbapenem-nonsusceptible	ICU	intensive care unit
CCI	Charlson Comorbidity Index	IQR	interquartile range
CHF	congestive heart failure	NS	non-susceptible
CI	confidence interval	PROVE	Retrospective Cefiderocol Chart Review Study
CKD	chronic kidney disease	RTI	respiratory tract infection
COVID-19	coronavirus disease 2019	S	susceptible
CR	carbapenem-resistant	SSSI	skin and skin structure infection
CR-GNB	carbapenem-resistant Gram-negative bacteria	TIA	transient ischemic attack
CR-GNBI	carbapenem-resistant Gram-negative bacterial infection	US	United States
CRRT	chronic renal replacement therapy	UTI	urinary tract infection
cUTI	complicated urinary tract infection	VABP	ventilator-associated bacterial pneumonia
CVD	cerebrovascular disease		

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6. Clancy CJ, Cornely OA, Marcella SW, Nguyen ST, Gozalo L, Cai B. Effectiveness and safety of cefiderocol in clinical practice for treatment of patients with Gram-negative bacterial infections: US interim results of the PROVE study [Supplementary Material]. *Infect Drug Resist*. 2024;17:4427-4443. [Web Link]

7. Fetroja® (cefiderocol) for injection, for intravenous use [Prescribing Information]. Shionogi Inc.

Enclosure

Fetroja® (cefiderocol) for injection, for intravenous use [Prescribing Information]. Shionogi Inc.

This medical response contains information in addition to that provided in the Fetroja® (cefiderocol) for injection, for intravenous use Full Prescribing Information approved by the U.S. Food and Drug Administration (FDA). Shionogi does not recommend the use of Fetroja in any manner other than as described in the Full Prescribing Information. **Please read the attached Fetroja Full Prescribing Information.**

Appendices

Appendix Table 1. Distribution of Pathogens and Infection Sites (Monomicrobial and Polymicrobial Infections)[3]

	Respiratory	Bloodstream	Urinary	Intra-abdominal	Bone and Joint	Skin and Skin Structure	Other	Overall
	n=136	n=24	n=15	n=12	n=14	n=41	n=2	N=244
Monomicrobial infections by pathogen	96 (70.6)	22 (91.7)	11 (73.3)	7 (58.3)	10 (71.4)	21 (51.2)	2 (100)	169 (69.3)
A. baumannii	22 (16.2)	7 (29.2)	2 (13.3)	0 (0)	5 (35.7)	7 (17.1)	0 (0)	43 (17.6)
P. aeruginosa	56 (41.2)	12 (50)	2 (13.3)	2 (16.7)	3 (21.4)	6 (14.6)	1 (50)	82 (33.6)
Enterobacterales	7 (5.1)	2 (8.3)	7 (46.7)	4 (33.3)	2 (14.3)	3 (7.3)	1 (50)	26 (10.7)
S. maltophilia	6 (4.4)	0 (0)	0 (0)	1 (8.3)	0 (0)	3 (7.3)	0 (0)	10 (4.1)
Other	5 (3.7)	1 (4.2)	0 (0)	0 (0)	0 (0)	2 (4.9)	0 (0)	8 (3.3)
Polymicrobial infections by pathogen	40 (29.4)	2 (8.3)	4 (26.7)	5 (41.7)	4 (28.6)	20 (48.8)	0 (0)	75 (30.7)
A. baumannii + *P. aeruginosa*	3 (2.2)	0 (0)	0 (0)	1 (8.3)	0 (0)	3 (7.3)	0 (0)	7 (2.9)
A. baumannii + Enterobacterales	4 (2.9)	0 (0)	0 (0)	0 (0)	2 (14.3)	4 (9.8)	0 (0)	10 (4.1)
A. baumannii + *S. maltophilia*	2 (1.5)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (0.8)
P. aeruginosa + Enterobacterales	9 (6.6)	1 (4.2)	1 (6.7)	3 (25)	1 (7.1)	5 (12.2)	0 (0)	20 (8.2)
P. aeruginosa + *S. maltophilia*	7 (5.1)	0 (0)	1 (6.7)	0 (0)	0 (0)	0 (0)	0 (0)	8 (3.3)
Any other combination of 2 pathogens	4 (2.9)	0 (0)	1 (6.7)	1 (8.3)	1 (7.1)	4 (9.8)	0 (0)	11 (4.5)
Any other combination of ≥3 pathogens	11 (8.1)	1 (4.2)	1 (6.7)	0 (0)	0 (0)	4 (9.8)	0 (0)	17 (7)

Table adapted from Clancy et al. *Infect Drug Resist*. 2024 (Supplementary Material).

This medical response contains information in addition to that provided in the Fetroja® (cefiderocol) for injection, for intravenous use Full Prescribing Information approved by the U.S. Food and Drug Administration (FDA). Shionogi does not recommend the use of Fetroja in any manner other than as described in the Full Prescribing Information. **Please read the attached Fetroja Full Prescribing Information.**

Appendices (Cont.)

Appendix Table 2. Concomitant Antimicrobial Agents Administered with Cefiderocol[3]

Antimicrobial/antifungal agents initiated during and continued with cefiderocol treatment (and potentially maintained afterwards)	N=106 n (%)
Tetracyclines	22 (20.8)
Colistin and/or polymyxin	13 (12.3)
Aminoglycosides	12 (11.3)
Penicillins with β-lactamase inhibitors	7 (6.6)
Fluoroquinolones	7 (6.6)
Trimethoprim-sulfamethoxazole	6 (5.7)
Carbapenems	3 (2.8)
Carbapenems with β-lactamase inhibitors	3 (2.8)
Ceftazidime-avibactam	3 (2.8)
Ceftolozane-tazobactam	2 (1.9)
Penicillins	2 (1.9)
Other/miscellaneous antibiotic	1 (0.9)
Additional drugs other than Gram-negative antibiotic (include antifungal, etc.)	63 (59.4)
Antimicrobial/antifungal agents initiated before and potentially continued with cefiderocol treatment	**N=65 n (%)**
Tetracyclines	11 (16.9)
Aminoglycosides	6 (9.2)
Carbapenems	5 (7.7)
Fluoroquinolones	3 (4.6)
Ceftazidime-avibactam	2 (3.1)
Trimethoprim-sulfamethoxazole	2 (3.1)
Penicillins with β-lactamase inhibitors	2 (3.1)
Colistin and/or polymyxin	2 (3.1)
Carbapenems with β-lactamase inhibitors	1 (1.5)
Penicillins	1 (1.5)
Other/miscellaneous antibiotic	3 (4.6)
Additional drugs other than Gram-negative antibiotic (include antifungal, etc.)	41 (63.1)
Antimicrobial/antifungal agents initiated at the end of or following cefiderocol treatment	**N=34 n (%)**
Carbapenems	7 (20.6)
Ceftazidime-avibactam	6 (17.6)
Trimethoprim-sulfamethoxazole	4 (11.8)
Tetracyclines	4 (11.8)
Penicillins with β-lactamase inhibitors	4 (11.8)
Carbapenems with β-lactamase inhibitors	3 (8.8)
Ceftolozane-tazobactam	2 (5.9)
Colistin and/or polymyxin	2 (5.9)
Aminoglycosides	2 (5.9)
Fluoroquinolones	2 (5.9)
Other/miscellaneous antibiotic	3 (8.8)
Additional drugs other than Gram-negative antibiotic (include antifungal, etc.)	5 (14.7)

Table adapted from Clancy et al. *Infect Drug Resist*. 2024 (Supplementary Material).

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Appendices (Cont.)

Appendix Table 3. Outcomes for Monomicrobial and Polymicrobial Infections (Infection Sites)[3]

	n	Clinical Response at EOT[a] n (%)	Clinical Cure[b] n (%)	14-Day ACM n (%)	30-Day ACM n (%)
Overall	244	**181 (74.2)**	**158 (64.8)**	**23 (9.4)**	**45 (18.4)**
Monomicrobial infections	169	125 (74)	107 (63.3)	20 (11.8)	35 (20.7)
Respiratory	96	67 (69.8)	54 (56.3)	14 (14.6)	26 (27.1)
Bloodstream	22	15 (68.2)	12 (54.6)	3 (13.6)	5 (22.7)
Urinary	11	10 (90.9)	10 (90.9)	1 (9.1)	1 (9.1)
Intra-abdominal	7	3 (42.9)	2 (28.6)	2 (28.6)	3 (42.9)
Bone and joint	10	9 (90)	8 (80)	0 (0)	0 (0)
Skin and skin structure (not including underlying bone)	22	20 (90.9)	20 (90.9)	0 (0)	0 (0)
Other site[c]	2	2 (100)	2 (100)	0 (0)	0 (0)
Polymicrobial infections	75	56 (74.7)	51 (68)	3 (4)	10 (13.3)
Respiratory	40	30 (75)	27 (67.5)	1 (2.5)	5 (12.5)
Bloodstream	2	2 (100)	2 (100)	0 (0)	0 (0)
Urinary	4	4 (100)	4 (100)	0 (0)	0 (0)
Intra-abdominal	5	3 (60)	3 (60)	0 (0)	0 (0)
Bone and joint	4	3 (75)	2 (50)	0 (0)	2 (50)
Skin and skin structure	19	13 (68.4)	12 (63.2)	2 (10.5)	3 (15.8)
Other site[c]	0	0 (0)	0 (0)	0 (0)	0 (0)

Abbreviations: ACM, all-cause mortality; EOT, end of treatment.
[a]Clinical response: signs/symptoms improved or resolved at EOT (patients who died at EOT were categorized as failures regardless of reasons).
[b]Clinical cure: signs/symptoms improved or resolved at EOT without a relapse or reinfection after EOT.
[c]Other: single infection site not included in any of the categories above.
Table adapted from Clancy et al. *Infect Drug Resist*. 2024 (Supplementary Material).