NON-INTERVENTIONAL FINAL STUDY REPORT

Appendix 4: Statistical Analysis Plan

Title	Real-World Observational Study of Zavicefta® (ceftazidime-avibactam) to Characterize Use Patterns, Effectiveness and Safety – EZTEAM Study
Protocol number	C3591031
Active substance	Ceftazidime-avibactam, ACT: J01DD52
Medicinal product	Zavicefta® (ceftazidime-avibactam)
Study report	Version 1.0

STATISTICAL ANALYSIS PLAN AND TABLES AND LISTING SHELLS

Non-Interventional Study Protocol

C3591031

Real-World Observational Study of Zavicefta® (ceftazidime-avibactam) to Characterize Use Patterns, Effectiveness and Safety – EZTEAM Study

Statistical Analysis Plan (SAP)

Version: 1.0

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LIST OF ABBREVIATIONS

Abbreviation	Definition
AE	Adverse Event
APACHE	Acute Physiology and Chronic Health Evaluation Score
BMI	Body Mass Index
BSI	Bloodstream Infection
CAI	Community-Acquired Infection
CI	Confidence Interval
cIAI	Complicated Intra-Abdominal Infection
CLABSI	Central Line Associated Blood Stream Infection
COD	Clinical Outcomes Dataset
CT	Computerized Tomography
cUTI	Complicated Urinary Tract Infection
DCCI	Deyo-Charlson Comorbidity Index
eCRF	Electronic Case Report Form
ENR	Enrolled Dataset
FAS	Full Analysis Set
FAS72+	Analysis Set With At Least 72 Hours Exposure To Ceftazidime-Avibactam
FAS72-	Analysis Set With Less Than 72 Hours Exposure To Ceftazidime-Avibactam
HAI	Hospital-Acquired Infection
HAP	Hospital-Acquired Pneumonia
HCAI	Healthcare-Associated Infection
ICU	Intensive Care Unit
IV	Intravenous
LOS	Length of Stay
MDR	Multidrug-Resistant
MRI	Magnetic Resonance Imaging
NI	Non-Interventional
NIS	Non-Interventional Study
NP	Nosocomial Pneumonia
PT	Preferred Term
Q1	First Quartile
Q3	Third Quartile
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SAS	Statistical Analysis System (SAS Institute)
SD	Standard Deviation
SOC	System Organ Class
TEAE	Treatment Emergent Adverse Event
VAP	Ventilator-Associated Pneumonia

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1 INTRODUCTION

Note: in this document any text taken directly from the non-interventional study (NIS) study protocol is *italicized*.

This statistical analysis plan (SAP) describes the rules and conventions to be used in the presentation and analysis of the general treatment patterns, effectiveness, and the safety of ceftazidime-avibactam. It describes the data to be summarized and analyzed, including full details of the planned statistical analyses. This is a NIS based on the review of patient medical records.

This SAP is based on Protocol number C3591031, Version 4.0, Amendment 3 dated 29th April 2020.

1.1 RATIONALE AND BACKGROUND

Antimicrobial resistance and healthcare-associated infections (HCAIs) are well known public health threats. Gram-negative bacteria cause common hospital-acquired infections (HAIs) and infection with multidrug-resistant gram-negative organisms (MDRGNs), and have been associated with increased morbidity, mortality, and healthcare costs. Zavicefta® (ceftazidime-avibactam) is a unique combination of ceftazidime and avibactam developed to treat infections caused by gram-negative pathogens.

In the European Union, Russia and several Latin American countries, ceftazidime-avibactam is an approved treatment of complicated intra-abdominal infection (cIAI), complicated urinary tract infections (cUTIs), hospital-acquired pneumonia/ventilator-associated pneumonia (HAP/VAP), and infection due to aerobic gram-negative organisms with limited treatment options. Ceftazidime-avibactam has proven efficacious in non-inferiority Phase III trials but real-world evidence is needed about treatment characteristics, safety, and efficacy against Pseudomonas and multidrug-resistant (MDR) bacteria including carbapenem-resistant Enterobacteriaceae (CRE).

1.2 STUDY DESIGN

This is a NI medical chart review study aiming to examine the treatment patterns, effectiveness, and safety of ceftazidime-avibactam in approximately 12 countries and 63 sites in Europe (including Russia) and Latin America.

Patients treated with at least one dose of ceftazidime-avibactam (for the indication that is approved as per country label) in routine clinical practice at a participating site since 01 January 2018 or the date of launch in the country if after 2018 can be enrolled.

As this is an observational study, patients are treated as per local label based on the standard of care at the discretion of their physician. No drugs are supplied for this study and patients receive treatment through standard local practice. Patients treated as part of a compassionate program of ceftazidime-avibactam are not eligible to participate in the study.

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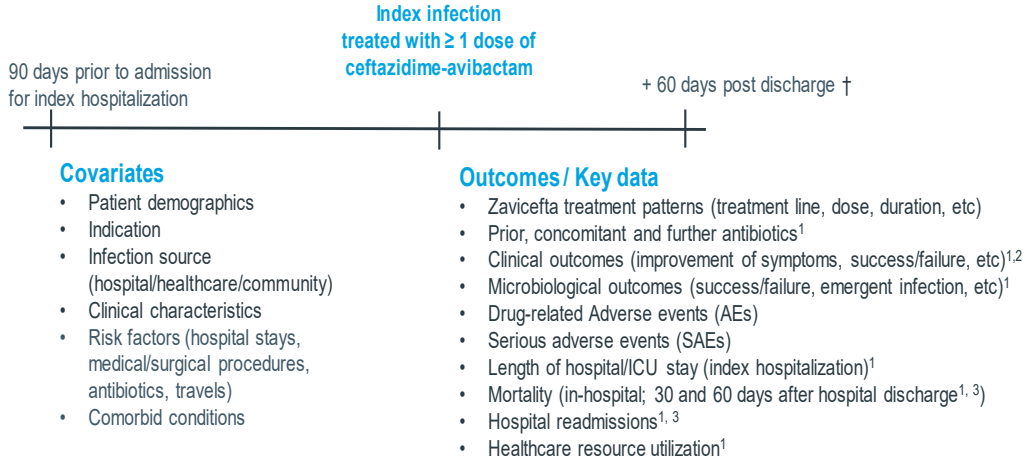
All data will be collected through the abstraction of hospital medical records. Collected study data will include but will not be limited to patient characteristics, clinical and microbiological characteristics of the infection, and treatment patterns, effectiveness, and safety of ceftazidime-avibactam. The study data collection and assessment schedule are described in Figure 1.

Figure 1. Study Flow Chart



[1] Indicates outcome that will be examined for patients exposed to ceftazidime-avibactam for ≥ 72 hours.
[2] Microbiological cultures performed during hospitalization.
[3] Information about hospital readmissions or death after hospital discharge not available via medical chart abstraction will be ascertained by contacting the patient or their legal representative by phone >60 days after hospital discharge
† Patients followed from ceftazidime-avibactam initiation until 60 days after hospital discharge or another censoring event (in-hospital death, withdrawal from the study, or loss-to-follow-up, whichever occurs first). Data will be abstracted from patient medical charts.

Patients who were exposed to ceftazidime-avibactam for ≥72 hours will be eligible for effectiveness analyses, including evaluation of treatment success. To avoid a selection bias that could result from restricting to patients with extended exposure, a small set of data elements will be collected and analyzed among patients with <72 hours of exposure. These data include details about exposure, indication, and safety. Safety data will be analyzed for all patients enrolled.

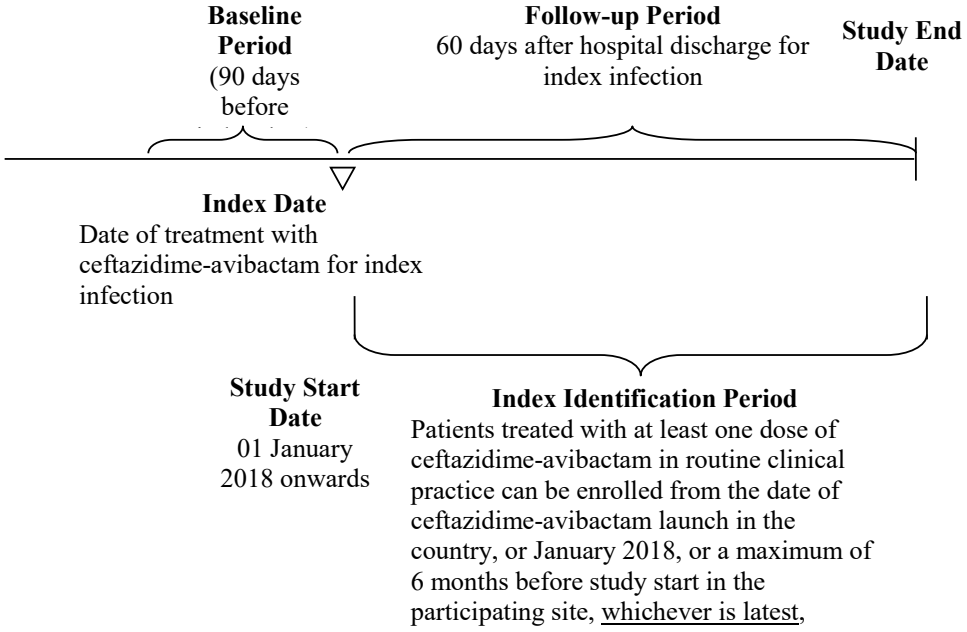
Patients who meet all the inclusion and exclusion criteria will be followed through their medical records up to 60 days after hospital discharge, death, withdrawal from the study, or loss-to-follow-up, whichever occurs first.

Besides routine treatment, no clinic visits are required as part of participation in this study. All data is intended to be collected by referencing the medical record. For patients missing any of the requested information, data will be reported as missing. Eligibility in the study has been summarized below in Section 3.2. *Patients participating in clinical*

trials are excluded from this study because protocol driven activities may be outside of normal practice and could confound safety assessments.

The study patient flow chart of events is presented in Figure 2.

Figure 2. Patient Flow Chart



1.3 STUDY POPULATION

Overall, 700 patients with a gram-negative infection who have received at least one dose of ceftazidime-avibactam will be enrolled in this study.

1.3.1 Study Size in Europe

Sample size for this study was calculated with the goal of maximizing precision when estimating clinical and microbiological treatment success.

Clinical Treatment Success Assumptions (1-3)*:*

- *25% of the enrolled patients discontinue ceftazidime-avibactam before 72 hours of exposure (e.g. due to adverse event (AE), microbiological results)*
- *75% of patients are exposed to ceftazidime-avibactam for ≥72 hours and are assessable for clinical effectiveness.70% of the assessable patients experience clinical treatment success, as defined in* Section 5.

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Table 1. Sample Size and Precision of the Estimate for Clinical Treatment Success

			Prevalence of Clinical Treatment Success			
		60%	***65%***	***70%***	***75%***	***80%***
N	**200**	(52.9% - 66.8%)	(58.0% - 71.6%)	(63.1% - 76.3%)	(68.4% - 80.8%)	(73.8% - 85.3%)
	300	*(54.2% - 65.6%)*	*(59.3% - 70.4%)*	*(64.5% - 75.1%)*	*(69.7% - 79.8%)*	*(75.0 % - 84.4%)*
	400	*(55.0% - 64.8%)*	*(60.1% - 69.7%)*	*(65.2 % - 74.5%)*	*(70.5% - 79.2%)*	*(75.7% - 83.8%)*
	500	*(55.6% - 64.3%)*	*(60.6% - 69.2%)*	*(65.8% - 74.0%)*	*(71.0% - 78.7%)*	*(76.2% - 83.4%)*
	600	*(56.0% - 63.9%)*	*(61.0% - 68.8%)*	*(66.2% - 73.6%)*	*(71.3% - 78.4%)*	*(76.6% - 83.1%)*

Note: Displayed range is the 95% confidence interval around the estimate of treatment success

Microbiological Treatment Success Assumption (1-3):

- *25% of the enrolled patients discontinue ceftazidime-avibactam before 72 hours of exposure (e.g. due to AE, microbiological results),*
- *75% of patients are exposed to ceftazidime-avibactam for ≥72 hours,*
- *10% of patients exposed ≥ 72 hours (across all indications) have no pathogen identification and are not assessable for microbiological success,*
- *80% of the assessable patients experience microbiological treatment success as defined in* Section 5.

Table 2. Sample Size and Precision of the Estimate for Microbiological Treatment Success

			Prevalence of Microbiological Treatment Success			
		70%	***75%***	***80%***	***85%***	***90%***
N	**200**	(63.1% - 76.3%)	(68.4% - 80.8%)	(73.8% - 85.3%)	(79.3% - 89.6%)	(85.0% - 93.8%)
	300	*(64.5% - 75.1%)*	*(69.7% - 79.8%)*	*(75.0% - 84.4%)*	*(80.4% - 88.8%)*	*(86.0% - 93.2%)*
	400	*(65.2% - 74.5%)*	*(70.5% - 79.2%)*	*(75.7% - 83.8%)*	*(81.1% - 88.4%)*	*(86.6% - 92.8%)*
	500	*(65.8% - 74.0%)*	*(71.0% - 78.7%)*	*(76.2% - 83.4%)*	*(81.6% - 88.0%)*	*(87.0% - 92.5%)*
	600	*(66.2% - 73.6%)*	*(71.3% - 78.4%)*	*(76.6% - 83.1%)*	*(81.9% - 87.8%)*	*(87.3% - 92.3%)*

Note: Displayed range is the 95% confidence interval around the estimate of treatment success

Table 1 and Table 2 display estimates of clinical and microbiological treatment success, respectively, and the asymptotic precision of each estimate (95% confidence interval (CI)), for sample sizes ranging from 300 to 600 evaluable patients.

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To obtain a 95% CI for treatment success that is approximately 12.3 percentage points or less for both clinical and microbiological treatment success, 225 evaluable patients are required. Given the assumptions above for both treatment outcomes, a minimum of 300 patients should be enrolled to obtain 225 evaluable patients. Minor gains in precision can be achieved by enrolling a larger number of patients.

Enrolling 300 patients would lead to 225 patients with ≥ 72 hours exposure to ceftazidime-avibactam evaluable for clinical success, and 202 patients evaluable for microbiological success. It would yield an expected 95% CI of 70.0% (63.6% - 75.9%) of patients experiencing clinical treatment success and 80.0% (73.8% - 85.3%) of patients experiencing microbiological treatment success using a two-sided exact method.

Note: The precision estimates were calculated using the Clopper Pearson (exact) CIs using statistical analysis system (SAS)® software version 9.2 (4).

1.3.2 Study size in Latin America

Based on the same assumptions for treatment outcomes as in Europe, to obtain a 95% CI for treatment success that is approximately 10.0 percentage points for both clinical and microbiological treatment success, 400 patients will be included in Latin America to obtain 300 evaluable patients for clinical success, and 270 evaluable patients for microbiological success. Using a two-sided exact method, enrolling 400 patients would yield an expected 95% CI of 70.0% (64.5% - 75.1%) of patients experiencing clinical treatment success and 80.0% (74.7% - 84.6%) of patients experiencing microbiological treatment success.

1.3.3 Potential COVID-19 Impact

Coronavirus disease (COVID-19) pandemic is likely to impact the final sample size in both Europe and LATAM. Many sites did not work during this period, e.g. in Europe and LATAM there were approximately 24 unresponsive sites during the April and May 2020, and around 12 unresponsive sites in June 2020. However, this should not impact the analyses, but the precision of the estimates may have to be revised.

1.4 DATA SOURCE

Patients will be enrolled from approximately 62 sites in 12 countries in Europe and in Latin America. Sites will be qualified and then selected based on responses to a series of questions intended to determine their capability of conducting the study and ability to contribute to the target patient population.

The data source for this study will be patient medical records. Data will be abstracted from records between the date of hospital admission and up to 60 days after hospital discharge or a censoring event (death, withdrawal from the study, or lost-to-follow-up). Patients should be carefully tracked to identify censoring events.

Adverse Events (AEs) will be collected as part of standard practice. Information regarding the reporting of AEs is described in Section 4.8.1 *of this SAP* and Section 11 of the protocol.

1.5 STUDY OBJECTIVES

The main objective of this NI medical chart review study is to describe the general treatment patterns, effectiveness, and safety of ceftazidime-avibactam in real-world settings.

The primary objective of this study is to describe the patterns of use of ceftazidime-avibactam in real-world practice.

1. *Describe the indications and reasons for use of ceftazidime-avibactam; provide detailed information about its use for the treatment of infections due to aerobic gram-negative organisms with limited treatment options.*
2. *Describe the usage patterns of ceftazidime-avibactam, including treatment line, dose, frequency of dose, duration, and polytherapy regimens.*
3. *Describe the microbiological evidence available for patients treated with ceftazidime-avibactam.*
4. *Describe the source of infection for which ceftazidime-avibactam is prescribed including community-acquired infections (CAIs), HCAIs, and HAIs.*

The secondary objective of this study is to determine the effectiveness and safety of ceftazidime-avibactam in real-world practice.

1. *Describe the clinical outcomes of patients treated with ceftazidime-avibactam (i.e. treatment success, failure, or indeterminate) in hospital and up to 30- and 60-days post hospital discharge.*
2. *Describe the microbiological outcomes among patients treated with ceftazidime-avibactam during the 14 days after ceftazidime-avibactam initiation*
3. *Describe safety outcomes in patients receiving ceftazidime-avibactam between treatment initiation and hospital discharge.*
4. *Describe the in-hospital length of stay (LOS), LOS in intensive care unit (ICU) and healthcare resource utilization in patients with infections treated by ceftazidime-avibactam.*
5. *Determine the prevalence of hospital readmissions for recurrence of the same infection within 30 and 60 days of hospital discharge among patients treated with ceftazidime-avibactam.*
6. *Determine the in-hospital mortality and mortality up to 30 and 60 days after hospital discharge.*

2 DECISION RULES

For patients treated with ceftazidime-avibactam, the clinical and microbiological outcomes will be evaluated according to the definitions in Section 5. Handling missing data, in general, is discussed in Section 6. The evaluation rules for missing clinical outcomes are provided in Table 5.

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3 ANALYSIS SETS/ POPULATIONS

The data from the chart reviews will be anonymized patient-level data that will be pooled to create the analysis data sets described below. Each country and patient will be assigned a unique identifier.

3.1 ALL PATIENTS ENROLLED SET

All the patients enrolled set (ENR) will contain all subjects who provide informed consent. This set will only be used to calculate the attrition table, i.e. the number of patients retained at each application of the study inclusion/exclusion criteria.

3.2 FULL ANALYSIS SET

The full analysis set (FAS) will contain all enrolled patients meeting the study eligibility criteria set out below. This set will also be used for safety analysis.

3.2.1 Inclusion criteria

Patients must meet all the following inclusion criteria to be eligible:

1. *Hospitalized patient ≥18 years old or considered an adult in accordance with the age of majority in the participant's country of residence at the time of treatment with ceftazidime-avibactam.*
2. *Patient received ≥1 dose of ceftazidime-avibactam in routine practice at participating site since the date of ceftazidime-avibactam launch in the country, or January 2018, or the date of launch in the country if after 2018.*
3. *Patient underwent microbiological sampling ≤5 days before the initiation of ceftazidime-avibactam (irrespective of results and actual bacteriological identification).*
4. *Patient has all required essential data elements which include:*
   a. *Start and stop dates of ceftazidime-avibactam,*
   b. *Start and stop dates of prior antibiotic therapy used for the index infection,*
   c. *Type of combined antibiotic therapy (if applicable) and start and stop dates of any antibiotic combined with ceftazidime-avibactam.*
5. *Evidence of a personally signed and dated informed consent document indicating that the patient (or a legally acceptable representative) has been informed of all pertinent aspects of the study where required by local regulations.*

3.2.2 Exclusion criteria

Patients must not meet any of the following exclusion criteria to be eligible:

1. *The patient is enrolled in any clinical trial of an investigational product. Patients who are enrolled in non-interventional studies (e.g. registries) are eligible for inclusion.*
2. *The patient has received ceftazidime-avibactam in a compassionate care program setting.*

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3. *The patient was exposed to ceftazidime-avibactam before use for the index infection.*

The FAS will be divided into patients with at least 72 hours of exposure to ceftazidime-avibactam, and patients with <72 hours exposure.

3.3 ANALYSIS SET WITH AT LEAST 72 HOURS EXPOSURE TO CEFTAZIDIME-AVIBACTAM.

Analysis set at least 72 hours (FAS72+) will be a subset of the FAS patients with at least 72 hours of exposure to ceftazidime-avibactam.

3.4 ANALYSIS SET WITH LESS THAN 72 HOURS EXPOSURE TO CEFTAZIDIME-AVIBACTAM.

Analysis set less than 72 hours (FAS72-) will be a subset of the FAS patients with <72 hours exposure to ceftazidime-avibactam.

3.5 ANALYSIS DATA SET FOR CLINICAL OUTCOMES

The clinical outcomes dataset (COD) will consist of all patients with at least 72 hours exposure to ceftazidime-avibactam and at least one non-missing clinical outcome. COD will be a subset of FAS72+.

3.6 ANALYSIS DATA SET FOR MICROBIOLOGY OUTCOMES

The microbiological outcomes dataset (MOD) will consist of patients with at least 72 hours exposure to ceftazidime-avibactam, identification of one or more pathogens before the start of ceftazidime-avibactam treatment, and at least one non-missing microbiological outcome. MOD will be a subset of FAS72+.

Figure 3 shows how the patients for each analysis data set are derived.

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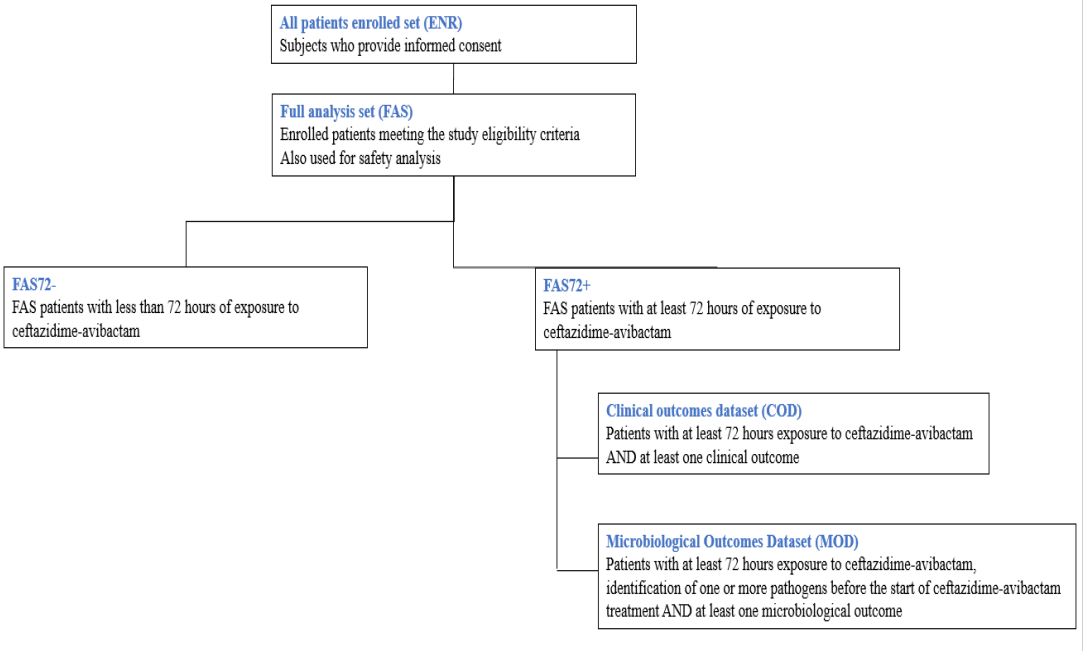
Figure 3. Data Sets



4 OUTCOMES AND COVARIATES

4.1 SITE CHARACTERISTICS

Site characteristics will be described as below, based on data from FAS.

- *Physician specialty:*
  - *Infectious disease*
  - *Microbiology*
  - *Surgery*
  - *Internal medicine*
  - *Intensive care*
  - *Anesthesiology*
  - *Other*
- *Hospital information:*
  - *Care level*
  - *Type*
  - *Total number of beds*
  - *Total number of ICU beds*
- *Local gram-negative resistance rates (between 01 Jan 2018 and 30 Jun 2019, or other duration) to:*
  - *3rd generation cephalosporins*
  - *Carbapenem*

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- *3rd generation cephalosporins and carbapenems*
- *Colistin*

4.2 BASELINE DEMOGRAPHIC CHARACTERISTICS FOR PATIENTS EXPOSED TO CEFTAZIDIME-AVIBACTAM FOR ≥72 HOURS

Baseline demographic characteristics of patients will be described as below, based on data from FAS72+.

- *Exposure to ceftazidime-avibactam:*
  - *Exposed to ceftazidime-avibactam for a duration of ≥ 72 hours*
  - *Exposed to ceftazidime-avibactam for a duration of < 72 hours*
- *Age*
- *Gender*
- *Height and weight (Body mass index [BMI] will be derived)*
- *Employment status*
- *Additional risk factors:*
  - *Travel to foreign country within the past 3 months;*
    - *Country*
    - *Duration of travel*
    - *Hospitalization*
  - *Pregnancy (weeks of gestation since last menstrual period);*
  - *Alcohol use (drinks per week);*
  - *Smoker status (current/previous/never/unknown) and cigarettes per day.*

4.3 BASELINE CLINICAL CHARACTERISTICS FOR PATIENTS EXPOSED TO CEFTAZIDIME-AVIBACTAM FOR ≥72 HOURS

Baseline clinical characteristics of patients will be described as below, based on data from FAS72+.

- *Comorbidities, individual comorbidities and Deyo-Charlson Comorbidity Index (DCCI), see Section 5 for detailed description.*
- *Indwelling devices that the patient had at the time of the infection diagnosis.*
- *Hospitalization within 90 days prior to index hospitalization:*
  - *LOS of hospitalization*
  - *Primary diagnosis at discharge.*
- *Type(s) of healthcare procedure within the 30 days before the index date.*
- *History of antibiotic exposure within 90 days prior to index hospitalization:*
  - *Antibiotic name(s)*
  - *Duration(s)*
  - *Reason for treatment*
    - *Therapeutic*
    - *Prophylactic*
- *Prior antibiotic exposure for the index infection:*
  - *Antibiotic name(s)*
  - *Dose(s)*
  - *Duration(s) of use*

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- *Reason for treatment*
  - *Microbiology*
  - *No improvement or worsening on previous antibiotic*
  - *Other*
- *Reason for discontinuation*
  - *Perceived clinical failure/disease no improvement or worsening*
  - *Isolation of a resistant pathogen*
  - *Preference for empiric coverage*
  - *Secondary infection requiring regimen change*
  - *Switch to oral therapy*
  - *De-escalation*
  - *Cure*
  - *Death*
  - *Other*

- *Pre-treatment disease severity Acute Physiology and Chronic Health Evaluation Score (APACHE II) or other prognostic assessment within 7 days prior to index date, for patients directly admitted to intensive care unit (ICU).*
- *Source of infection: HAI, HCAI, CAI.*
- *Indication for ceftazidime-avibactam:*
  - *cIAI, cUTI, HAP/VAP, other (primary and secondary diagnosis)*
  - *Initial site of infection (organ)*
- *Indication for ceftazidime-avibactam other:*
  - *Type of infection (e.g., SSI, Central line associated blood stream infection (CLABSI), primary Bloodstream infection (BSI), meningitis, other)*
  - *Initial site of infection (organ)*
- *Pre-treatment microbiology sample*
  - *Microbiological culture(s) of current infection during the 5 days of ceftazidime-avibactam initiation (sample date(s), sample source(s)).*
- *Pre-treatment microbiology results*
- *Results from microbiological culture (method of testing, identified pathogen(s), susceptibility, MDR).*

4.4 PATTERN OF USE OF CEFTAZIDIME-AVIBACTAM FOR PATIENTS EXPOSED TO CEFTAZIDIME-AVIBACTAM FOR ≥72 HOURS

Patterns of use of ceftazidime-avibactam will be described as below, based on data from FAS.

- *Ceftazidime-avibactam treatment patterns:*
  - *Dose(s), frequency, and duration*
  - *Reason for initiating*
  - *Reason for discontinuation (if applicable) (e.g. AE, perceived clinical failure, isolation of a resistant pathogen, preference for empiric coverage, secondary infection requiring regimen change, switch to oral therapy, de-escalation, cure, death).*

Patterns of use of antibiotics will be as described below, based on data from FAS72+.

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- *Antibiotic(s) used for the index infection before ceftazidime-avibactam initiation.*
  - *Lines of treatments*
  - *Dose(s), frequency, duration and route of administration*
  - *Reason for initiating (microbiology, no improvement or worsening on previous antibiotic), reason for discontinuation (AE, perceived clinical failure, isolation of a resistant pathogen, preference for empiric coverage, secondary infection requiring regimen change, switch to oral therapy, de-escalation).*
- *Lines of antibiotic therapy(s)*
  - *Number of lines*
  - *Reason for change in line (e.g. AE, perceived clinical failure, isolation of a resistant pathogen, preference for empiric coverage, secondary infection requiring regimen change, switch to oral therapy, de-escalation, cure, death).*
- *Concomitant antibiotic therapy*
  - *Antibiotic(s) used concurrently with ceftazidime-avibactam,*
  - *Dose(s), frequency, duration and route of administration,*
  - *Reason for initiating and reason for discontinuation (e.g. AE, perceived clinical failure, isolation of a resistant pathogen, preference for empiric coverage, secondary infection requiring regimen change, switch to oral therapy, de-escalation, cure, death) (if applicable).*

4.5 EFFECTIVENESS OUTCOMES FOR PATIENTS EXPOSED TO CEFTAZIDIME-AVIBACTAM FOR ≥72 HOURS

4.5.1 Clinical outcomes

Each line of therapy that includes ceftazidime-avibactam will be evaluated for the clinical effectiveness outcomes and will be described according to the variables listed below, based on data from COD.

- *Clinical symptoms improvement*
  - *Symptoms improvement or worsening within 48 and 72 hours of ceftazidime-avibactam initiation*
- *Resolution of all signs and symptoms of infection with no need for escalation of antimicrobials.*
  - *De-escalation of antibiotic therapy is considered a treatment success unless ceftazidime-avibactam was used in a regimen with one or more other antibiotics and is the only antibiotic de-escalated.*
- *Hospital readmission during the 30 and 60 days after initial discharge, by reason for readmission.*
- *Clinical treatment outcome:*
  - *Success, failure, or indeterminate (see Section 5 for definitions).*

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4.5.2 Microbiological outcomes

Each line of therapy that includes ceftazidime-avibactam will be evaluated for the microbiological effectiveness outcomes, providing that a pathogen was identified. *Microbiological treatment outcome should be assessed at the end of each regimen containing ceftazidime-avibactam.*

The microbiological effectiveness outcomes will be described according to the variables listed below, based on data from MOD.

- *Post treatment initiation microbiology sample. Microbiological culture(s) during the 14 days after ceftazidime-avibactam initiation (sample date, sample site).*
- *Post treatment initiation microbiology results*
  - *Results from microbiological culture after treatment initiation (method of testing, identified pathogen(s), susceptibility, MDR).*
- *Microbiological treatment outcome*
  - *Success, failure, emergent infections and unevaluable. See Section 8.7 or details on microbiological treatment outcomes.*

4.5.3 Prevalence of hospital readmissions

Prevalence of hospital readmissions for recurrence of the index infection within 30 and 60 days of hospital discharge among patients treated with ceftazidime-avibactam.

  - readmissions within 60 days
    - reason for readmission
  - readmissions within 30 days
    - reason for readmission
- Summary of the number of days readmitted
- Prevalence rates of readmission for index infection at 30 days and 60 days post-discharge.

Results will be presented overall, stratified by country, indication, and bacteria.

4.6 MORTALITY OUTCOMES

Mortality outcomes will be described according to the variables listed below, based on data from FAS72+.

- In-hospital mortality occurring after treatment initiation but before hospital discharge
  - Numbers of days after treatment initiation
  - Cause of death.
- 30-day mortality - mortality within 30 days after hospital discharge
  - Numbers of days after hospital discharge
  - Cause of death.
- 60-day mortality - mortality within 60 days after hospital discharge
  - Numbers of days after hospital discharge
  - Cause of death.
- Cumulative 30-day mortality - mortality within 30 days after hospital discharge

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(in-hospital + 30 days after discharge)
  - Numbers of days after treatment initiation
  - Cause of death.
- Cumulative 60-day mortality - mortality within 60 days after hospital discharge (in-hospital + 60 days after discharge)
  - Numbers of days after treatment initiation
  - Cause of death.

4.7 HEALTHCARE UTILIZATION OUTCOMES FOR PATIENTS EXPOSED TO CEFTAZIDIME-AVIBACTAM FOR ≥72 HOURS

The outcomes related to healthcare utilization will be described according to the variables listed below, based on data from the FAS72+.

- *Hospital stay*
  - *LOS*
  - *Diagnosis at admission*
  - *Hospital ward*
    - *All wards attended, ward of admission, ward of diagnosis (surgical, medical, onco-hematology, infectious disease, ICU, other)*
- *ICU stay*
  - *LOS*
  - *diagnosis at admission*
- *Healthcare utilization*
  - *Detailed list of healthcare utilization (diagnosis at admission, departments admitted/discharged, discharge diagnosis, mechanical ventilation, dialysis, computerized tomography (CT)/magnetic resonance imaging(MRI) imaging, tracheostomy, surgical intervention, percutaneous procedures, other) and dates of service.*

4.8 SAFETY OUTCOMES FOR PATIENTS EXPOSED TO CEFTAZIDIME-AVIBACTAM FOR ≥72 HOURS

The safety outcomes are defined as AEs and serious adverse events (SAEs) attributable to ceftazidime-avibactam as captured in the patients' medical charts. The safety outcomes will be described according to the variables listed below, based on data from the FAS72+.

- *Safety*
  - *All serious and non-serious AEs with explicit attribution to ceftazidime-avibactam that appear in the reviewed information and scenarios involving drug exposure to ceftazidime-avibactam, including exposure during pregnancy, exposure during breastfeeding, medication error, overdose, misuse, extravasation, lack of efficacy and occupational exposure associated with the use of ceftazidime-avibactam.*

4.8.1 Adverse Events

- *Adverse Events (AEs) will be coded using MedDRA Version 21.0 or higher.*

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- *See Section 6 for the handling of partial dates for AEs.*
- *An overall summary of numbers of patients within each of the categories described in the sub-section below, will be provided. If a patient reports an AE more than once within a System Organ Class (SOC)/ Preferred Term (PT), then all AEs will be described.Number and percent of serious and non-serious AEs will be presented by SOC and PT and broken down further by maximum severity and relationship to study medication.*

The protocol requires human review of patient-level unstructured data with reporting of AEs with explicit attribution to any Pfizer drug that appear in the reviewed information (defined per the patient population and study period). Explicit attribution is not inferred by a temporal relationship between drug administration and an AE but will be based on a definite statement of causality by a healthcare provider linking drug administration to the AE.

Pfizer Safety requirements include the following:

- All serious and non-serious AEs with explicit attribution to any Pfizer drug.
- Scenarios involving exposure to any Pfizer drug, including exposure during pregnancy, exposure during breast feeding, medication error, overdose, misuse, extravasation, lack of efficacy and occupational exposure associated with the use of a Pfizer product

For these safety events with an explicit attribution to or associated with use of, respectively, a Pfizer product, the data captured in the medical record will constitute all clinical information known regarding these AEs. No follow-up on related AEs will be conducted.

4.8.2 Serious Adverse Events

SAEs are those events recorded as "Serious" on the AEs Form of the electronic case report form (eCRF). An SAE is defined as any untoward medical occurrence that at any dose:

- Results in death
- Is life-threatening
- Requires hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability or incapacity
- Is a congenital anomaly or birth defect
- Is an important medical event.

Number and percent of serious AEs will be presented by SOC and PT.

4.9 VARIABLES AND OUTCOMES FOR ANALYSIS AMONG PATIENTS EXPOSED TO CEFTAZIDIME-AVIBACTAM <72 HOURS

- *Age*
- *Sex*

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- *Source of infection: HAI, HCAI, CAI*
- *Indication for ceftazidime-avibactam*
  - *cIAI, cUTI, HAP/VAP, other*
  - *Initial site of infection (organ)*
- *Indication for ceftazidime-avibactam Other*
  - *Type of infection (e.g., SSI, CLABSI, primary BSI, meningitis, other)*
  - *Initial site of infection (organ).*

Patterns of use of ceftazidime-avibactam will be described as below.

- *Ceftazidime-avibactam treatment patterns:*
  - *Dose(s), frequency, and duration*
  - *Reason for initiating*
  - *Reason for discontinuation (if applicable) (e.g. AE, perceived clinical failure, isolation of a resistant pathogen, preference for empiric coverage, secondary infection requiring regimen change, switch to oral therapy, de-escalation, cure, death).*
- *In-hospital mortality occurring after treatment initiation but before hospital discharge*
  - *Numbers of days after treatment initiation*
  - *Cause of death.*
- *Safety*
  - *All serious and non-serious AEs with explicit attribution to ceftazidime-avibactam that appear in the reviewed information and scenarios involving drug exposure to ceftazidime-avibactam, including exposure during pregnancy, exposure during breastfeeding, medication error, overdose, misuse, extravasation, lack of efficacy and occupational exposure*

5 DEFINITIONS

1. ***Indication*** *for ceftazidime-avibactam prescription*
   - cUTI
   - cIAI
   - HAP/VAP
   - Other infection with limited treatment options: any infection, based upon empiric or microbiological evidence, for which ceftazidime-avibactam is prescribed. Detailed information on the infection should be collected for analysis including type of infection (e.g. primary BSI, SSI, CLABSI, meningitis, HAP), and original source of infection (i.e. specific organ/locale).
2. ***Pathogen****:*
   In this NIS, any microorganism(s) that the investigator has considered as a pathogen likely to cause the infection presented by the patient.
3. ***Multidrug-resistance:***
   The isolate is non-susceptible to at least one agent in ≥3 antimicrobial categories, excluding the therapeutic classes to which the bacteria is intrinsically resistant.

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Categories include but are not limited to aminoglycosides, carbapenems, cephalosporins, cephamycins, fluoroquinolones, folate pathway inhibitors, glycylcyclines, penicillins, monobactams, phosphonic acids, polymyxins, tetracyclines.

4. ***Source of infection***:
   - HCAI
   - HAI
   - CAI
5. ***Infection site***:
   This refers to the origin of the infection (e.g. appendix, bladder, kidney, large intestine, lungs, liver, gall bladder, pancreas, peritoneum small intestine, stomach, urethra, other).
6. ***Antibiotic regimens***
   An antibiotic regimen is a planned therapeutic intervention which may involve 1 or more drugs.
7. ***Lines of therapy***:
   Each regimen is a line of therapy.
8. ***A new line of therapy is defined by***:
   1. *Where a treatment regimen is discontinued, and a different regimen is started, the new regimen is considered a new line of therapy.*
   2. *A line of treatment is considered finished when at least one antibiotic given in combination is modified.*
   3. *Escalation, increasing the dosage, the dose or the unplanned addition or substitution of ≥1 drug(s) in an existing regimen is considered a new line of therapy.*
      Escalation after 4 days of treatment (dose increase or addition of another antibiotic for gram negative), will be considered as a failure
   4. *De-escalation, or reducing the dosage or eliminating ≥1 drug(s) from an existing regimen, or switching to oral antibiotics, is not considered a new line of therapy.*
      Stream lining (stop an antibiotic) or conversion to oral therapy will be considered as a success
9. ***Treatment line number***:
   A new line of therapy starts when the antibiotic therapy is modified because an antibiotic is discontinued, the dose increased, patient is switched to an oral antibiotic therapy/regimen or a new antibiotic is added. Up to 5 lines of therapy will be collected. Assessment of treatment line will be based on generic name (i.e. active ingredient) of the drug (i.e. change in trade name with the same active ingredient, dose and strength will not be classified as a treatment line change).
10. ***The Deyo-Charlson Comorbidity Index (DCCI)***
    Table 3. *outlines the Deyo-Charlson Comorbidity Index. To quantify comorbidity, the Deyo-Charlson Comorbidity score is computed by adding the weights that are assigned to the specific diagnoses. A score of 1 is attributed to myocardial infarction, congestive heart failure, peripheral vascular disease, cerebrovascular*

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disease, dementia, chronic obstructive pulmonary disease, rheumatologic disease, peptic ulcer disease, mild liver disease, depression, use of warfarin, hypertension and diabetes mild to moderate. The following diseases are scored as 2: hemiplegia or paraplegia, moderate or severe renal disease, skin ulcers/cellulitis, diabetes and complications and malignancy including leukemia and lymphoma. Moderate or severe liver disease is scored 3. Finally, a score of 6 is assigned to metastatic solid tumor, AIDS, and any transplant (bone marrow or sold organ).

Table 3. Deyo-Charlson Comorbidity Index

Comorbidity	Deyo-Charlson Weight
Myocardial Infarction	1
Congestive Heart Failure	1
Peripheral Vascular Disease	1
Cerebrovascular Disease (except hemiplegia)	1
Dementia	1
Chronic Obstructive Pulmonary Disease	1
Rheumatologic Disease	1
Peptic Ulcer Disease	1
Depression	1
Use of Warfarin	1
Hypertension	1
Mild Liver Disease	1
Diabetes Mild to Moderate	1
Hemiplegia	2
Paraplegia	2
Moderate or Severe Renal Disease	2
Diabetes with Complications	2
Skin Ulcers/Cellulitis	2
Malignancy (solid, non-metastatic)	2
Hematological malignancy (leukemia, lymphoma)	2
Moderate to Severe Liver Disease	3
Metastatic Solid Tumor	6
AIDS	6
Any transplant (bone marrow, solid organ)	6

11. ***Index date***
    Start date of ceftazidime-avibactam.
12. ***Index infection***
    Infection treated with ceftazidime-avibactam.
13. ***Index hospitalization****:*
    Current hospitalization at time of index date.
14. ***Baseline period****:*

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The baseline period is defined as the 90 days period preceding the date (inclusive) of diagnosis date for the index infection.

15. ***Follow-up period:***
    Each patient (in FAS72+) *will be followed from index date, through their medical records up to 60 days after hospital discharge, in-hospital death, withdrawal from the study, or loss-to-follow-up, whichever occurs first.*
16. ***Clinical success (cure):***
    - *Resolution of all signs and symptoms of infection with no need for escalation of antimicrobials for gram-negative coverage.*
    - *If there is stream lining. i.e., stopping an antibiotic treatment.*
    - *If there is a de-escalation of antibiotic therapy unless ceftazidime-avibactam was used in a regimen with one or more other antibiotics and is the only antibiotic de-escalated.*
    - *A clinical treatment outcome of "success" before discharge can be invalidated as "failure" if readmitted for recurrence of the same infection.*
    - *Secondary infection will be not considered as failure.*
17. ***Clinical failure:***
    Inadequate response to ceftazidime-avibactam therapy or resistant, worsening, or new recurrent signs and symptoms at the end of ceftazidime-avibactam therapy. Includes any of the following:
    - In case of escalation within 4 days (addition of another antibiotic for gram-negative).
    - Antimicrobial escalation (with ceftazidime-avibactam or an additional antibiotic for gram-negative coverage within 4 days).
    - Discontinuation of ceftazidime-avibactam without clinical cure (e.g. AE, insufficient effect).
    - Readmission to a hospital with the same infection within 60 days of the initial hospital discharge date.
    - cIAI patient who required an additional unplanned source control procedure after ceftazidime-avibactam initiation.
      A clinical treatment "failure" at any time cannot be redeemed

    Note: Source control procedure: additional procedure (surgical, percutaneous) to control the infection, e.g. abscess drainage. All patients with cIAI are expected to have at least one source control procedure before or at start of the antibiotics.
18. ***Clinical indeterminate****:*
    There is not enough information to conclude whether the antibiotic regimen containing ceftazidime-avibactam was a clinical failure or a success.
19. ***Microbiological success****:*
    - Eradication: Absence of causative pathogen from appropriately obtained specimens at the site of infection.
    - Presumed eradication: Repeat cultures were not performed/clinically indicated in a patient who had a clinical response of cure (clinical success).
    - Colonization: Detection of a new pathogen from the site of infection during therapy without the need for antimicrobial treatment or superinfection with a

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microbiological agent outside the treatment spectrum of ceftazidime-avibactam (Gram+/fungi).

20. ***Microbiological failure****:*
- Verified persistence: The failure to eradicate the original pathogen from the site of isolation after completion of therapy.
- Presumed persistence: Absence of appropriate material for culture or absence of results of control microbiological tests coupled with lack of clinical improvement after a pathogen was initially isolated.
- Persistence with increasing minimal inhibitory concentration: Continued presence of the causative organism in culture during or upon completion of treatment with intravenous (IV) study therapy that displays a ≥4-fold higher minimum inhibitory concentration (MIC) to IV study therapy after treatment with IV study therapy.

21. ***Emergent infections****:*
- *Superinfection: Detection of a new pathogen from the site of infection during therapy with the need for antimicrobial treatment.*
- *New Infection:*
  - *Detection of a new pathogen from the site of infection after therapy with the need for antimicrobial treatment.*
  - *Detection of a new pathogen on a different site.*

22. ***Multi-bacteria infections****:*
- For patients with multi-bacterial infections, the list of bacteria that must be considered pathogens.

23. ***Microbiological unevaluable****:*
- Unevaluable: Patients without cultures or evident pathogens from the presumed site of infection.

24. ***Hospital LOS*** *will be calculated as:*

1) the total number of consecutive days the patient was treated in the hospital from admission to discharge during their initial hospitalization;
2) the total number of hospital days between diagnosis of infection and discharge;
3) the total number of days the patient was treated in the hospital after ceftazidime-avibactam initiation up to hospital discharge, including the first day of treatment.

Hospital LOS is defined as: (Date of hospital discharge - Date of hospital admission) +1 day.

25. ***ICU LOS*** *will be calculated as: 1) the total number of consecutive or non-consecutive days the patient was treated in the ICU during their initial hospitalization; and 2) the total number of days the patient was treated in the ICU after ceftazidime-avibactam initiation, including the first day of treatment.*
ICU LOS is defined as: (Date of ICU discharge - Date of ICU admission) +1 day.

26. ***In-hospital mortality rate*** is defined as: (# of patients who died in-hospital from index infection) / (total # of patients who received treatment with ceftazidime-

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avibactam).

27. ***Cumulative mortality rate at 30 days post-discharge*** is defined as: (# patients who died in-hospital or within 30 days post-discharge for the index hospitalization.) / (total # of patients who received treatment with ceftazidime-avibactam).
28. ***Cumulative mortality rate at 60 days post-discharge*** is defined as: (# patients who *died in-hospital or within* 60 days post-discharge for the index hospitalization.) / (total # of patients who received treatment with ceftazidime-avibactam).
29. ***Duration (days) of an event*** = stop date of event – start date of event + 1. Note: Duration =1 day, if stop date = start date.
30. ***Total cumulative dose*** (in ml or mg) of ceftazidime-avibactam or other antibiotics is defined as the sum of all doses received over the follow-up period.

6 HANDLING OF MISSING VALUES

Missing data will not be imputed, and data will be analyzed and presented as they are recorded in the eCRF as they were entered in the study database following resolution of all queries from data management. The number of missing cases will be reported for each variable of interest in the analysis. Patients with completely missing data for a variable will be excluded from the denominator when calculating proportions involving observed data for that variable.

For partial dates, a missing day element will default to the 15th of the month. Any event date occurring prior to the index hospitalization will not be imputed. Any event date occurring during the index hospitalization period must not be imputed beyond patient discharge or death during hospitalization. Any event occurring after discharge cannot be

imputed on the left prior to discharge and on the right after the 60 days of follow-up. See Appendix for additional rules for partial dates.

All data, including missing data, will be used for analysis of clinical outcomes. In data listings, all partial dates will be reported with the same precision as they appear in the eCRF.

7 STATISTICAL METHODS

Unless otherwise specified, continuous/quantitative variables will be summarized using descriptive statistics which will include the number of patients with data to be summarized (n), mean, standard deviation (SD), 95% confidence interval (CI), median, first quartile (Q1) and third quartile (Q3), minimum and maximum.

All categorical/qualitative data will be presented using frequency counts and percentage with exact 95% CIs. The total number of patients with non-missing data (N) will be used as the denominator for percentage calculations, unless otherwise specified. Percentages equal to 100 will be presented as 100% and the percentage will not be presented for zero frequencies.

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Missing data will be described in all summaries. Summary statistics will be displayed with decimal places as per Table 4.

Table 4. Decimal Placees for Table Shells

Description	Characteristic	Number of decimal places
Count	N	0
Count corresponding to the number of subject for a group	N	0
Percentage	%	1*
Mean, Median, First quartile, Third quartile	Mean, Median, Q1, Q3	As in CRF + 1
Standard deviation	SD	As in CRF + 2
Confidence interval	CI (LL, UL)	1
Minimum, maximum	Min, Max	As in CRF
p-value	p-value	4, e.g. 0.0001. If the p-value is rounded to below 0.0001 then write as p<0.0001

*Number of decimal places maybe 2, if necessary; CI lower limit (LL), CI upper limit (UL), CRF=case report form, Min= minimum, Max= maximum, Q1= quartile 1, and Q3=quartile 3. If there is no observation, a hyphen '-' will be displayed with no other statistics. If there is only one observation, the SD will be displayed as a hyphen '-'.

All computations and generation of Tables, Listings and Data for figures will be performed using SAS® Version 9.4 or higher (SAS Institute, Cary, NC, USA).

8 STATISTICAL ANALYSES

All analyses will be carried out separately for Europe and Latin America regions. Finally, on completion of the separate regional analyses, a pooled analysis combining data from both regions will be carried out.

8.1 GENERAL CONSIDERATIONS

A detailed flow diagram will be provided to describe the patient selection process.

Antibiotic regimens including ceftazidime-avibactam will be examined.

All analyses, unless stated otherwise, will be performed among patients with exposure to ceftazidime-avibactam ≥72 hours (i.e., using the dataset FAS72+). Results will be presented overall and stratified by indication. For each analysis, there will an overall table that includes all countries and separate tables per country. The indication are: cIAI, cUTI, HAP/VAP, and other (use the primary diagnosis).

The effectiveness outcomes (see Section 4.5) will also be stratified by bacteria (*Escherichia coli*, *Klebsiella* spp., *Enterobacter* spp., *Pseudomonas* spp., and others).

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A subgroup of patients with <72 hours of ceftazidime-avibactam exposure will be analysed to examine patient, infection, treatment characteristics, safety, and mortality. These analyses will be based on data from FAS72-.

Descriptive statistics will be used to summarize the baseline characteristics (study entry), treatment patterns (e.g. dosage, indications, infection source), effectiveness (e.g. clinical and microbiological outcomes), and safety (e.g. mortality, AEs) of ceftazidime-avibactam and healthcare resource utilization by patients prescribed ceftazidime-avibactam.

AEs will be recorded and summarized as the proportion of patients with each safety event out of all treated patients. Hospital readmissions will be analyzed as the proportion of patients readmitted to the hospital for recurrent infection out of all patients discharged from the initial hospitalization.

The Tables, Listings and Figure shells will be provided in a separate document. For the list of Tables see Section 12, and for the list of Listings see Section 13.

8.2 SITE CHARACTERISTICS

- Site characteristics wiil be summarized overall and by country (variables described Section 4.1).

8.3 PATIENT DISPOSITION

Summary statistics including number and percentages for the enrolled population will be presented for the following variables:

- Patients who included in the study.
- Patients in FAS population.
- Patients' study completion status and primary reasons for not completing the study.

8.4 BASELINE DEMOGRAPHIC CHARACTERISTICS

The baseline charecteristics will be summarized by patients overall, by country and by indication..

- The number of enrolled patients.
- Socio-demographics data and risk factors of enrolled patients.

Variables are described Section 4.2

8.5 BASELINE CLINICAL CHARACTERISTICS

- Recent medical history , overall, stratified by country and indication:
  - Prior hospitalizations (within 90 days of index hospitalization).
    - Primary diagnosis at discharge.
    - LOS (days) of prior hospitalization.
  - Prior healthcare procedures (within 30 days of index hospitalization).

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- Number of procedure by type.

- History of antibiotic exposure overall, stratified by country and indication:
  - Prior antibiotics by class and molecule (within 90 days of index hospitalization).
  - Reasons for treatment (therapeutic or prophylactic).
  - Duration of use of these antibiotics.
- Pre-treatment disease severity (APACHE score if available).
- Comorbidities will be described according to the list of comorbidities presented in Table 3, and by a summary of the DCCI index.
- Indwelling devices that the patient had at the time of the infection diagnosis.

Variables are described in Section 4.3.

8.6 PATTERN OF USE OF CEFTAZIDIME-AVIBACTAM

8.6.1 Source of infection

Results will be presented overall stratified by country, indication, and bacteria.
Descriptive analysis of the source of infection (HAI, HCAI and CAI).

8.6.2 Indication for ceftazidime-avibactam

Results will be presented, overall, and stratified by country and bacteria. Indication for ceftazidime-avibactam prescription (will vary depending on country local label)
Descriptive analysis of the indication for ceftazidime-avibactam:

- *cIAI, cUTI, HAP, VAP, other*
- *Initial site of infection (organ).*

Descriptive analysis of the Indication for ceftazidime-avibactam Other (this indication is not approved in all participating countries):

- Type of infection (e.g., SSI, CLABSI, primary BSI, meningitis, other)
- Initial site of infection (organ).

8.6.3 Antibiotics used for index infection before ceftazidime-avibactam *initiation*

The outcome of each line of therapy used for gram-negative coverage will be determined. The addition, modification or discontinuation of any antibiotic for coverage of gram-positive microorganisms co-prescribed with ceftazidime avibactam will be described but will not affect the outcome of the antibiotic regimen targeted at gram-negative microorganisms.

Results will be presented overall and stratified by country and indication (variables described Section 4.4).

Tables will include:

- *Type of antibiotic by class and by molecule*
- *Dose*
- *Duration (days)*

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- *Frequency of administration*
- *Route of administration*
- *Reason for initiating*
- *Reason for discontinuation*

8.6.4 Use of ceftazidime-avibactam

Results will be presented overall, and stratified by country, indication, and bacteria (variables described Section 4.4).

Tables will include:

- *Dose*
- *Duration of treatment (days)*
- *Duration of dose administration*
- *Frequency of administration*
- *Route of administration*
- *Reason for initiating*
- *Reason for discontinuation*

8.6.5 Concomitant antibiotic therapy during index hospitalization

Results will be presented and, overall, and stratified by country and indication (variables described Section 4.4).

Tables will include:

- *Type of antibiotic by class and by molecule*
- *Dose*
- *Duration of treatment (days)*
- *Frequency of administration*
- *Route of administration*
- *Reason for initiating*
- *Reason for discontinuation*

8.6.6 Antibiotic therapy after ceftazidime-avibactam during the index hospitalization:

Results will be presented and, overall, and stratified by country and indication.

Tables will include:

- Type of antibiotic by class and by molecule
- Dose
- Duration of treatment (days)
- Frequency of administration
- Route of administration
- Reason for initiating
- Reason for discontinuation

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8.7 MICROBIOLOGICAL EVALUATION

This will capture pre-treatment microbiology sample and results, *i.e.* microbiological culture(s) of the index infection within 5 days prior to ceftazidime-avibactam initiation. Results will be presented, overall, and stratified by country and indication.

Frequency distributions of:

- Timing of sample collection,
- Type of specimen,
- Any fungal pathogens identified,
- Number of bacterial pathogens identified,
- Bacterial pathogens identified.

Frequency distributions of:
Resistance of pathogen to antibiotics identified by drug class and antibiotic.

Pathogen susceptibility Tables will include:

- Pathogens
- Antibiotic susceptibility tests

8.8 EFFECTIVENESS

8.8.1 Clinical outcomes

Clinical outcomes (success, failure, indeterminate) will be described at 30 days and at 60 days post-discharge according to the evaluation of the physician and based on the definitions mentioned in Section 5. In case of missing data for readmission to hospital (at 30 days or at 60 days post-discharge), the rules described in the Table 5 will be applied.

Table 5. Clinical Outcomes Missing Data Rules at 30 Days or at 60 Days Post-Discharge

Clinical Outcome	Missing Outcome	Computed Clinical Outcome
Success (cure)	Readmission for index infection	Indeterminate
Failure	Readmission for index infection	Failure
Indeterminate	Readmission for index infection	Indeterminate

Note: Readmission information based on paper by Casapao AM, Davis SL, Barr VO, et al. Large retrospective evaluation of the effectiveness and safety of ceftaroline fosamil therapy. Antimicrob Agents Chemother. 2014;58(5):2541-6.

Results will be presented stratified by country, indication and bacteria.

Frequency distributions of:

- *Clinical evaluation: success, failure or indeterminate*
- *Reasons for failure, if applicable.*

For logistic regression, outcomes will be coded as follows:

- *1 = Success*

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- *0 = Failure*

Indeterminate set to missing for logistic regression.
Based on the number and reasons for indeterminate results in the data, analysis with indeterminate as a level in a multinomial logistic may also be performed. Variables with $p < 0.20$ in the univariate analysis will be included in multivariable regression analysis as potential risk factors will be used as covariates in the multivariable analysis, regardless of their univariate or multivariable p-value. The final model will include variables with p-value <0.2, after backward selection.

Potential risk factors include age, gender, country, employment status, BMI, hospitalization within 90 days prior to the index date, LOS of recent hospitalization, history of antibiotic exposure (yes/no), treated with beta-lactam within the past 3 months duration, of recent antibiotic exposure (yes/no), recent healthcare procedure (yes/no), recent healthcare procedure (type), pre-treatment disease severity, foreign travel, DCCI, number of comorbidities, source of infection (HAI, HCAI, CAI), bacteria (*Escherichia coli*, *Klebsiella* spp., *Acinetobacter* spp., *Enterobacter* spp., *Pseudomonas* spp., and others), pregnancy (yes/no, for females), alcohol use (yes/no), smoker (yes/no), patient's infection by multi-resistant pathogen.

Note: *Acinetobacter* spp. a risk factor for failure as zavicefta is not active against the *Acinetobacter* spp.

8.8.2 Microbiological outcomes

Results will be presented, overall, and stratified by country, indication, and bacteria.

Microbiological treatment outcome is *stricto sensu;* it is solely evaluated within the hospital stay (actually only during 14 days following the first dose of zavicefta) and there are no microbiology or mandatory sampling, but failure may be assumed in case of hospital readmission due to same infection or secondary infection (see definitions in Section 5).

Reasons for initiating or discontinuing antibiotic therapy (any line) include but are not limited to AE, perceived clinical failure, isolation of a resistant pathogen, secondary infection requiring regimen change, switch to oral therapy, de-escalation, cure, death.

For a given patient, all lines of therapy that include ceftazidime-avibactam will be evaluated altogether for the final microbiological outcome. Results will be presented overall, stratified by country and the source of the index infection (HAI, HCAI, and CAI).

8.8.3 Prevalence of hospital readmissions

Prevalence of hospital readmissions for recurrence of the index infection within 30 and 60 days of hospital discharge among patients treated with ceftazidime-avibactam.

- Frequency distributions of:
  - readmissions within 60 days
    - reason for readmission
  - readmissions within 30 days
    - reason for readmission
- Summary of the number of days readmitted.
- Prevalence rates of readmission for index infection at 30 days and 60 days post-discharge.

Prevalence of hospital readmissions; analyzed as the proportion of patients readmitted to the hospital for recurrence of the index infection out of all patients discharged from the initial hospitalization.

Results will be presented overall, stratified by country, indication, and bacteria.

8.9 MORTALITY

Descriptive analysis of in-hospital mortality, and 60-day and 30-day mortality post hospital discharge, following index hospitalization.

1. Frequency distributions of:
   a. Time of death:
      - In-hospital, i.e. after treatment initiation but before hospital discharge
      - In-hospital and up to 30 days after hospital discharge
      - In-hospital and up to 60 days after hospital discharge
      - Unknown/lost to follow-up
      - After end of ceftazidime-avibactam treatment
      - After end of antibiotic treatment.

   b. Cause of death
2. Number of days from treatment initiation with ceftazidime-avibactam to death, overall, and by cause of death.
3. Mortality rates in-hospital, and between hospital discharge and 30 and 60 days post-discharge.
4. Cumulative mortality rates up to 30 and 60 days post-discharge, including in-hospital mortality.

Results will be presented stratified by country, indication, and bacteria.

8.10 HEALTHCARE RESOURCE UTILIZATION

8.10.1 Hospital length of stay

- Frequency distributions for initial hospitalization of:
  - Mode of admission,
  - Source of admission,

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- Ward admitted to,
- Wards visited,
- Diagnosis at admission,
- Diagnosis at discharge,
- Patients discharge by end of study.

- Frequency distributions for ICU admission.
- Summary of consecutive hospital LOS from hospital admission to hospital discharge.
- Summary of hospital LOS from infection diagnosis to hospital discharge.
- Summary of hospital LOS from treatment initiation with ceftazidime-avibactam to hospital discharge.
- Summary of consecutive or non-consecutive ICU LOS from ICU admission to ICU discharge.
- Summary of ICU LOS from treatment initiation with ceftazidime-avibactam to ICU discharge.

Results will be presented overall, stratified by country, indication, and bacteria.

8.10.2 Resource utilization

Healthcare resource utilization data (medical/surgical/percutaneous procedures, CT/MRI imaging, days of mechanical ventilation, days of dialysis) will be abstracted from the patient medical records.

- Frequency distributions of healthcare resource utilization during initial hospitalization:
  - any resource use,
  - resource utilized:
    - mechanical ventilation
    - hemodialysis:
      - intermittent or continuous renal replacement therapy
        - number of episodes
    - CTCT/MRI imaging
    - tracheostomy
  - surgical intervention:
    - type
    - indication
    - procedure performed to control infection?
  - percutaneous procedures:
    - type
    - was procedure performed to control infection?
  - other procedures
    - type
    - was procedure performed to control infection?

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- Summary of number of days on mechanical ventilation
- Summary of number of days on intermittent or continuous renal replacement therapy

Results will be presented overall, stratified by country and indication.
Safety

8.11 ADVERSE EVENTS

AEs and SAEs will be summarized as the proportion of patients with each safety event out of all treated patients. Results will be presented, overall, and stratified by country and indication. Tables will include:

- AE term
- LOS of AE
- Relationship with ceftazidime-avibactam
- Serious AE with criteria of seriousness

Safety data will be summarized by using counts and percentages.

9 PATIENTS WITH <72 HOURS OF CEFTAZIDIME-AVIBACTAM EXPOSURE

9.1 DEMOGRAPHIC CHARACTESITICS

- Age
- Sex

9.2 SOURCE OF INFECTION

Results will be presented, overall, and stratified by country and indication.
Descriptive analysis of the source of infection (HAI, HCAI, and CAI).

9.3 INDICATION FOR CEFTAZIDIME-AVIBACTAM

Results will be presented by country and indication.
Descriptive analysis of the indication for ceftazidime-avibactam:

- cIAI, cUTI, HAP/VAP, other
- Initial site of infection (organ).

Descriptive analysis of the Indication for ceftazidime-avibactam Other

- Type of infection (e.g., SSI, CLABSI, primary BSI, meningitis, other)
- Initial site of infection (organ).

9.4 USE OF CEFTAZIDIME-AVIBACTAM

Results will be presented overall, stratified by country, indication, and bacteria. Variables described Section 4.4.

Tables will include:

- Dose
- Duration of treatment (days)
- Duration of dose administration

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- Frequency of administration
- Route of administration
- Reason for initiating
- Reason for discontinuation

9.5 IN-HOSPITAL MORTALITY

- In-hospital mortality occurring after treatment initiation but before hospital discharge.
    - Numbers of days after treatment initiation
    - Cause of death.

Results will be presented stratified by country, indication, and bacteria.

10 SAFETY

AEs and SAEs will be summarized as the proportion of patients with each safety event out of all treated patients. Results will be presented overall, stratified by country and indication. Tables will include:

- AE term
- LOS of AE
- Relationship with ceftazidime-avibactam, concomitant drug or other Pfizer drug
- Serious AE with criteria of seriousness
- Outcome (recovered, resolved, fatal…)

.

11 REFERENCES

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12 LIST OF TABLE SHELLS

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14 APPENDIX

14.1 PARTIAL DATE CONVENTIONS

Imputed dates will not be presented in the listings.

Table 6. Algorithm for Treatment Emergence of Adverse Events

START DATE	STOP DATE	ACTION
Known	Known	If start date < study medication (medication) start date, then not TEAE If start date >= study medication start date, then TEAE If Zavicefta is discontinued, then the start date of TEAE should be >= date of initiation of the antibiotic and <= date of discontinuation + 1.
	Partial	If start date < study medication start date, then not TEAE If start date >= study medication start date, then TEAE
	Missing	If start date < study medication start date, then not TEAE If start date >= study medication start date, then TEAE
Partial, but known components show that it cannot be on or after study medication start date [1]	Known	Not TEAE
	Partial	Not TEAE
	Missing	Not TEAE
Partial, could be on or after study medication start date	Known	If stop date < study medication start date, then not TEAE If stop date >= study medication start date, then TEAE
	Partial	Impute stop date as latest possible date (i.e. last day of month if day unknown or 31st December if day and month are unknown), then: If stop date < study medication start date, then not TEAE If stop date >= study medication start date, then TEAE
	Missing	Assumed TEAE

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START DATE	STOP DATE	ACTION
Missing	Known	If stop date < study medication start date, then not TEAE If stop date >= study medication start date, then TEAE
	Partial	Impute stop date as latest possible date (i.e. last day of month if day unknown or 31st December if day and month are unknown), then: If stop date < study medication start date, then not TEAE If stop date >= study medication start date, then TEAE
	Missing	Assumed TEAE

[1] E.g. if treatment start date is 18-11-2019 and AE date is UNK-12-2019 and since from the "known component" we know that regardless of the actual day, AE started always after treatment start date, therefore, it is a TEAE.
AE: Adverse event; TEAE: Treatment emergent event; UNK: Unknown

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Statistical Analysis Plan - SAP - 28-Aug-2020

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Signer Full Name	Meaning of Signature	Date and Time
Juzer Lotya	Document Approval (I certify that I have the education, training and experience to perform this task)	06 Aug 2020 08:17:18 UTC
Richard Chambers	Document Approval (I certify that I have the education, training and experience to perform this task)	28 Aug 2020 15:13:13 UTC

NON-INTERVENTIONAL STUDY PROTOCOL *C3591031*

REAL-WORLD OBSERVATIONAL STUDY OF ZAVICEFTA® (CEFTAZIDIME-AVIBACTAM) TO CHARACTERIZE USE PATTERNS, EFFECTIVENESS AND SAFETY – EZTEAM STUDY

ANNOTATED SHELLS

Version: **2.0**

Author: **Juzer Lotya**

Date: 11 January 2022

Table of Contents

Description of Global Rules:

Global Rules	Description

General information	• **All Tables will be performed overall, by region, and then by country.**
	  ○ **First, overall;**
	  ○ **Then only for EUFL = "Y"**
	  ○ **Afterwards, only for LATAMFL = "Y"**
	  ○ **Finally, for each country.**
	  Follow the same logic detailed in Table 2.

Decimal place rules	• **Minimum, Maximum – Same decimal places as raw data** • **Mean, Median, Q1, Q3- 1 more decimal places than the raw data** • **SD – 2 more decimal places than the raw data** • **Percentages, 95% CI – 1 decimal place** • **P-values – 3 decimal places**
Standard deviation rules	• **2 more decimal places than the raw data** • **If n=1, SD displayed as "-"**
Percentages	• **Based on the number of number of patients with no missing data** • **For zero, only count and no percentage will be displayed.** • **For 100, it shall be displayed as an integer (100)**
Lack of observations	• **If there is no observation, summary statistics will be displayed as "-"** • **Table completely empty will be prepared with the respective title and a footnote, but with the text "- No Observations -" in the body of the output** • **If a column has N=0, percentages should be represented by "(-)"** • **If a Country has N=0 in ADSL, then it should not be presented in tables**
P-values	• **3 decimal places** • **P-values rounded to less than 0.001 will be reports as <0.001**

Global Rules	Description
Confidence intervals	• **Presented as "xx.x, xx.x"**
Listings	• **Sorted by subject number, unless specified otherwise.**

Table 1.1 Site Characteristics by Country (FAS)

Characteristic	Austria (N=xx)	France (N=xx)	Germany (N=xx)	Greece (N=xx)	Italy (N=xx)	Russia (N=xx)	Spain (N=xx)	United Kingdom (N=xx)	Overall (N=xx)
Physician specialty, n (%)[1]									
n	xx	xx	xx	xx	xx	xx	xx	xx	xx
Infectious disease	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Microbiology	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Surgery	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Internal medicine	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Intensive care	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Anesthesiology	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Total # of physician	xx	xx	xx	xx	xx	xx	xx	xx	xx
Missing, n	xx	xx	xx	xx	xx	xx	xx	xx	xx
Hospital care level, n (%)[1]									
n	xx	xx	xx	xx	xx	xx	xx	xx	xx
Secondary	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Tertiary	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing, n	xx	xx	xx	xx	xx	xx	xx	xx	xx
Hospital type, n (%)[3]									

Characteristic	Austria (N=xx)	France (N=xx)	Germany (N=xx)	Greece (N=xx)	Italy (N=xx)	Russia (N=xx)	Spain (N=xx)	United Kingdom (N=xx)	Overall (N=xx)
n	xx	xx	xx	xx	xx	xx	xx	xx	xx
Teaching	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Non-teaching	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Total number of beds, n(%)									
n	xx	xx	xx	xx	xx	xx	xx	xx	xx
<500	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
[500-1000)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
[1000-1500)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
[1500-2000)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
≥2000	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Missing, n	xx	xx	xx	xx	xx	xx	xx	xx	xx
Total number of beds									
n	xx	xx	xx	xx	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x

Characteristic	Austria (N=xx)	France (N=xx)	Germany (N=xx)	Greece (N=xx)	Italy (N=xx)	Russia (N=xx)	Spain (N=xx)	United Kingdom (N=xx)	Overall (N=xx)
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Unknown, n	xx	xx	xx	xx	xx	xx	xx	xx	xx
Missing, n	xx	xx	xx	xx	xx	xx	xx	xx	xx
Total number of ICU beds									
n	xx	xx	xx	xx	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Unknown, n	xx	xx	xx	xx	xx	xx	xx	xx	xx
Missing, n	xx	xx	xx	xx	xx	xx	xx	xx	xx

FAS-Full analysis set
SD- Standard deviation, Q1- Quartile one, Q3- Quartile three, Min- Minimum, Max- Maximum. ICU-Intensive care unit
[1] n Number of physicians by specialty. Percentages computed among the total number of physicians (only principal investigator) by Country.
[2] n Number of hospitals by level. Percentages computed among the total number of hospitals by Country.
[3] n Number of hospitals by type. Percentages computed among the total number of hospitals by Country.

Characteristic	Argentina (N=xx)	Brazil (N=xx)	Colombia (N=xx)	Overall (N=xx)
Physician specialty, n (%)[1]				
Infectious disease	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Microbiology	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Surgery	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Internal medicine	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Intensive care	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Anesthesiology	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Total # of physician	xx	xx	xx	xx
Missing, n	xx	xx	xx	xx
Hospital care level, n (%)[1]				
n	xx	xx	xx	xx
Secondary	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Tertiary	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing, n	xx	xx	xx	xx
Hospital type, n (%)[3]				
Teaching	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Non-teaching	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Total number of beds, n(%)				
n	xx	xx	xx	xx
<500	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)

Characteristic	Argentina (N=xx)	Brazil (N=xx)	Colombia (N=xx)	Overall (N=xx)
[500-1000)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
[1000-1500)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
[1500-2000)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
≥2000	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Missing, n	xx	xx	xx	xx
Total number of beds				
n	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Unknown, n	xx	xx	xx	xx
Missing, n	xx	xx	xx	xx
Total number of ICU beds				
n	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Unknown, n	xx	xx	xx	xx
Missing, n	xx	xx	xx	xx

FAS-Full analysis set

SD- Standard deviation, Q1- Quartile one, Q3- Quartile three, Min- Minimum, Max- Maximum. ICU-Intensive care unit
[1] n Number of physicians by specialty. Percentages computed among the total number of physicians (only principal investigator) by Country.
[2] n Number of hospitals by level. Percentages computed among the total number of hospitals by Country.
[3] n Number of hospitals by type. Percentages computed among the total number of hospitals by Country.

Table 1.2 Site Characteristics Gram-Negative Resistance Patterns by Country (FAS)

Characteristic	Austria (N=xx)	France (N=xx)	Germany (N=xx)	Greece (N=xx)	Italy (N=xx)	Russia (N=xx)	Spain (N=xx)	United Kingdom (N=xx)	Overall (N=xx)
Sites with information on percentage of gram-negative isolates that exhibit resistance to the following antibiotics, n(%)									
n	xx	xx	xx	xx	xx	xx	xx	xx	xx
3rd generation cephalosporins [1]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Carbapenems [1]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3rd generation cephalosporins and carbapenems (cross-resistance) [1]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Colistin	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing, n	xx	xx	xx	xx	xx	xx	xx	xx	xx
If yes, for which year? [2]									
YYYY	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
YYYY	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
YYYY	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
YYYY…	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Rate of resistance to 3rd generation cephalosporins									
n(%)[3]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Median	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Q1, Q3	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x	xx.x,xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Unknown, n	xx	xx	xx	xx	xx	xx	xx	xx	xx
Missing, n	xx	xx	xx	xx	xx	xx	xx	xx	xx

Characteristic	Austria (N=xx)	France (N=xx)	Germany (N=xx)	Greece (N=xx)	Italy (N=xx)	Russia (N=xx)	Spain (N=xx)	United Kingdom (N=xx)	Overall (N=xx)
Rate of resistance to carbapenems									
n(%)[3]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Q1, Q3	xx.x, x.x	xx.x, x.x	xx.x, x.x	xx.x, x.x	xx.x,xx.x	xx.x, x.x	xx.x,xx.x	xx.x, x.x	xx.x,xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Unknown, n	xx	xx	xx	xx	xx	xx	xx	xx	xx
Missing, n	xx	xx	xx	xx	xx	xx	xx	xx	xx
Rate of cross-resistance to 3rd generation cephalosporins and carbapenems									
n(%)[3]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Q1, Q3	xx.x, x.x	xx.x,xx.x	xx.x, x.x	xx.x,xx.x	xx.x, x.x	xx.x,xx.x	xx.x, x.x	xx.x,xx.x	xx.x, x.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Unknown, n	xx	xx	xx	xx	xx	xx	xx	xx	xx
Missing, n	xx	xx	xx	xx	xx	xx	xx	xx	xx
Rate of resistance to colistin									
n(%)[3]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Mean (SD)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Unknown, n	xx	xx	xx	xx	xx	xx	xx	xx	xx
Missing, n	xx	xx	xx	xx	xx	xx	xx	xx	xx

SD- Standard deviation, Q1- Quartile one, Q3- Quartile three, Min- Minimum, Max- Maximum.
[1] Percentages computed among the total number of sites by Country.
[2] The latest available rates.
[3] Percentages computed among the total number of sites within the sub-category.

Table 2 Patients Disposition by Indication Overall (ENR)

Characteristic	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL [1] (N=xx)
Overall (N=xxx)					
Signed informed consent, n(%)					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Applicable as per Local Regulations	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Informed consent provided by, n(%)					
Patient	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Next of kin	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Patient followed through medical records up to 60 days after hospital discharge, n(%)					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Reasons patient not followed through medical records up to 60 days after hospital discharge, n(%)					
In-hospital death	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Withdrawal from the study	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Lost to follow-up	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Analysis Population, n (%)					

ENR	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
FAS	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
FAS72+	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
FAS72-	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
COD	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
MOD	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Europe (N=xx)					
Signed informed consent, n (%)					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Applicable as per Local Regulations	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Informed consent provided by, n(%)					
Patient	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Next of kin	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Patient followed through medical records up to 60 days after hospital discharge, n(%)					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Reasons patient not followed through medical records up to 60 days after hospital discharge, n(%)					
In-hospital death	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Withdrawal from the study	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Lost to follow-up	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Analysis Population datasets, n (%)					
ENR	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
FAS	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
FAS72+	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
FAS72-	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
COD	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
MOD	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Latin America (N=xx)					
Signed informed consent, n (%)					
Yes	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
No	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Not Applicable as per Local Regulations	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Informed consent provided by, n(%)					
Patient	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Next of kin	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Patient followed through medical records up to 60 days after hospital discharge, n(%)					
Yes	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
No	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Reasons patient not followed through medical records up to 60 days after hospital discharge, n(%)					
In-hospital death [2]	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Withdrawal from the study	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Lost to follow-up	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Other	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**

Analysis Population, n (%)					
ENR	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
FAS	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
FAS72+	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
FAS72-	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
COD	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
MOD	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

[1] There is xx patient with indication missing.
cIAI-Complicated Intra-Abdominal Infection; cUTI-Complicated Urinary Tract Infection; HAP-Hospital-Acquired Pneumonia; VAP-Ventilator-Associated Pneumonia.
The enrolled set (ENR) has all patients who complied with local requirements of informed consent (provided signed informed consent or informed consent was not applicable per local regulations).
The full analysis set (FAS) has all eligible patients.
FAS72+ analysis set has all patients exposed to ceftazidime-avibactam ≥ 72 hours
FAS72- analysis set has all patients exposed to ceftazidime-avibactam < 72 hours.
The clinical outcomes analysis set (COD) has all patients exposed to ceftazidime-avibactam ≥ 72 hours and ≥ 1 non-missing clinical outcome.
The microbiological outcomes analysis set (MOD) has all exposed to ceftazidime-avibactam ≥ 72 hours and ≥ 1 non-missing microbiological outcome.

Table 3 Patients by Indication Overall (FAS72+ and FAS72-)

Characteristic	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Exposure to ceftazidime-avibactam, n (%)					
n	xx	xx	xx	xx	xx
Duration of exposure ≥ 72 hours	xx(xx)	xx(xx)	xx(xx)	xx(xx)	xx(xx)
Duration of exposure < 72 hours	xx(xx)	xx(xx)	xx(xx)	xx(xx)	xx(xx)
Missing, n	xx	xx	xx	xx	xx

cIAI-Complicated Intra-Abdominal Infection; cUTI-Complicated Urinary Tract Infection; HAP-Hospital-Acquired Pneumonia; VAP-Ventilator-Associated Pneumonia.
FAS72+ analysis set has all patients exposed to ceftazidime-avibactam ≥ 72 hours.
FAS72- analysis set has all patients exposed to ceftazidime-avibactam < 72 hours.

Table 4.1 Demographic and Baseline Characteristics by Indication Overall (FAS72+)

Characteristic	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Exposure to ceftazidime-avibactam, n (%)					
n	xx	xx	xx	xx	xx
Missing, n	xx	xx	xx	xx	xx
Age (years)					
n	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing, n	xx	xx	xx	xx	xx
Age group, n(%)					
n	xx	xx	xx	xx	xx
<40	xx(xx)	xx(xx)	xx(xx)	xx(xx)	xx(xx)
40-49	xx(xx)	xx(xx)	xx(xx)	xx(xx)	xx(xx)
50-59	xx(xx)	xx(xx)	xx(xx)	xx(xx)	xx(xx)
60-69	xx(xx)	xx(xx)	xx(xx)	xx(xx)	xx(xx)
70-79	xx(xx)	xx(xx)	xx(xx)	xx(xx)	xx(xx)
80-89	xx(xx)	xx(xx)	xx(xx)	xx(xx)	xx(xx)
>=90	xx(xx)	xx(xx)	xx(xx)	xx(xx)	xx(xx)
Missing, n	xx	xx	xx	xx	xx
Gender, n(%)					
n	xx	xx	xx	xx	xx
Male	xx(xx)	xx(xx)	xx(xx)	xx(xx)	xx(xx)
Female	xx(xx)	xx(xx)	xx(xx)	xx(xx)	xx(xx)

Characteristic	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Missing, n	xx	xx	xx	xx	xx
Height, cm					
n	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing, n	xx	xx	xx	xx	xx
Weight, kg					
n	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing, n	xx	xx	xx	xx	xx
BMI (kg/m^2)					
n	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing, n	xx	xx	xx	xx	xx
Employment status					
n	xx	xx	xx	xx	xx
Full Time	xx(xx)	xx(xx)	xx(xx)	xx(xx)	xx(xx)
Part Time	xx(xx)	xx(xx)	xx(xx)	xx(xx)	xx(xx)
Unemployed	xx(xx)	xx(xx)	xx(xx)	xx(xx)	xx(xx)
Retired	xx(xx)	xx(xx)	xx(xx)	xx(xx)	xx(xx)

Characteristic	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Not Available	xx(xx)	xx(xx)	xx(xx)	xx(xx)	xx(xx)
Missing, n	xx	xx	xx	xx	xx

FAS72+ analysis set has all patients exposed to ceftazidime-avibactam ≥ 72 hours.
cIAI-Complicated Intra-Abdominal Infection; cUTI-Complicated Urinary Tract Infection; HAP-Hospital-Acquired Pneumonia; VAP-Ventilator-Associated Pneumonia.
SD- Standard deviation, Q1- Quartile one, Q3- Quartile three, Min- minimum, Max- Maximum.

Table 4.2 Baseline Demographic Characteristics of Patients Exposed to Ceftazidime-Avibactam for <72 hours by Indication Overall (FAS72-)

FAS72- analysis set has all patients exposed to ceftazidime-avibactam < 72 hours.
Programming Note: Besides Overall, Europe, and LATAM; repeat for each Country. Each section will start in a new page.
Possible countries:

Table 5 Prior Hospitalizations, Healthcare Resource Utilization and Antibiotic Exposure by Indication Overall (FAS72+)

Characteristic	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Any prior hospitalizations within 90 days prior to date of current hospitalization, n (%) PRIORHP count unique(SUBNUM)					
n	xx	xx	xx	xx	xx
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing, n	xx	xx	xx	xx	xx
Hospital LOS for prior hospitalization (days)[1] HOSPDUR					
n (%)[2]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing, n	xx	xx	xx	xx	xx
Any healthcare procedure within the 30 days prior to index date, n (%) [3]					
n	xx	xx	xx	xx	xx
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing/Unknown	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Type of procedure, n (%)					
n	xx	xx	xx	xx	xx
Mechanical ventilation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Dialysis	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Tracheostomy	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Surgical intervention	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Percutaneous procedure	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing, n	xx	xx	xx	xx	xx

Characteristic	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Antibiotic exposure within 90 days prior to index hospitalization, n (%)					
Antibiotic					
n	xx	xx	xx	xx	xx
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing/unknown	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic Class and name [4]					
n	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ATC class 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 3 etc.	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ATC class 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 2 etc.	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ATC class 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 2 etc.	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ATC class 4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 2 etc.	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ATC class 5	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 2 etc.	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
… …					
Duration of antibiotic treatment (days)					
n (%)	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing, n	xx	xx	xx	xx	xx
Reason for antibiotic treatment, n (%)					
n	xx	xx	xx	xx	xx
Therapeutic	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Prophylactic	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Characteristic	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Missing, n	xx	xx	xx	xx	xx

cIAI-Complicated Intra-Abdominal Infection; cUTI-Complicated Urinary Tract Infection; HAP-Hospital-Acquired Pneumonia; VAP-Ventilator-Associated Pneumonia.
FAS72+ analysis set has all patients exposed to ceftazidime-avibactam ≥ 72 hours.
SD- Standard deviation, Q1- Quartile one, Q3- Quartile three, Min- minimum, Max- Maximum, LOS- Length of Stay.
[1] Hospital LOS: (Date of hospital discharge - Date of hospital admission)
[2] n for LOS for prior hospitalization, is the number of patients with a prior hospitalization.
[3] A patient may have had more than one procedure during this period.
[4] Some patients may be administered multiple antibiotics; the Antibiotic totals may exceed the number of patients. Likewise, the sum of percentages may exceed 100%.

Table 6 Additional Risk Factors by Indication Overall (FAS72+)

Risk Factors	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL
Travel to foreign country within the last 3 months, n (%)					
n	xx	xx	xx	xx	xx
Yes [1]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No [1]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown [2]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Country [2]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing, n	xx	xx	xx	xx	xx
Travel duration [3]					
n (%)[2]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing, n	xx	xx	xx	xx	xx
Subject hospitalized during travel, n (%)[2]	xx	xx	xx	xx	xx
n	xx	xx	xx	xx	xx
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing, n	xx	xx	xx	xx	xx
Pregnancy, n (%)[1]					
n	xx	xx	xx	xx	xx
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Applicable	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing, n	xx	xx	xx	xx	xx
Number of weeks of gestation since last menstrual period					
n (%)[4]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x

Risk Factors	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing, n	xx	xx	xx	xx	xx
Does the patient drink alcohol, n (%)[1]					
n	xx	xx	xx	xx	xx
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing, n	xx	xx	xx	xx	xx
Alcohol use > 14 drinks/week					
n	xx	xx	xx	xx	xx
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing, n	xx	xx	xx	xx	xx
Number of drinks per week					
n (%)[2]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing, n	xx	xx	xx	xx	xx
Tobacco use, n (%) [1]					
n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Current Smoker	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Previous Smoker	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Never Smoked	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Cigarettes per day for current smokers					
n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing, n	xx	xx	xx	xx	xx

Risk Factors	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL
Cigarettes per day for previous smokers					
n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing, n	xx	xx	xx	xx	xx
Number of years smoking					
n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing, n	xx	xx	xx	xx	xx

FAS72+ analysis set has all patients exposed to ceftazidime-avibactam ≥ 72 hours.
cIAI-Complicated Intra-Abdominal Infection; cUTI-Complicated Urinary Tract Infection; HAP-Hospital-Acquired Pneumonia; VAP-Ventilator-Associated Pneumonia.
SD- Standard deviation, Q1- Quartile one, Q3- Quartile three. Min- minimum, Max- Maximum
[1] Percentages computed among the total number of patients by Country.
[2] Percentages computed among the total number of patients within the category.
[3] Duration of travel = [End date of travel – Start date of travel]
[4] Percentages computed among the total number of pregnant patients.

Table 7 Comorbidities by Indication Overall (FAS72+)

Comorbidities	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Any comorbidities, n (%) [1]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No comorbidities, n (%) [1]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Number of comorbidities by patient,					
n (%)[2]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Q1, Q3	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x(xx.xx)
Min, Max	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x(xx.xx)
Missing, n	xx	xx	xx	xx	xx
Any Deyo-Charlson comorbidity, n (%)					
n [1]	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x(xx.xx)
Missing, n	xx	xx	xx	xx	xx
Deyo-Charlson comorbidity score [3], n (%)					
0	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x(xx.xx)
1	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x(xx.xx)
2	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x(xx.xx)
3	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x(xx.xx)
>=4	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x(xx.xx)
Deyo-Charlson comorbidity score					
n (%)[2]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Deyo-Charlson comorbidities					
Myocardial Infarction, n (%)[2]					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Comorbidities	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Congestive heart failure, n (%) [2]					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Peripheral vascular disease, n (%)[2]					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Chronic obstructive pulmonary Disease, n (%)[2]					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Rheumatologic disease, n (%)[2]					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Peptic ulcer disease, n (%)[2]					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Moderate or severe renal disease, n (%)[2]					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Skin ulcers/cellulitis, n (%)[2]					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
AIDS, n (%)[2]					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Cerebrovascular disease (except hemiplegia), n (%)[2]					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Comorbidities	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Hemiplegia, n (%)[2]					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Paraplegia, n (%)[2]					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Mild liver disease, n (%)[2]					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Moderate to severe liver disease, n (%)[2]					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Dementia, n (%)[2]					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Use of warfarin, n (%)[2]					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Depression, n (%)[2]					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Hypertension, n (%)[2]					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Diabetes mild to moderate, n (%)[2]					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Diabetes + complications, n (%)[2]					

Comorbidities	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Malignancy (solid tumor, non-metastic, n (%)[2]					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Metastatic solid tumor, n (%)[2]					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Hematological malignancy/leukemia or lymphoma, n (%)[2]					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Bone marrow transplant, n (%)[2]					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other transplant (solid organ), n (%)[2]					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any Non-Deyo-Charlson comorbidity , n (%) [1]					
Yes.	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No ,	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Reduced consciousness, n (%)[2]					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Glasgow coma score					

Comorbidities	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
n	xx	xx	xx	xx	xx
5	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
6	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
7	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
9	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
10	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
11	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
12	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
13	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
14	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not done	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other, n (%)[2]					
n	xx	xx	xx	xx	xx
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing, n	xx	xx	xx	xx	xx
Indwelling devices at the time of the infection diagnosis, n (%)					
Any Indwelling device n	xx	xx	xx	xx	xx
None [2]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Intravenous peripheric catheter [2]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Intravenous central catheter [2]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Urinary catheter[2]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Arterial catheter [2]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Arteriovenous cannula [2]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Tracheal intubation [2]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Tracheal cannula [2]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Any drain [2]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other [2]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

FAS72+ analysis set has all patients exposed to ceftazidime-avibactam ≥ 72 hours.

cIAI-Complicated Intra-Abdominal Infection; cUTI-Complicated Urinary Tract Infection; HAP-Hospital-Acquired Pneumonia; VAP-Ventilator-Associated Pneumonia.
SD- Standard deviation, Q1- Quartile one, Q3- Quartile three, Min- minimum, Max- Maximum
[1] Percentages computed among the total number of patients by Country.
[2] Percentages computed among the total number of patients within the category.
[3] Deyo-Charlson comorbidity score is a derived variable. For the comorbidities to be included and the corresponding weights please refer to the SAP.

Table 8.1 Source of Infection by Indication Overall (FAS72+)

Characteristic	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Source of infection, n (%)					
n	xx	xx	xx	xx	xx
HCAI	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
HAI	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
CAI	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing, n	xx	xx	xx	xx	xx

FAS72+ analysis set has all patients exposed to ceftazidime-avibactam ≥ 72 hours.
cIAI-Complicated Intra-Abdominal Infection; cUTI-Complicated Urinary Tract Infection; HAP-Hospital-Acquired Pneumonia; VAP-Ventilator-Associated Pneumonia.
HCAI-Healthcare-Associated Infection, HAI-Hospital-Acquired Infection, CAI-Community-Acquired Infection
Note: HCAI and HAI are not mutually exclusive, in principle HCAI include the HAI

Table 8.2 Source of Infection by Indication Overall (FAS72-)

Characteristic	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Source of infection, n (%)					
n	xx	xx	xx	xx	xx
HCAI	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
HAI	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
CAI	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing, n	xx	xx	xx	xx	xx

FAS72- analysis set has all patients exposed to ceftazidime-avibactam < 72 hours.
cIAI-Complicated Intra-Abdominal Infection; cUTI-Complicated Urinary Tract Infection; HAP-Hospital-Acquired Pneumonia; VAP-Ventilator-Associated Pneumonia.
HCAI-Healthcare-Associated Infection, HAI-Hospital-Acquired Infection, CAI-Community-Acquired Infection
Note: HCAI and HAI are not mutually exclusive, in principle HCAI include the HAI.

Table 8.3 Indication for Ceftazidime-Avibactam Overall (FAS72+ and FAS72-)

Indication for ceftazidime-avibactam	FAS+ (N=XX)	FAS- (N=XX)	Total
Complicated Urinary Tract Infection (cUTI), n (%)[1]	xx (xx.x)	xx (xx.x)	xx (xx.x)
Complicated Intra-Abdominal Infection (cIAI),n (%)[1]	xx (xx.x)	xx (xx.x)	xx (xx.x)
Hospital-Acquired Pneumonia/Ventilator-Associated Pneumonia (HAP/VAP),n (%)[1]	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other, n (%)[1]	xx (xx.x)	xx (xx.x)	xx (xx.x)
Was the patient diagnosed with COVID-19?			
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not applicable	xx (xx.x)	xx (xx.x)	xx (xx.x)
If yes, indication for ceftazidime-avibactam			
Complicated Urinary Tract Infection (cUTI), n (%)[2]	xx (xx.x)	xx (xx.x)	xx (xx.x)
Complicated Intra-Abdominal Infection (cIAI),n (%)[2]	xx (xx.x)	xx (xx.x)	xx (xx.x)
Hospital-Acquired Pneumonia/Ventilator-Associated Pneumonia (HAP/VAP), n (%)[2]	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other, n (%)[1]	xx (xx.x)	xx (xx.x)	xx (xx.x)

If No, indication for ceftazidime-avibactam			
Complicated Urinary Tract Infection (cUTI), n (%)[2]	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Complicated Intra-Abdominal Infection (cIAI),n (%)[2]	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Hospital-Acquired Pneumonia/Ventilator-Associated Pneumonia (HAP/VAP), n (%)[2]	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Other, n (%)[1]	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**

FAS72+ analysis set has all patients exposed to ceftazidime-avibactam ≥ 72 hours.
FAS72- analysis set has all patients exposed to ceftazidime-avibactam < 72 hours.
cIAI-Complicated Intra-Abdominal Infection; cUTI-Complicated Urinary Tract Infection; HAP-Hospital-Acquired Pneumonia; VAP-Ventilator-Associated Pneumonia.
SD- Standard deviation, Q1- Quartile one, Q3- Quartile three. Min- minimum, Max- Maximum
[1] Percentages computed among the total number of patients by Country.
[2] Percentages computed among the total number of patients within the category.

Table 9.1 Diagnoses and Symptoms Associated with UTI (Including Pyelonephritis) by Bacteria Overall (FAS72+)

Overall/Region/Country Indication for ceftazidime-avibactam	*Escherichia coli* (N=xx)	*Klebsiella* spp. (N=xx)	*Enterobacter* spp. (N=xx)	*Pseudomonas* spp. (N=xx)	Other pathogen (N=xx)	No pathogen identified (N=xx)	TOTAL (N=xx)
Complicated Urinary Tract Infection (cUTI), n (%)[1] INDIC =2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Primary diagnosis of UTI (including pyelonephritis) that occurs associated with, n (%) [2]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Calculi/Stone	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Indwelling catheter or other drainage device	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Obstruction	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Immunosuppression	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Renal failure	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Renal transplantation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Pregnancy	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Functional or anatomical abnormalities of the urinary tract	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Partial obstructive uropathy (Acquired or congenital)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Elevated postvoidal residual volume (>100 mL residual)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Established diagnosis of neurogenic bladder	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Instrumentation of the urinary tract	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Overall/Region/Country	*Escherichia coli* (N=xx)	*Klebsiella* spp. (N=xx)	*Enterobacter* spp. (N=xx)	*Pseudomonas* spp. (N=xx)	Other pathogen (N=xx)	No pathogen identified (N=xx)	TOTAL (N=xx)
Secondary diagnosis of UTI (including pyelonephritis), n (%)[1]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Secondary diagnosis of UTI (including pyelonephritis) that occurs associated with, n (%)[2]							
Calculi/Stone	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Indwelling catheter or other drainage device	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Obstruction	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Immunosuppression	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Renal failure	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Renal transplantation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Pregnancy	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Functional or anatomical abnormalities of the urinary tract	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Partial obstructive uropathy (Acquired or congenital)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Elevated postvoidal residual volume (>100 mL residual)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Established diagnosis of neurogenic bladder	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Instrumentation of the urinary tract	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Symptoms of UTI, n (%)[2]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Fever	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Overall/Region/Country	*Escherichia coli* (N=xx)	*Klebsiella* spp. (N=xx)	*Enterobacter* spp. (N=xx)	*Pseudomonas* spp. (N=xx)	Other pathogen (N=xx)	No pathogen identified (N=xx)	TOTAL (N=xx)
Flank pain or suprapubic pain or costovertebral angle (CVA) tenderness on examination	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Dysuria, urgency, frequency, incontinence or nausea/vomiting with no other recognized cause	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Pyuria	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Symptoms of UTI: Positive dipstick for leukocyte esterase and/or nitrite, n (%)[2]							
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Symptoms of UTI: Did the patient have a secondary bacteremia, n (%)[2]							
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

FAS72+ analysis set has all patients exposed to ceftazidime-avibactam ≥ 72 hours.
UTI-Urinary tract infection
SD- Standard deviation, Q1- Quartile one, Q3- Quartile three. Min- minimum, Max- Maximum
[1] Percentages computed among the total number of patients by Country.
[2] Percentages computed among the total number of patients within the category.
Patients may have more than one pathogen identified.

Table 9.2 Diagnoses and Symptoms Associated with UTI (Including Pyelonephritis) for Patients with Ceftazidime-Avibactam Exposure <72 Hours (FAS72-)

Overall/Region/Country Indication for ceftazidime-avibactam	TOTAL (N=xx)
Complicated Urinary Tract Infection (cUTI), n (%)[1]	xx (xx.x)
Primary diagnosis of UTI (including pyelonephritis) that occurs associated with, n (%) [2]	xx (xx.x)
Calculi/Stone	xx (xx.x)
Indwelling catheter or other drainage device	xx (xx.x)
Obstruction	xx (xx.x)
Immunosuppression	xx (xx.x)
Renal failure	xx (xx.x)
Renal transplantation	xx (xx.x)
Pregnancy	xx (xx.x)
Functional or anatomical abnormalities of the urinary tract	xx (xx.x)
Partial obstructive uropathy (Acquired or congenital)	xx (xx.x)
Elevated postvoidal residual volume (>100 mL residual)	xx (xx.x)
Established diagnosis of neurogenic bladder	xx (xx.x)
Instrumentation of the urinary tract	xx (xx.x)
Other	xx (xx.x)
Secondary diagnosis of UTI (including pyelonephritis), n (%)[1]	xx (xx.x)
Secondary diagnosis of UTI (including pyelonephritis) that occurs associated with, n (%)[2]	
Calculi/Stone	xx (xx.x)
Indwelling catheter or other drainage device	xx (xx.x)
Obstruction	xx (xx.x)
Immunosuppression	xx (xx.x)
Renal failure	xx (xx.x)

Overall/Region/Country	TOTAL (N=xx)
Renal transplantation	xx (xx.x)
Pregnancy	xx (xx.x)
Functional or anatomical abnormalities of the urinary tract	xx (xx.x)
Partial obstructive uropathy (Acquired or congenital)	xx (xx.x)
Elevated postvoidal residual volume (>100 mL residual)	xx (xx.x)
Established diagnosis of neurogenic bladder	xx (xx.x)
Instrumentation of the urinary tract	xx (xx.x)
Other	xx (xx.x)
Symptoms of UTI, n (%)[2]	xx (xx.x)
Fever	xx (xx.x)
Flank pain or suprapubic pain or costovertebral angle (CVA) tenderness on examination	xx (xx.x)
Dysuria, urgency, frequency, incontinence or nausea/vomiting with no other recognized cause	xx (xx.x)
Pyuria	xx (xx.x)

UTI-Urinary tract infection
SD- Standard deviation, Q1- Quartile one, Q3- Quartile three. Min- minimum, Max- Maximum
[1] Percentages computed among the total number of patients by Country.
[2] Percentages computed among the total number of patients within the category.

Table 10.1 Diagnoses and Symptoms Associated with IAI by Bacteria Overall (FAS72+)

Overall/Region/Country Indication for ceftazidime-avibactam	*Escherichia coli* (N=xx)	*Klebsiella* spp. (N=xx)	*Enterobacter* spp. (N=xx)	*Pseudomonas* spp. (N=xx)	Other pathogen (N=xx)	No pathogen identified (N=xx)	TOTAL (N=xx)
Complicated Intra-Abdominal Infection (cIAI),n (%)[1]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Primary diagnosis of IAI, n (%)[2]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Peritonitis	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Intraperitoneal abscess	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Liver abscess	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Pancreatic abscess	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Appendicitis	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Diverticulitis	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gastric or duodenal ulcers	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Cholecystitis	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Cholangitis	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Traumatic population	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Secondary diagnosis of IAI, n (%)[2]							
Peritonitis	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Intraperitoneal abscess	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Liver abscess	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Pancreatic abscess	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Overall/Region/Country	*Escherichia coli* (N=xx)	*Klebsiella* spp. (N=xx)	*Enterobacter* spp. (N=xx)	*Pseudomonas* spp. (N=xx)	Other pathogen (N=xx)	No pathogen identified (N=xx)	TOTAL (N=xx)
Appendicitis	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Diverticulitis	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gastric or duodenal ulcers	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Cholecystitis	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Cholangitis	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Traumatic population	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Symptoms of IAI, n (%)[2]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Fever	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Hypothermia	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Abdominal pain	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Tenderness on palpation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Guarding and rebound tenderness	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Abdominal fullness or/ distension	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Nausea or vomiting	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ileus	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Diarrhea	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Tachycardia	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Hypotension	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Shock	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Symptoms of IAI: Did the patient have a secondary bacteremia? [2]							
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Overall/Region/Country	*Escherichia coli* (N=xx)	*Klebsiella* spp. (N=xx)	*Enterobacter* spp. (N=xx)	*Pseudomonas* spp. (N=xx)	Other pathogen (N=xx)	No pathogen identified (N=xx)	TOTAL (N=xx)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

FAS72+ analysis set has all patients exposed to ceftazidime-avibactam ≥ 72 hours.
IAI-Intra-abdominal infection
SD- Standard deviation, Q1- Quartile one, Q3- Quartile three. Min- minimum, Max- Maximum
[1] Percentages computed among the total number of patients by Country.
[2] Percentages computed among the total number of patients within the category.
Patients may have more than one pathogen identified.

Table 10.2 Diagnoses and Symptoms Associated with IAI for Patients with Ceftazidime-Avibactam Exposure <72 Hours Overall (FAS72-)

Overall/Region/Country Indication for ceftazidime-avibactam	TOTAL (N=xx)
Complicated Intra-Abdominal Infection (cIAI),n (%)[1]	xx (xx.x)
Primary diagnosis of IAI, n (%)[2]	xx (xx.x)
Peritonitis	xx (xx.x)
Intraperitoneal abscess	xx (xx.x)
Liver abscess	xx (xx.x)
Pancreatic abscess	xx (xx.x)
Appendicitis	xx (xx.x)
Diverticulitis	xx (xx.x)
Gastric or duodenal ulcers	xx (xx.x)
Cholecystitis	xx (xx.x)
Cholangitis	xx (xx.x)
Traumatic population	xx (xx.x)
Other	xx (xx.x)
Secondary diagnosis of IAI, n (%)[2]	
Peritonitis	xx (xx.x)
Intraperitoneal abscess	xx (xx.x)
Liver abscess	xx (xx.x)
Pancreatic abscess	xx (xx.x)
Appendicitis	xx (xx.x)
Diverticulitis	xx (xx.x)
Gastric or duodenal ulcers	xx (xx.x)
Cholecystitis	xx (xx.x)
Cholangitis	xx (xx.x)

Overall/Region/Country	TOTAL (N=xx)
Traumatic population	xx (xx.x)
Other	xx (xx.x)
Symptoms of IAI, n (%)[2]	xx (xx.x)
Fever	xx (xx.x)
Hypothermia	xx (xx.x)
Abdominal pain	xx (xx.x)
Tenderness on palpation	xx (xx.x)
Guarding and rebound tenderness	xx (xx.x)
Abdominal fullness or/ distension	xx (xx.x)
Nausea or vomiting	xx (xx.x)
Ileus	xx (xx.x)
Diarrhea	xx (xx.x)
Tachycardia	xx (xx.x)
Hypotension	xx (xx.x)
Shock	xx (xx.x)

FAS72- analysis set has all patients exposed to ceftazidime-avibactam < 72 hours.

Table 11.1 Diagnoses and Symptoms of NP Associated with HAP/VAP by Bacteria Overall (FAS72+)

Overall/Region/Country Indication for ceftazidime-avibactam	*Escherichia coli* (N=xx)	*Klebsiella* spp. (N=xx)	*Enterobacter* spp. (N=xx)	*Pseudomonas* spp. (N=xx)	Other pathogen (N=xx)	No pathogen identified (N=xx)	TOTAL[3] (N=xx)
Hospital-Acquired Pneumonia/Ventilator-Associated Pneumonia (HAP/VAP),n (%)[1]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Hospital acquired pneumonia, n (%)[1]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ventilator-associated pneumonia, n (%)[1]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Symptoms of NP diagnosis, n (%)[2]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Fever	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
White blood cell	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
For adults 70 years or older,	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
A new onset of cough	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
New onset of purulent sputum	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Auscultatory findings consistent with pneumonia/pulmonary consolidation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Dyspnea, tachypnea or hypoxemia	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
A need for mechanical ventilation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Overall/Region/Country	*Escherichia coli* (N=xx)	*Klebsiella* spp. (N=xx)	*Enterobacter* spp. (N=xx)	*Pseudomonas* spp. (N=xx)	Other pathogen (N=xx)	No pathogen identified (N=xx)	TOTAL[3] (N=xx)
Symptoms of NP: Did the patient have a secondary bacteremia?, n (%) [2]							
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown, n	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

FAS72+ analysis set has all patients exposed to ceftazidime-avibactam ≥ 72 hours.
HAP- Hospital Associated Pneumonia; VAP- Ventilator-Associated Pneumonia.
SD- Standard deviation, Q1- Quartile one, Q3- Quartile three. Min- minimum, Max- Maximum
[1] Percentages computed among the total number of patients by Country.
[2] Percentages computed among the total number of patients with Hospital-Acquired Pneumonia/Ventilator-Associated Pneumonia.
[3] The total column are unique patients with the specific characteristic.
Patients may have more than one pathogen identified.

Table 11.2 Diagnoses and Symptoms of NP Associated with HAP/VAP for Patients with Ceftazidime-Avibactam Exposure <72 Hours Overall (FAS72-)

Overall/Region/Country	TOTAL[3] (N=xx)
Indication for ceftazidime-avibactam	
Hospital-Acquired Pneumonia/Ventilator-Associated Pneumonia (HAP/VAP),n (%)[1]	**xx (xx.x)**
Hospital acquired pneumonia, n (%)[1]	**xx (xx.x)**
Ventilator-associated pneumonia, n (%)[1]	**xx (xx.x)**
Symptoms of NP diagnosis, n (%)[2]	**xx (xx.x)**
Fever	**xx (xx.x)**
White blood cell	**xx (xx.x)**
For adults 70 years or older,	**xx (xx.x)**
A new onset of cough	**xx (xx.x)**
New onset of purulent sputum	**xx (xx.x)**
Auscultatory findings consistent with pneumonia/pulmonary consolidation	**xx (xx.x)**
Dyspnea, tachypnea or hypoxemia	**xx (xx.x)**
A need for mechanical ventilation	**xx (xx.x)**
Symptoms of NP: Did the patient have a secondary bacteremia?, n (%) [2]	
Yes	**xx (xx.x)**
No	**xx (xx.x)**
Unknown, n	**xx (xx.x)**

FAS72-: is a subset of the FAS patients with <72 hours exposure to ceftazidime-avibactam

Table 12.1 Diagnoses and Symptoms Associated with Other Indication by Bacteria Overall (FAS72+)

	Escherichia coli (N=xx)	*Klebsiella* spp. (N=xx)	*Enterobacter* spp. (N=xx)	*Pseudomonas* spp. (N=xx)	Other Gram-negative pathogen (N=xx)	No pathogen identified (N=xx)	TOTAL [3] (N=xx)
Indication for ceftazidime-avibactam:							
Other n (%)[1]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
SSI [2] INDICOTH	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
CLABSI	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
BSI/Sepsis	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Meningitis	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Endocarditis	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Osteomyelitis	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Febrile neutropenia	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Initial site of infection (organ), n (%) [1]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Appendix [2]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Bladder	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Kidney	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Large Intestine	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Lungs	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Liver	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gall Bladder	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Pancreas	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Peritoneum	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Small Intestine	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Stomach	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Urethra	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

	Escherichia coli (N=xx)	*Klebsiella* spp. (N=xx)	*Enterobacter* spp. (N=xx)	*Pseudomonas* spp. (N=xx)	Other Gram-negative pathogen (N=xx)	No pathogen identified (N=xx)	TOTAL [3] (N=xx)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Did the patient have a secondary bacteremia? [1]							
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

FAS72+ analysis set has all patients exposed to ceftazidime-avibactam ≥ 72 hours.
SD- Standard deviation, Q1- Quartile one, Q3- Quartile three. Min- minimum, Max- Maximum
[1] Percentages computed among the total number of patients by Country.
[2] Percentages computed among the total number of patients within the category.
[3] The total column are unique patients with the specific characteristic.
Patients may have more than one pathogen identified.

Table 12.2 Diagnoses and Symptoms of NP Associated with Other Indication for Patients with Ceftazidime-Avibactam Exposure <72 Hours Overall (FAS72-)

	TOTAL [3] (N=xx)
Indication for ceftazidime-avibactam:	
Other n (%)[1]	xx (xx.x)
SSI [2]	xx (xx.x)
CLABSI	xx (xx.x)
BSI/Sepsis	xx (xx.x)
Meningitis	xx (xx.x)
Endocarditis	xx (xx.x)
Osteomyelitis	xx (xx.x)
Febrile neutropenia	xx (xx.x)
Other	xx (xx.x)
Initial site of infection (organ), n (%) [1]	xx (xx.x)
Appendix [2]	xx (xx.x)
Bladder	xx (xx.x)
Kidney	xx (xx.x)
Large Intestine	xx (xx.x)
Lungs	xx (xx.x)
Liver	xx (xx.x)
Gall Bladder	xx (xx.x)
Pancreas	xx (xx.x)
Peritoneum	xx (xx.x)
Small Intestine	xx (xx.x)
Stomach	xx (xx.x)
Urethra	xx (xx.x)
Other	xx (xx.x)
Did the patient have a secondary bacteremia? [1]	

	TOTAL [3] (N=xx)
Yes	**xx (xx.x)**
No	**xx (xx.x)**
Unknown	**xx (xx.x)**

FAS72-: is a subset of the FAS patients with <72 hours exposure to ceftazidime-avibactam

Table 13 Initial Hospitalization by Indication Overall (FAS72+)

	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Mode of admission, n (%)[1]					
Emergency	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Scheduled	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing, n	xx	xx	xx	xx	xx
Source of admission, n (%)[1]					
n	xx	xx	xx	xx	xx
Outpatient	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Long-term care facility	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Transfer from acute care hospital	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing, n	xx	xx	xx	xx	xx
Initial ward admitted at hospitalization, n (%)[1]					
n	xx	xx	xx	xx	xx
Surgical	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Medical	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Onco-hematology	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Infectious disease	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ICU	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing, n	xx	xx	xx	xx	xx
All wards attended during hospitalization, n (%)[1,2]					
n	xx	xx	xx	xx	xx
Surgical	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Medical	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Onco-hematology	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Infectious disease	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ICU	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing, n	xx	xx	xx	xx	xx
LOS from hospital admission [3]					

	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
n	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing, n	xx	xx	xx	xx	xx
LOS from start of Ceftazidime-avibactam [4]					
n	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing, n	xx	xx	xx	xx	xx
Was the patient admitted to the ICU, n(%)[1]					
n	xx	xx	xx	xx	xx
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing/Unknown	xx	xx	xx	xx	xx
Cumulative ICU LOS from hospital admission [5]					
n	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing, n	xx	xx	xx	xx	xx
Was APACHE II evaluated upon admission to ICU?, n(%)[3]					
n	xx	xx	xx	xx	xx
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing, n	xx	xx	xx	xx	xx
APACHE II Score					

	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
n	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing, n	xx	xx	xx	xx	xx
Was another disease severity score evaluated?					
[1]					
n	xx	xx	xx	xx	xx
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing, n	xx	xx	xx	xx	xx

FAS72+ analysis set has all patients exposed to ceftazidime-avibactam ≥ 72 hours.
SD- Standard deviation, Q1- Quartile one, Q3- Quartile three. Min- minimum, Max- Maximum, LOS- Length of Stay, ICU- Intensive care unit
[1] Percentages computed among the total number of patients by Country.
[2] A subject can attend more than one ward during hospitalization.
[3] Consecutive Hospital LOS: (Date of hospital discharge - Date of hospital admission)
[4] Hospital LOS from treatment initiation: (Date of hospital discharge - Date of ceftazidime-avibactam initiation)
[5] Consecutive or non-consecutive ICU LOS: (Date of ICU discharge - Date of ICU admission)
[6] ICU LOS from treatment initiation: (Date of ICU discharge - Date of ceftazidime-avibactam initiation)

Table 14 Healthcare Resource Utilization by Indication Overall (FAS72+)

	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Did the patient use any healthcare resources during the index hospitalization? n (%) [1]					
n	xx	xx	xx	xx	xx
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing, n	xx	xx	xx	xx	xx
Healthcare resource utilized during the index hospitalization, n (%) [1]					
Mechanical ventilation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Hemodialysis	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
CT/MRI imaging	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Tracheostomy	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Surgical intervention	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Percutaneous procedures	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Mechanical ventilation: number of Days (for patients who received ventilation) [2]					
n	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing, n	xx	xx	xx	xx	xx
Hemodialysis (including intermittent or continuous renal replacement therapy), n (%) [1]					
n, (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Intermittent	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Continuous	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Hemodialysis: number of days [2]					
n	xx	xx	xx	xx	xx

	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing, n	xx	xx	xx	xx	xx
Surgical intervention, n (%)[1]					
n	xx	xx	xx	xx	xx
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing, n	xx	xx	xx	xx	xx
Number of surgical interventions, n (%)					
n	xx	xx	xx	xx	xx
1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3+	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Percutaneous procedure, n (%)[1]					
n	xx	xx	xx	xx	xx
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing, n	xx	xx	xx	xx	xx
Number of percutaneous procedures, n (%)					
n	xx	xx	xx	xx	xx
1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3+	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other procedure, n (%)[1]					
n	xx	xx	xx	xx	xx
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing, n	xx	xx	xx	xx	xx
Number of other procedures, n (%)					

	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
n	xx	xx	xx	xx	xx
1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3+	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Procedure performed to control infection? , n (%)[3]					
Any procedure	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Surgical intervention	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Percutaneous procedure	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other procedure	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Number of surgical interventions to control infection, n (%)					
n	xx	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx
1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3+	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Number of percutaneous procedures to control infection, n(%)					
n	xx	xx	xx	xx	xx
1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3+	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Number of other procedures to control infection, n(%)					
n	xx	xx	xx	xx	xx
1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3+	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

FAS72+ analysis set has all patients exposed to ceftazidime-avibactam ≥ 72 hours.
SD- Standard deviation, Q1- Quartile one, Q3- Quartile three. Min- minimum, Max- Maximum
[1] Percentages computed among the total number of patients by Country.
[2] Number of Days = Stop Date – Start Date
[3] Percentages computed among the total number of patients.

Table 15 Antibiotic Therapy: Prior Lines of Treatment Prior to Ceftazidime-Avibactam by Indication Overall (FAS72+)

Repeat table for each of Gram-Negative/ Gram-Positive/ Anaerobic/ other (include antifungal, antiviral, other)	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
table					
n	xx	xx	xx	xx	xx
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing, n	xx	xx	xx	xx	xx
Antibiotic class and name (generic name, n(%) [2]					
n	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Therapeutic class 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 3 etc.	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Therapeutic class 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 2 etc.	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Therapeutic class 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 2 etc.	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Therapeutic class 4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 2 etc.	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Therapeutic class 5	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 2 etc.	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
… …					
Total duration (days) of antibiotics used for current infection up to the start of Ceftazidime-avibactam [3]					
n	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing, n	xx	xx	xx	xx	xx
n	xx	xx	xx	xx	xx

Repeat table for each of Gram-Negative/ Gram-Positive/ Anaerobic/ other (include antifungal, antiviral, other)	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Reason for initiating per antibiotic, n(%)[2]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
n	xx	xx	xx	xx	xx
Clostridium difficile	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Disease progression	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Empiric treatment	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Failure of antimicrobial therapy	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Infection	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Microbiology	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Prophylaxis	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing, n	xx	xx	xx	xx	xx
Reason for discontinuation per antibiotic, n(%) [2]					
n	xx	xx	xx	xx	xx
AE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Perceived clinical failure/disease progression	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Isolation of a resistant pathogen	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preference for empiric coverage	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Secondary infection requiring regimen change	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Switch to oral therapy	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
De-escalation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Cure	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Death	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing, n	xx	xx	xx	xx	xx
Antibiotics that were continued after start of ceftazidime-avibactam					
n	xx	xx	xx	xx	xx
Therapeutic class 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 3 etc.	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Repeat table for each of Gram-Negative/ Gram-Positive/ Anaerobic/ other (include antifungal, antiviral, other)	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Therapeutic class 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 3 etc.	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Therapeutic class 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 3 etc.	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

FAS72+ analysis set has all patients exposed to ceftazidime-avibactam ≥ 72 hours.
AE - Adverse event, SD - Standard deviation, Q1- Quartile one, Q3 - Quartile three. Min - minimum, Max - Maximum

[1] Percentages computed among the total number of patients by Country.
[2] Percentages computed among the total number of patients within the category. For the variable, "Reason for initiating per Antibiotic", percentages may exceed 100% due to cases where one individual was treated with more than one antibiotic.
[3] Duration of Antibiotic = [Stop Date of Antibiotic – Start Date of Antibiotic]

Table 16.1 Ceftazidime-Avibactam Usage by Indication Overall (FAS72+)

	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	Total (N=xx)
Use of ceftazidime-avibactam overall, n(%)[2]					
Monotherapy	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Combination Therapy	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram-negative coverage	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other coverage	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram-negative and Other coverage	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Total Duration of administration of ceftazidime-avibactam (days), n(%)					
n	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing, n	xx	xx	xx	xx	xx
Outcome/Reason for discontinuation of ceftazidime-avibactam, n (%) [1]					
n	xx	xx	xx	xx	xx
AE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Perceived clinical failure/disease progression	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Isolation of a resistant pathogen	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preference for empiric coverage	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Secondary infection requiring regimen change	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Switch to oral therapy	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
De-escalation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Cure	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Death	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing, n	xx	xx	xx	xx	xx

Dose and frequency of ceftazidime-avibactam, duration of infusion and treatment duration for each dosage n (%)					
Dose1*Frequency1					
Duration of Infusion					
2 hours	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
3 hours	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Other	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Treatment duration (days)					
n	**xx**	**xx**	**xx**	**xx**	**xx**
Mean (SD)	**xx.x (xx.xx)**	**xx.x (xx.xx)**	**xx.x (xx.xx)**	**xx.x (xx.xx)**	**xx.x (xx.xx)**
Median	**xx.x**	**xx.x**	**xx.x**	**xx.x**	**xx.x**
Q1, Q3	**xx.x, xx.x**	**xx.x, xx.x**	**xx.x, xx.x**	**xx.x, xx.x**	**xx.x, xx.x**
Min, Max	**xx.x, xx.x**	**xx.x, xx.x**	**xx.x, xx.x**	**xx.x, xx.x**	**xx.x, xx.x**
Missing, n	**xx**	**xx**	**xx**	**xx**	**xx**
Total dose of ceftazidime-avibactam					
n	**xx**	**xx**	**xx**	**xx**	**xx**
Mean (SD)	**xx.x (xx.xx)**	**xx.x (xx.xx)**	**xx.x (xx.xx)**	**xx.x (xx.xx)**	**xx.x (xx.xx)**
Median	**xx.x**	**xx.x**	**xx.x**	**xx.x**	**xx.x**
Q1, Q3	**xx.x, xx.x**	**xx.x, xx.x**	**xx.x, xx.x**	**xx.x, xx.x**	**xx.x, xx.x**
Min, Max	**xx.x, xx.x**	**xx.x, xx.x**	**xx.x, xx.x**	**xx.x, xx.x**	**xx.x, xx.x**
Missing, n	**xx**	**xx**	**xx**	**xx**	**xx**
Daily dose of ceftazidime-avibactam (mg)					
n	**xx**	**xx**	**xx**	**xx**	**xx**
Mean (SD)	**xx.x (xx.xx)**	**xx.x (xx.xx)**	**xx.x (xx.xx)**	**xx.x (xx.xx)**	**xx.x (xx.xx)**
Median	**xx.x**	**xx.x**	**xx.x**	**xx.x**	**xx.x**
Q1, Q3	**xx.x, xx.x**	**xx.x, xx.x**	**xx.x, xx.x**	**xx.x, xx.x**	**xx.x, xx.x**
Min, Max	**xx.x, xx.x**	**xx.x, xx.x**	**xx.x, xx.x**	**xx.x, xx.x**	**xx.x, xx.x**
Missing, n	**xx**	**xx**	**xx**	**xx**	**xx**
Antibiotics combined with ceftazidime-avibactam, by WHO Drug Class and preferred term					
Class 1	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**

Antibiotic name	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Antibiotic name	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Class 2	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Antibiotic name	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Antibiotic name	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Reason for initiation of antibiotics combined with ceftazidime-avibactam					
Clostridium difficile	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Disease progression	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Empiric treatment	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Failure of antimicrobial treatment	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Infection	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Microbiology	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Prophylaxis	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Other	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Please order Antibiotics by: Gram-negative coverage (GRAMNFL = 'Y'), Gram-positive coverage (GRAMPFL = 'Y'), Anaerobe coverage (ANAEFL = 'Y')and Other (OTHFL = 'Y')					
Reason for discontinuation of antibiotics combined with ceftazidime-avibactam					
Reason 1	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Reason 2	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Etc…-					

FAS72+ analysis set has all patients exposed to ceftazidime-avibactam ≥ 72 hours.
SD- Standard deviation, Q1- Quartile one, Q3- Quartile three. Min- minimum, Max- Maximum
[1] Percentages computed among the total number of patients within the category.
[2] Percentages computed among the total number of patients by Country.

Antibiotic class and name are sorted by Therapeutic class and antibiotics by alphabetical order.
'Other agents' class are in the order: 1. Polymyxins, 2. Sulfonamides and Trimethoprim, 3. Other antibiotics, 4. Antiviral drugs, 5. Antimycotic drugs, 6. Antiparasitic drugs.
Reason for initiation/discontinuation of antibiotics is sorted by alphabetical order.

Table 16.2 Ceftazidime-Avibactam Usage <72 Hours by Indication Overall (FAS72-)

FAS72- analysis set has all patients exposed to ceftazidime-avibactam < 72 hours.

Footnote: Antibiotic class and name is sorted by Therapeutic class and antibiotics by alphabetical order.
'Other agents' class are in the order: 1. Polymyxins, 2. Sulfonamides and Trimethoprim, 3. Other antibiotics, 4. Antiviral drugs, 5. Antimycotic drugs, 6. Antiparasitic drugs.

Reason for initiation/discontinuation will be sorted by alphabetical order.

Table 17.1 Ceftazidime-Avibactam by Indication in Patients Infected by *Escherichia coli* Overall (FAS72+)

Table 17.2 Ceftazidime-Avibactam by Indication in Patients Infected by *Klebsiella* spp. Overall (FAS72+)

Table 17.3 Ceftazidime-Avibactam by Indication in Patients Infected by *Enterobacter* spp. Overall (FAS72+)

Table 17.4 Ceftazidime-Avibactam by Indication in Patients Infected by *Pseudomonas* spp. Overall (FAS72+)

Table 17.5 Ceftazidime-Avibactam by Indication in Patients Infected by Other Gram-negative Bacteria Overall (FAS72+)

Table 17.6 Ceftazidime-Avibactam Usage >72 Hours by Indication in Patients with no pathogen identified (FAS72+)

Table 18. Immunocompromised patients by indication (FAS72+)

	cIAI (N=xx)	cUTI(N=xx)	HAP/VAP (N=xx)	Other (N=xx)	Total (N=xx)
Immunocompromised patients overall, n(%)					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subgroups by Comorbidities					
AIDS diagnosis, n(%)					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Malignancy (solid tumor, non-metastatic), n(%)					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Chemotherapy received in the last 3 months? n(%)					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Metastatic solid tumor, n(%)					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Chemotherapy received in the last 3 months? n(%)					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Hematological malignancy/Leukaemia or lymphoma, n(%)					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Chemotherapy received in the last 3 months?					
n(%)					
Yes	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
No	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Bone marrow transplant, n(%)					
Yes	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
No	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Other transplant (Solid organ), n(%)					
Yes	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
No	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Overall outcome of ceftazidime-avibactam for immunocompromised patients					
n(%)	**xx**	**xx**	**xx**	**xx**	**xx**
Treatment Success	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Treatment Failure	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Indeterminate	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Overall outcome of ceftazidime-avibactam for Non-immunocompromised patients					
n(%)	**xx**	**xx**	**xx**	**xx**	**xx**
Treatment Success	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Treatment Failure	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Indeterminate	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**

Table 19. Patients with primary/secondary Bacteriemia by indication (FAS72+)

	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	Total (N=xx)
Patients with bacteriemia overall, n(%)					
Primary					xx (xx.x)
Secondary	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No or Unknown	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Patients with primary bacteriemia overall, n(%)					
Yes					xx (xx.x)
No					xx (xx.x)
Patients with secondary bacteriemia overall, n(%)					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Overall outcome of ceftazidime-avibactam for patients with primary bacteriemia					
n(%)	xx	xx	xx	xx	xx
Treatment Success	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Treatment Failure	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Indeterminate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Overall outcome of ceftazidime-avibactam for patients without primary bacteriemia					
n(%)	xx	xx	xx	xx	xx
Treatment Success	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Treatment Failure	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Indeterminate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Overall outcome of ceftazidime-avibactam for patients with secondary bacteriemia					
n(%)	xx	xx	xx	xx	xx
Treatment Success	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Treatment Failure	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Indeterminate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Overall outcome of ceftazidime-avibactam for patients without secondary bacteriemia					
n(%)	**xx**	**xx**	**xx**	**xx**	**xx**
Treatment Success	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Treatment Failure	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Indeterminate	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Overall outcome of ceftazidime-avibactam for patients without primary or secondary bacteriemia					
n(%)	**xx**	**xx**	**xx**	**xx**	**xx**
Treatment Success	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Treatment Failure	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Indeterminate	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**

Table 20. Patients with lower dose of Ceftazidime-Avibactam by indication (FAS72+)

	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	Total (N=xx)
Patients with lower dose of Ceftazidime-Avibactam overall, n(%)					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Overall outcome of ceftazidime-avibactam for patients with lower dose of Ceftazidime-Avibactam					
n(%)	xx	xx	xx	xx	xx
Treatment Success	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Treatment Failure	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Indeterminate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Overall outcome of ceftazidime-avibactam for patients without lower dose of Ceftazidime-Avibactam					
n(%)	xx	xx	xx	xx	xx
Treatment Success	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Treatment Failure	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Indeterminate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Population with lower dose of Ceftazidime-Avibactam will include those subjects with average ≤4 g.

Table 21. Clinical Outcome for patients with COVID-19 diagnosis (FAS72+)

	cIAI N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	Total (N=xx)
Overall outcome of ceftazidime-avibactam for patients with COVID-19 diagnosis					
n(%)	xx	xx	xx	xx	xx
Treatment Success	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Treatment Failure	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Indeterminate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Overall outcome of ceftazidime-avibactam for patients without COVID-19 diagnosis					
n(%)	xx	xx	xx	xx	xx
Treatment Success	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Treatment Failure	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Indeterminate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Table 22.1 Microbiological Evaluation Before Initial Antibiotic Therapy by Indication Overall (FAS72+)

	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Patient Level					
Samples taken, n(%)					
N	xx	xx	xx	xx	xx
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing, n	xx	xx	xx	xx	xx
Number of bacterial pathogens, n(%)					
N	xx	xx	xx	xx	xx
0	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Known	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Same pathogen in >1 sample	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Was a fungal pathogen identified?, n(%)					
N	xx	xx	xx	xx	xx
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing, n	xx	xx	xx	xx	xx
Type of specimen, n(%)					
N	xx	xx	xx	xx	xx
Blood	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Catheter tip	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Urine	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Bronchoalveolar lavage	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Sputum	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Abscess drainage	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Swab	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Surgical/biopsy specimen	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Pathogens identified					
Gram-negative, Escherichia Coli, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram-negative, Klebsiella pneumoniae, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram-negative, Klebsiella spp.	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram-negative, Proteus mirabilis, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram-negative, Proteus spp., n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram-negative, Acinetobacter baumanii, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram-negative, Acinetobacter spp., n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram-negative, Enterobacter cloacae, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram-negative, Enterobacter spp., n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram-negative, Citrobacter spp., n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram-negative, Serratia spp., n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram-negative, Morganella morganii, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram-negative, Salmonella spp., n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram-negative, Shigella spp., n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram-negative, Pseudomonas aeruginosa, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram-negative, Pseudomonas spp., n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram-negative, Haemophilus influenzae, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram-negative, Haemophilus spp., n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram-negative, Other, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram positive, Staphylococcus aureus, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram positive, Enterococcus spp., n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Mycobacterium abscessus	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Anaerobes, Bacteroides spp.	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Anaerobes, Peptostreptococcus spp.	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Anaerobes, Clostridium spp.	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Anaerobes, Prevotella spp.	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Anaerobes, other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Anaerobes, other specify	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Pathogen Level					
Gram-negative, *Escherichia Coli*, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Beta-lactamase identified:					
0	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown/not tested	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ambler's class, n(%)					
n	xx	xx	xx	xx	xx
A	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
B	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
C	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
D	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ambler's type, n(%)					
n	xx	xx	xx	xx	xx
Carba-R	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
KPC	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
NDM	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Oxa-48	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
MBL	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ESBL	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram-negative, *Klebsiella* pneumoniae, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Beta-lactamase identified:					
0	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown/not tested	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ambler's class, n(%)					
n	xx	xx	xx	xx	xx
A	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
B	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
C	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
D	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ambler's type, n(%)					
n	xx	xx	xx	xx	xx
Carba-R	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
KPC	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
NDM	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Oxa-48	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
MBL	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ESBL	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram-negative, *Klebsiella* spp.	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Beta-lactamase identified:					
0	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown/not tested	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ambler's class, n(%)					
n	xx	xx	xx	xx	xx
A	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
B	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
C	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
D	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ambler's type, n(%)					
n	xx	xx	xx	xx	xx
Carba-R	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
KPC	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
NDM	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Oxa-48	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
MBL	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ESBL	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram-negative, Proteus Mirabilis, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Beta-lactamase identified:					
0	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown/not tested	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ambler's class, n(%)					
N	xx	xx	xx	xx	xx
A	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
B	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
C	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
D	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ambler's type, n(%)					
n	xx	xx	xx	xx	xx
Carba-R	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
KPC	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
NDM	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Oxa-48	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
MBL	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ESBL	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram-negative, Proteus spp., n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Beta-lactamase identified:					
0	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown/not tested	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ambler's class, n(%)					
n	xx	xx	xx	xx	xx
A	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
B	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
C	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
D	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ambler's type, n(%)					

	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
n	xx	xx	xx	xx	xx
Carba-R	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
KPC	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
NDM	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Oxa-48	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
MBL	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ESBL	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram-negative, *Acinetobacter baumanii*, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Beta-lactamase identified:					
0	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown/not tested	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ambler's class, n(%)					
n	xx	xx	xx	xx	xx
A	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
B	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
C	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
D	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ambler's type, n(%)					
n	xx	xx	xx	xx	xx
Carba-R	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
KPC	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
NDM	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Oxa-48	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
MBL	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ESBL	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram-negative, *Acinetobacter* spp., n(%)					
Beta-lactamase identified:					
0	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown/not tested	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ambler's class, n(%)					
n	xx	xx	xx	xx	xx
A	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
B	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
C	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
D	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ambler's type, n(%)					
n	xx	xx	xx	xx	xx
Carba-R	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
KPC	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
NDM	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Oxa-48	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
MBL	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ESBL	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram-negative, *Enterobacter cloacae*, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Beta-lactamase identified:					
0	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown/not tested	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ambler's class, n(%)					
n	xx	xx	xx	xx	xx
A	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
B	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
C	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
D	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ambler's type, n(%)					
n	xx	xx	xx	xx	xx
Carba-R	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
KPC	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
NDM	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Oxa-48	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
MBL	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ESBL	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram-negative, *Enterobacter* spp., n(%)					
Beta-lactamase identified:					
0	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown/not tested	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ambler's class					
n	xx	xx	xx	xx	xx
A	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
B	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
C	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
D	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ambler's type, n(%)					
n	xx	xx	xx	xx	xx
Carba-R	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
KPC	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
NDM	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Oxa-48	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
MBL	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ESBL	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram-negative, Citrobacter spp, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Beta-lactamase identified:					
0	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Unknown/not tested	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ambler's class, n(%)					
n	xx	xx	xx	xx	xx
A	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
B	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
C	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
D	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ambler's type, n(%)					
n	xx	xx	xx	xx	xx
Carba-R	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
KPC	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
NDM	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Oxa-48	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
MBL	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ESBL	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram-negative, Serratia spp., n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Beta-lactamase identified:					
0	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown/not tested	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ambler's class, n(%)					
n	xx	xx	xx	xx	xx
A	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
B	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
C	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
D	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ambler's type, n(%)					
n	xx	xx	xx	xx	xx
Carba-R	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
KPC	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
NDM	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Oxa-48	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
MBL	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ESBL	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram-negative, Morganella morganii, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Beta-lactamase identified:					
0	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown/not tested	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ambler's class, n(%)					
n	xx	xx	xx	xx	xx
A	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
B	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
C	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
D	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ambler's type, n(%)					
n	xx	xx	xx	xx	xx
Carba-R	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
KPC	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
NDM	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Oxa-48	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
MBL	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ESBL	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram-negative, Salmonella spp., n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Beta-lactamase identified:					
0	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown/not tested	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Ambler's class, n(%)					
n	xx	xx	xx	xx	xx
A	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
B	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
C	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
D	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ambler's type, n(%)					
n	xx	xx	xx	xx	xx
Carba-R	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
KPC	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
NDM	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Oxa-48	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
MBL	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ESBL	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram-negative, Shigella spp, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Beta-lactamase identified:					
0	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown/not tested	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ambler's class, n(%)					
n	xx	xx	xx	xx	xx
A	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
B	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
C	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
D	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ambler's type, n(%)					
n	xx	xx	xx	xx	xx
Carba-R	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
KPC	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
NDM	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Oxa-48	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
MBL	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
ESBL	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram-negative, *Pseudomonas* aeruginosa, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Beta-lactamase identified:					
0	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown/not tested	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ambler's class, n(%)					
n	xx	xx	xx	xx	xx
A	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
B	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
C	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
D	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ambler's type, n(%)					
n	xx	xx	xx	xx	xx
Carba-R	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
KPC	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
NDM	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Oxa-48	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
MBL	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ESBL	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram-negative, *Pseudomonas* spp., n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Beta-lactamase identified:					
0	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown/not tested	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ambler's class, n(%)					
n	xx	xx	xx	xx	xx

	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
A	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
B	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
C	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
D	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ambler's type, n(%)					
n	xx	xx	xx	xx	xx
Carba-R	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
KPC	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
NDM	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Oxa-48	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
MBL	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ESBL	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
CTM-X	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram-negative, Haemophilus influenzae, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram-negative, Haemophilus spp., n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram-negative, Other, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Beta-lactamase identified:					
0	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown/not tested	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ambler's class, n(%)					
n	xx	xx	xx	xx	xx
A	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
B	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
C	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
D	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ambler's type, n(%)					
n	xx	xx	xx	xx	xx
Carba-R	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
KPC	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
NDM	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Oxa-48	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
MBL	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
ESBL	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
CTM-X	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx(xx.x)
Gram positive, Staphylococcus aureus, n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Is it an MRSA (methicillin-resistant S. aureus)?					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown, n	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram positive, Enterococcus spp., n(%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Is it a VRE (vancomycin resistant Enterococcus)?					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown, n	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram positive, Streptococcus spp.	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Gram-positive, other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Mycobacterium abscessus	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Anaerobes, Bacteroides spp.	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Anareobes, Peptostreptococcus spp.	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Anaerobes, Clostridium spp.	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Anaerobes, Prevotella spp.	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Anaerobes, other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Anaerobes, other specify	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other Bacterial Agent	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

FAS72+ analysis set has all patients exposed to ceftazidime-avibactam ≥ 72 hours.

The microbiological outcomes analysis set (MOD) has all exposed to ceftazidime-avibactam ≥ 72 hours and ≥ 1 non-missing microbiological outcome.

Table 22.2 Clinical Microbiological Evaluation after initial antibiotic therapy but before ceftazidime-avibactam therapy by Indication Overall (FAS72+)

Table 22.3 Clinical Microbiological Evaluation after initiation or during ceftazidime-avibactam therapy by Indication Overall (FAS72+)

Table 22.4 Clinical Microbiological Evaluation after end of ceftazidime-avibactam therapy by Indication Overall (FAS72+)

Table 22.5 Clinical Microbiological Evaluation after end of any antibiotic therapy by Indication Overall (FAS72+)
Table 22.6 Latest Microbiological Evaluation before start of ceftazidime-avibactam therapy by Indication Overall (FAS72+)

Table 23.1.1 Gram-negative Pathogen Susceptibility to Antibiotics by cIAI Overall (FAS72+)

Timing on Sample collection	Before initial antibiotic Therapy	After initial antibiotic therapy but before ceftazidime-avibactam therapy	After initiation or during ceftazidime-avibactam therapy	After end of ceftazidime-avibactam therapy	After end of any antibiotic therapy
Overall					
All Gram-negative bacterial pathogens, n [1]					
Pathogen identified and tested for susceptibility	xx	xx	xx	xx	xx
Antibiotic resistance by Gram-negative bacterial pathogens (all pathogens,) n (%)[2]					
n [1](pathogens)	xx	xx	xx	xx	xx
Aminoglycosides	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Amphenicol	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Carbapenems	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
individual antibiotics	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Cephalosporins	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
individual antibiotics	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Cephalosporin/beta-lactamase inhibitor	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
individual antibiotics	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Glycopeptides	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Glycylcicline	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Lipopeptides	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Macrolides	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Mono Bactam	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Nitroimidazole	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Oxalolidinones	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Penicillins	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Penicillins and beta-lactamase inhibitors	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
individual antibiotics	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Quinolones	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Streptogramins	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Tetracycline	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Other Agents	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Repeat this table for the following specific pathogens:

- **Antibiotic resistance by** Gram negative, Escherichia Coli, **n (%)[2]**
- **Antibiotic resistance by** Gram negative, Proteus spp. , **n (%)[2]**
- **Antibiotic resistance by** Gram negative, Klebsiella spp. , **n (%)[2]**
- **Antibiotic resistance by** Gram negative, Enterobacter spp. , **n (%)[2]**
- **Antibiotic resistance by** Gram negative, Citrobacter spp. , **n (%)[2]**
- **Antibiotic resistance by** Gram negative, Serratia spp., **n (%)[2]**
- **Antibiotic resistance by** Gram negative, Haemophilus spp., **n (%)[2]**
- **Antibiotic resistance by** Gram negative, Morganella morganii , **n (%)[2]**
- **Antibiotic resistance by** Gram negative, Acinetobacter spp. , **n (%)[2]**
- **Antibiotic resistance by** Gram negative, Pseudomonas aeruginosa, **n (%)[2]**
- **Antibiotic resistance by** Gram negative, Salmonella spp., **n (%)[2]**

- **Antibiotic resistance by** Gram negative, Shigella spp., **n (%)[2]**
- **Antibiotic resistance by** Gram negative, Other, **n (%)[2]**

FAS72+ analysis set has all patients exposed to ceftazidime-avibactam ≥ 72 hours.
[1] The n is the number of pathogens identified and tested for pathogen susceptibility.
[2] The n and percentage in each table cell are: number of pathogens tested against the particular antibiotic (or class), and the percentage which were found resistant to the particular antibiotic (or class), respectively.

Antibiotic resistance is sorted by Therapeutic class, and antibiotics by alphabetical order.
Antibiotics are sorted by therapeutic class and antibiotics within the class are sorted by alphabetical order.

Table 23.1.2 Gram-negative Pathogen Susceptibility to Antibiotics by cUTI Overall (FAS72+)
Table 23.1.3 Gram-negative Pathogen Susceptibility to Antibiotics by HAP/VAP Overall (FAS72+)
Table 23.1.4 Gram-negative Pathogen Susceptibility to Antibiotics by Other Overall (FAS72+)
Table 23.1.5 Gram-negative Pathogen Susceptibility to Antibiotics by All indications Overall (FAS72+)
Table 23.2.1 Gram-negative Multi Drug Resistance for cIAI Overall (FAS72+)

Timing on Sample collection	Before initial antibiotic Therapy	After initial antibiotic therapy but before ceftazidime-avibactam therapy	After initiation or during ceftazidime-avibactam therapy	After end of ceftazidime-avibactam therapy	After end of any antibiotic therapy
Overall					
Gram-negative Multi-resistant pathogen n (%)[1]					
n [1](pathogens)	**xx**	**xx**	**xx**	**xx**	**xx**
Yes	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
No	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Antibiotic resistance by Gram-negative bacterial pathogens (all MDR pathogens) n (%)[2]					
n [1](pathogens)	**xx**	**xx**	**xx**	**xx**	**xx**
Aminoglycosides	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Amphenicol	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Carbapenems	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Individual antibiotics…	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Cephalosporins	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Individual antibiotics…	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Cephalosporin/beta-lactamase inhibitor	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Individual antibiotics…	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Glycopeptides	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Glycylcicline	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Lipopeptides	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Macrolides	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Mono Bactam	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Nitroimidazole	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Oxalolidinones	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**

Penicillins	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Penicillins and beta-lactamase inhibitors	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Individual antibiotics…	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Quinolones	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Streptogramins	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Tetracycline	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**
Other Agents	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**	**xx (xx.x)**

Repeat this table for the following specific pathogens:

- **Gram negative, Escherichia Coli**
- **Gram negative, Proteus spp.**
  Gram negative, Klebsiella spp.
- **Gram negative, Enterobacter spp.**
- **Gram negative, Citrobacter spp.**
- **Gram negative, Serratia spp.**
- **Gram negative, Haemophilus spp.**
- **Gram negative, Morganella morganii**
- **Gram negative, Acinetobacter spp.**
- **Gram negative, Pseudomonas aeruginosa**
- **Gram negative, Salmonella spp.**
- **Gram negative, Shigella spp.**
- **Gram negative, Other**

FAS72+ analysis set has all patients exposed to ceftazidime-avibactam ≥ 72 hours.
[1] The n is the number of pathogens identified and tested for multi-drug resistance.
[2] The n and percentage in each table cell are: number of pathogens tested against the particular antibiotic (or class), and the percentage which were found resistant to the particular antibiotic (or class), respectively.

Table 26 Clinical Evaluation Outcome (Success, Failure, Indeterminate) by Indication Overall (COD)

	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Clinical outcome for the initial hospitalization					
Overall outcome of ceftazidime-avibactam (any therapy)					
n(%)	xx	xx	xx	xx	xx
Treatment Success	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Treatment Failure [2]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Indeterminate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Therapy type					
n(%)	xx	xx	xx	xx	xx
Monotherapy	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Combination therapy	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Overall outcome of ceftazidime-avibactam in monotherapy (All monotherapy regimens)					
n (%)	xx	xx	xx	xx	xx
Treatment Success	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Treatment Failure	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Indeterminate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Overall outcome of ceftazidime-avibactam in combined therapy (All combined therapy regimens)					
n (%)	xx	xx	xx	xx	xx
Treatment Success	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Treatment Failure	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Indeterminate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Clinical outcome at 60 days post-discharge [b]					
Overall Outcome of ceftazidime-avibactam (any therapy)					

	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
n (%)	xx	xx	xx	xx	xx
Treatment success	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Treatment failure	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Indeterminate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Therapy type					
n (%)	xx	xx	xx	xx	xx
Monotherapy	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Combination Therapy	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Overall outcome of ceftazidime-avibactam in monotherapy (All monotherapy regimens)					
n (%)	xx	xx	xx	xx	xx
Treatment Success	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Treatment Failure	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Indeterminate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Overall outcome of ceftazidime-avibactam in combined therapy (All combined therapy regimens)					
n (%)	xx	xx	xx	xx	xx
Treatment Success	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Treatment Failure	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Indeterminate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Clinical outcome at 60 days post-treatment [a]					
Overall Outcome of ceftazidime-avibactam (any therapy)					
n (%)	xx	xx	xx	xx	xx
Treatment success	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Treatment failure	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Indeterminate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Therapy type					
n (%)	xx	xx	xx	xx	xx
Monotherapy	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Combination Therapy	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Overall outcome of ceftazidime-avibactam in monotherapy (All monotherapy regimens)					
n (%)	xx	xx	xx	xx	xx
Treatment Success	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Treatment Failure	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Indeterminate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Overall outcome of ceftazidime-avibactam in combined therapy (All combined therapy regimens)					
n (%)	xx	xx	xx	xx	xx
Treatment Success	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Treatment Failure	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Indeterminate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

The clinical outcomes analysis set (COD) has all patients exposed to ceftazidime-avibactam ≥ 72 hours and ≥ 1 non-missing clinical outcome.
cIAI: Complicated Intra-Abdominal Infection; cUTI: Complicated Urinary Tract Infection; HAP: Hospital-Acquired Pneumonia; VAP: Ventilator-Associated Pneumonia.

125 patients not evaluated (97 died during initial hospitalization, 10 died after discharge, 12 missing evaluation/death date, 6 criteria not met).

Table 26.1 Clinical Evaluation Outcome (Success, Failure, Indeterminate) by Indication in Patients Infected by *Escherichia coli* Overall (COD)

Table 26.2 Clinical Evaluation Outcome (Success, Failure, Indeterminate) by Indication in Patients Infected by *Klebsiella* spp. Overall (COD)

Table 26.3 Clinical Evaluation Outcome (Success, Failure, Indeterminate) by Indication in Patients Infected by *Enterobacter* spp. Overall (COD)

Table 26.4 Clinical Evaluation Outcome (Success, Failure, Indeterminate) by Indication in Patients Infected by *Pseudomonas* spp. Overall (COD)

Table 26.5 Clinical Evaluation Outcome (Success, Failure, Indeterminate) by Indication in Patients Infected by Other Gram-negative Bacteria Overall (COD)

Table 26.6 Clinical Evaluation Outcome (Success, Failure, Indeterminate) by Indication in Patients with no Pathogens identified (COD)

Table 27 Logistic Regression Univariate Model 1 for Clinical Success at Initial Hospitalization (COD)

	n (%)	Odds Ratio	95% CI	p-value
Age at Baseline	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Baseline BMI kg/m²)	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Gender	x(xx.x)			
Male	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Female	x(xx.x)	Reference		
Region	x(xx.x)			
Latam	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Europe	x(xx.x)	Reference		
Country	x(xx.x)			
Austria	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Germany	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
France	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Italy	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Russia	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Spain	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Argentina	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Brazil	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Colombia	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
UK	x(xx.x)	Reference		
Employment status	x(xx.x)			
Full Time	x.xx	x.xx, x.xx	x.xxxx	x.xxxx
Part Time	x.xx	x.xx, x.xx	x.xxxx	x.xxxx
Retired	x.xx	x.xx, x.xx	x.xxxx	x.xxxx
Unemployed	x(xx.x)	Reference		
Recent hospitalization	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
LOS of recent hospitalization	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx

	n (%)	Odds Ratio	95% CI	p-value
History of antibiotic exposure	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Treated with betalactam within the past 3 months	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Recent healthcare procedure	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Healthcare Resource Utilization during Initial Hospitalization	x(xx.x)			
Mechanical ventilation	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Dialysis	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Tracheostomy	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Surgical intervention	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Percutaneous procedure	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Other	x(xx.x)	Reference		
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Foreign travel in the past 3 months	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Pre-treatment disease severity (APACHE II score)	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx

	n (%)	Odds Ratio	95% CI	p-value
Any Deyo-Carlson Comorbidity				
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
DCCI score	x(xx.x)			
0	x(xx.x)	Reference		
1	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
2	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
3	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
≥4	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Any non Deyo-Carlson Comorbidity				
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Indication	x(xx.x)			
Other	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
cIAI	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
HAP/VAP	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
cUTI	x(xx.x)	Reference		
Source of admission	x(xx.x)			
Outpatient	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Long-term care facility	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Transfer from acute care hospital	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Other	x(xx.x)	Reference		
Ward admitted for initial hospitalization	x(xx.x)			
Surgical	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Medical	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Onco-hematology	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Infectious disease	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
ICU	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Other	x(xx.x)	Reference		
Patient attended ICU during hospitalization, n (%)	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		

	n (%)	Odds Ratio	95% CI	p-value
Source of infection	x(xx.x)			
HAI	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
HCAI	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
CAI	x(xx.x)	Reference		
Bacteria (categorical)				
Escherichia coli	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
***Klebsiella* spp.,**	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
***Enterobacter* spp.**	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
***Pseudomonas* spp.**	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Other Gram-negative bacteria	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Pregnancy (only Female)	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Alcohol use	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Alcohol use > 14 drinks/week	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Smoker	x(xx.x)			

	n (%)	Odds Ratio	95% CI	p-value
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Smoker status				
Current smoker	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Previous smoker	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Unknown	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Never smoked	x(xx.x)	Reference		
Patient's infection by multi-resistant pathogen	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		

BMI-body mass index
LOS- Length of Stay, VAP- Ventilator-associated pneumonia
n represents the number of non-Missing, n values per regression variable.

Table 28 Logistic Regression Multivariable Model 1 for Clinical Success (COD)

	n (%)	Odds Ratio	95% CI	p-value
Age at Baseline	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Baseline BMI kg/m²)	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Gender	x(xx.x)			
Male	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Female	x(xx.x)	Reference		
Region	x(xx.x)			
Latam	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Europe	x(xx.x)	Reference		
Country	x(xx.x)			
Austria	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Germany	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
France	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Italy	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Russia	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Spain	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Argentina	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Brazil	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Colombia	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
UK	x(xx.x)	Reference		
Employment status	x(xx.x)			
Full Time	x.xx	x.xx, x.xx	x.xxxx	x.xxxx
Part Time	x.xx	x.xx, x.xx	x.xxxx	x.xxxx
Retired	x.xx	x.xx, x.xx	x.xxxx	x.xxxx
Unemployed	x(xx.x)	Reference		
Recent hospitalization	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
LOS of recent hospitalization	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx

History of antibiotic exposure	**x(xx.x)**			
Yes	**x(xx.x)**	**x.xx**	**x.xx, x.xx**	**x.xxxx**
No	**x(xx.x)**	**Reference**		
Treated with betalactam within the past 3 months	**x(xx.x)**			
Yes	**x(xx.x)**	**x.xx**	**x.xx, x.xx**	**x.xxxx**
No	**x(xx.x)**	**Reference**		
Recent healthcare procedure	**x(xx.x)**			
Yes	**x(xx.x)**	**x.xx**	**x.xx, x.xx**	**x.xxxx**
No	**x(xx.x)**	**Reference**		
Healthcare Resource Utilization during Initial Hospitalization	**x(xx.x)**			
Mechanical ventilation	**x(xx.x)**			
Yes	**x(xx.x)**	**x.xx**	**x.xx, x.xx**	**x.xxxx**
No	**x(xx.x)**	**Reference**		
Dialysis	**x(xx.x)**			
Yes	**x(xx.x)**	**x.xx**	**x.xx, x.xx**	**x.xxxx**
No	**x(xx.x)**	**Reference**		
Tracheostomy	**x(xx.x)**			
Yes	**x(xx.x)**	**x.xx**	**x.xx, x.xx**	**x.xxxx**
No	**x(xx.x)**	**Reference**		
Surgical intervention	**x(xx.x)**	**x.xx**	**x.xx, x.xx**	**x.xxxx**
Yes	**x(xx.x)**	**x.xx**	**x.xx, x.xx**	**x.xxxx**
No	**x(xx.x)**	**Reference**		
Percutaneous procedure	**x(xx.x)**	**x.xx**	**x.xx, x.xx**	**x.xxxx**
Yes	**x(xx.x)**	**x.xx**	**x.xx, x.xx**	**x.xxxx**
No	**x(xx.x)**	**Reference**		
Other	**x(xx.x)**	**Reference**		
Yes	**x(xx.x)**	**x.xx**	**x.xx, x.xx**	**x.xxxx**
No	**x(xx.x)**	**Reference**		
Foreign travel in the past 3 months	**x(xx.x)**			
Yes	**x(xx.x)**	**x.xx**	**x.xx, x.xx**	**x.xxxx**
No	**x(xx.x)**	**Reference**		
Pre-treatment disease severity (APACHE II score)	**x(xx.x)**	**x.xx**	**x.xx, x.xx**	**x.xxxx**
Any Deyo-Carlson Comorbidity				

Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
DCCI score	x(xx.x)			
0	x(xx.x)	Reference		
1	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
2	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
3	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
≥4	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Any non Deyo-Carlson Comorbidity				
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Indication	x(xx.x)			
Other	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
cIAI	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
HAP/VAP	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
cUTI	x(xx.x)	Reference		
Source of admission	x(xx.x)			
Outpatient	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Long-term care facility	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Transfer from acute care hospital	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Other	x(xx.x)	Reference		
Ward admitted for initial hospitalization	x(xx.x)			
Surgical	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Medical	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Onco-hematology	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Infectious disease	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
ICU	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Other	x(xx.x)	Reference		
Patient attended ICU during hospitalization, n (%)	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Source of infection	x(xx.x)			
HAI	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx

HCAI	**x(xx.x)**	**x.xx**	**x.xx, x.xx**	**x.xxxx**
CAI	**x(xx.x)**	**Reference**		
Bacteria (categorical)				
Escherichia coli	**x(xx.x)**			
Yes	**x(xx.x)**	**x.xx**	**x.xx, x.xx**	**x.xxxx**
No	**x(xx.x)**	**Reference**		
***Klebsiella* spp.,**	**x(xx.x)**			
Yes	**x(xx.x)**	**x.xx**	**x.xx, x.xx**	**x.xxxx**
No	**x(xx.x)**	**Reference**		
***Enterobacter* spp.**	**x(xx.x)**			
Yes	**x(xx.x)**	**x.xx**	**x.xx, x.xx**	**x.xxxx**
No	**x(xx.x)**	**Reference**		
***Pseudomonas* spp.**	**x(xx.x)**			
Yes	**x(xx.x)**	**x.xx**	**x.xx, x.xx**	**x.xxxx**
No	**x(xx.x)**	**Reference**		
Other Gram-negative bacteria	**x(xx.x)**			
Yes	**x(xx.x)**	**x.xx**	**x.xx, x.xx**	**x.xxxx**
No	**x(xx.x)**	**Reference**		
Pregnancy (only Female)	**x(xx.x)**			
Yes	**x(xx.x)**	**x.xx**	**x.xx, x.xx**	**x.xxxx**
No	**x(xx.x)**	**Reference**		
Alcohol use	**x(xx.x)**			
Yes	**x(xx.x)**	**x.xx**	**x.xx, x.xx**	**x.xxxx**
No	**x(xx.x)**	**Reference**		
Alcohol use > 14 drinks/week	**x(xx.x)**			
Yes	**x(xx.x)**	**x.xx**	**x.xx, x.xx**	**x.xxxx**
No	**x(xx.x)**	**Reference**		
Smoker	**x(xx.x)**			
Yes	**x(xx.x)**	**x.xx**	**x.xx, x.xx**	**x.xxxx**
No	**x(xx.x)**	**Reference**		

Smoker status				
Current smoker	**x(xx.x)**	**x.xx**	**x.xx, x.xx**	**x.xxxx**
Previous smoker	**x(xx.x)**	**x.xx**	**x.xx, x.xx**	**x.xxxx**
Unknown	**x(xx.x)**	**x.xx**	**x.xx, x.xx**	**x.xxxx**
Never smoked	**x(xx.x)**	**Reference**		
Patient's infection by multi-resistant pathogen	**x(xx.x)**			
Yes	**x(xx.x)**	**x.xx**	**x.xx, x.xx**	**x.xxxx**
No	**x(xx.x)**	**Reference**		

[1] Note: Since Zavicefta is not active against Acinetobacter; it's then a good factor for failure
The clinical outcomes analysis set (COD) has all patients exposed to ceftazidime-avibactam ≥ 72 hours and ≥ 1 non-missing clinical outcome.

Table 29 Logistic Regression Univariate Model 2 for Clinical Success at Initial Hospitalization (COD)

	n (%)	Odds Ratio	95% CI	p-value
Age at Baseline	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Baseline BMI kg/m²)	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Gender	x(xx.x)			
Male	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Female	x(xx.x)	Reference		
Region	x(xx.x)			
Latam	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Europe	x(xx.x)	Reference		
Country	x(xx.x)			
Austria	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Germany	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
France	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Italy	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Russia	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Spain	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Argentina	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Brazil	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Colombia	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
UK	x(xx.x)	Reference		
Employment status	x(xx.x)			
Full Time	x.xx	x.xx, x.xx	x.xxxx	x.xxxx
Part Time	x.xx	x.xx, x.xx	x.xxxx	x.xxxx
Retired	x.xx	x.xx, x.xx	x.xxxx	x.xxxx
Unemployed	x(xx.x)	Reference		
Recent hospitalization	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
LOS of recent hospitalization	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx

	n (%)	Odds Ratio	95% CI	p-value
History of antibiotic exposure	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Treated with betalactam within the past 3 months	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Recent healthcare procedure	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Healthcare Resource Utilization during Initial Hospitalization	x(xx.x)			
Mechanical ventilation	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Dialysis	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Tracheostomy	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Surgical intervention	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Percutaneous procedure	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Other	x(xx.x)	Reference		
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Foreign travel in the past 3 months	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Pre-treatment disease severity (APACHE II score)	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx

	n (%)	Odds Ratio	95% CI	p-value
Any Deyo-Carlson Comorbidity				
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
DCCI score	x(xx.x)			
0	x(xx.x)	Reference		
1	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
2	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
3	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
≥4	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Any non Deyo-Carlson Comorbidity				
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Indication	x(xx.x)			
Other	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
cIAI	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
HAP/VAP	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
cUTI	x(xx.x)	Reference		
Source of admission	x(xx.x)			
Outpatient	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Long-term care facility	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Transfer from acute care hospital	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Other	x(xx.x)	Reference		
Ward admitted for initial hospitalization	x(xx.x)			
Surgical	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Medical	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Onco-hematology	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Infectious disease	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
ICU	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Other	x(xx.x)	Reference		
Patient attended ICU during hospitalization, n (%)	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		

	n (%)	Odds Ratio	95% CI	p-value
Source of infection	x(xx.x)			
HAI	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
HCAI	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
CAI	x(xx.x)	Reference		
Bacteria (categorical)				
Escherichia coli	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
***Klebsiella* spp.,**	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
***Enterobacter* spp.**	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
***Pseudomonas* spp.**	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Other Gram-negative bacteria	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Pregnancy (only Female)	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Alcohol use	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Alcohol use > 14 drinks/week	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Smoker	x(xx.x)			

	n (%)	Odds Ratio	95% CI	p-value
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Smoker status				
Current smoker	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Previous smoker	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Unknown	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Never smoked	x(xx.x)	Reference		
Patient's infection by multi-resistant pathogen	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Was the patient diagnosed with COVID-19?	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Not applicable	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Patients with bacteriemia overall, n(%)				
Primary	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Secondary	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Immunocompromised patients overall, n(%)	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Patients with lower dose of Zavicefta overall, n(%)	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		

Table 30 Logistic Regression Multivariable Model 2 for Clinical Success at Initial Hospitalization

	n (%)	Odds Ratio	95% CI	p-value
Age at Baseline	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx

	n (%)	Odds Ratio	95% CI	p-value
Baseline BMI kg/m²)	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Gender	x(xx.x)			
Male	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Female	x(xx.x)	Reference		
Region	x(xx.x)			
Latam	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Europe	x(xx.x)	Reference		
Country	x(xx.x)			
Austria	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Germany	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
France	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Italy	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Russia	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Spain	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Argentina	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Brazil	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Colombia	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
UK	x(xx.x)	Reference		
Employment status	x(xx.x)			
Full Time	x.xx	x.xx, x.xx	x.xxxx	x.xxxx
Part Time	x.xx	x.xx, x.xx	x.xxxx	x.xxxx
Retired	x.xx	x.xx, x.xx	x.xxxx	x.xxxx
Unemployed	x(xx.x)	Reference		
Recent hospitalization	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
LOS of recent hospitalization	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
History of antibiotic exposure	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Treated with betalactam within the past 3 months	x(xx.x)			

	n (%)	Odds Ratio	95% CI	p-value
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Recent healthcare procedure	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Healthcare Resource Utilization during Initial Hospitalization	x(xx.x)			
Mechanical ventilation	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Dialysis	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Tracheostomy	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Surgical intervention	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Percutaneous procedure	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Other	x(xx.x)	Reference		
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Foreign travel in the past 3 months	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Pre-treatment disease severity (APACHE II score)	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Any Deyo-Carlson Comorbidity				
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
DCCI score	x(xx.x)			

	n (%)	Odds Ratio	95% CI	p-value
0	x(xx.x)	Reference		
1	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
2	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
3	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
≥4	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Any non Deyo-Carlson Comorbidity				
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Indication	x(xx.x)			
Other	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
cIAI	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
HAP/VAP	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
cUTI	x(xx.x)	Reference		
Source of admission	x(xx.x)			
Outpatient	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Long-term care facility	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Transfer from acute care hospital	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Other	x(xx.x)	Reference		
Ward admitted for initial hospitalization	x(xx.x)			
Surgical	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Medical	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Onco-hematology	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Infectious disease	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
ICU	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Other	x(xx.x)	Reference		
Patient attended ICU during hospitalization, n (%)	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Source of infection	x(xx.x)			
HAI	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
HCAI	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
CAI	x(xx.x)	Reference		

	n (%)	Odds Ratio	95% CI	p-value
Bacteria (categorical)				
Escherichia coli	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
***Klebsiella* spp.,**	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
***Enterobacter* spp.**	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
***Pseudomonas* spp.**	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Other Gram-negative bacteria	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Pregnancy (only Female)	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Alcohol use	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Alcohol use > 14 drinks/week	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Smoker	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Smoker status				
Current smoker	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx

	n (%)	Odds Ratio	95% CI	p-value
Previous smoker	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Unknown	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Never smoked	x(xx.x)	Reference		
Patient's infection by multi-resistant pathogen	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Was the patient diagnosed with COVID-19?	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Not applicable	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Patients with bacteriemia overall, n(%)				
Primary	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
Secondary	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Immunocompromised patients overall, n(%)	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		
Patients with lower dose of Zavicefta overall, n(%)	x(xx.x)			
Yes	x(xx.x)	x.xx	x.xx, x.xx	x.xxxx
No	x(xx.x)	Reference		

[1] Note: Since Zavicefta is not active against Acinetobacter; it's then a good factor for failure
The clinical outcomes analysis set (COD) has all patients exposed to ceftazidime-avibactam ≥ 72 hours and ≥ 1 non-missing clinical outcome.

The logistic regression is modelling clinical success versus failure with clinical indeterminate set to missing.

Table 31 Microbiological Evaluation Outcome (Success, Failure, Emergent Infections) by Indication Overall (MOD) –

Since few patients had samples taken after start of Zavicefta, table will not me produced.

Table 31.1 Microbiological Evaluation Outcome by Indication in Patients Infected by *Escherichia Coli* Overall (MOD)

Since few patients had samples taken after start of Zavicefta, table will not me produced.

Table 31.2 Microbiological Evaluation Outcome by Indication in Patients Infected by *Klebsiella* spp. Overall (MOD)

Since few patients had samples taken after start of Zavicefta, table will not me produced.

Table 31.3 Microbiological Evaluation Outcome by Indication in Patients Infected by *Enterobacter* spp. Overall (MOD)

Since few patients had samples taken after start of Zavicefta, table will not me produced.

Table 31.4 Microbiological Evaluation Outcome by Indication in Patients Infected by *Pseudomonas* spp. Overall (MOD)

Since few patients had samples taken after start of Zavicefta, table will not me produced.

Table 31.5 Microbiological Evaluation Outcome by Indication in Patients Infected by Other Gram-negative bacteria Overall (MOD)

Since few patients had samples taken after start of Zavicefta, table will not me produced.

Table 32 Prevalence of Hospital Readmissions by Indication Overall (FAS72+)

	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
The number of patients readmitted to hospital within 60 days post-initial discharge, n (%)					
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown, n	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing, n	xx	xx	xx	xx	
The number of hospital readmissions within 60 days post-initial discharge, n					
n	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Patient readmitted within, n (%)					
Discharge-30 Days	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
31-60 days	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Duration of re-hospitalization (Days)[1]					
n	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Missing, n	xx	xx	xx	xx	xx
Reason for readmission					
n	xx	xx	xx	xx	xx

	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Unrelated to the infection	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Infection recurrence	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Secondary infection	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing, n	xx	xx	xx	xx	xx

FAS72+ analysis set has all patients exposed to ceftazidime-avibactam ≥ 72 hours.
SD- Standard deviation, Q1- Quartile one, Q3- Quartile three. Min- minimum, Max- Maximum
[1] Duration of Re-hospitalization = Date of discharge - Date of readmission

Table 32.1 Prevalence of Hospital Readmissions by Indication in Patients Infected by *Escherichia Coli* Overall (FAS72+)

For all tables 34.1 through 34.6: add the footnotes:
FAS72+ analysis set has all patients exposed to ceftazidime-avibactam ≥ 72 hours.
SD- Standard deviation, Q1- Quartile one, Q3- Quartile three. Min- minimum, Max- Maximum
[1] Duration of Re-hospitalization = Date of discharge - Date of readmission

Table 32.2 Prevalence of Hospital Readmissions by Indication in Patients Infected by *Klebsiella* spp. Overall (FAS72+)

Table 32.3 Prevalence of Hospital Readmissions by Indication in Patients Infected by *Enterobacter* spp. Overall (FAS72+)

Table 32.4 Prevalence of Hospital Readmissions by Indication in Patients Infected by *Pseudomonas* spp. Overall (FAS72+)

Table 32.5 Prevalence of Hospital Readmissions by Indication in Patients Infected by Other Gram-negative Bacteria Overall (FAS72+)

Table 32.6 Prevalence of Hospital Readmissions by Indication in Patients Infected by no Pathogen Identified Overall (FAS72+)

Table 33 Vital Status and Mortality Rates by Indication Overall (FAS72+)

	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Patient status at date of last available record					
n(%)	xx	xx	xx	xx	xx
Alive	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Patient Died	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	xx	xx	xx	xx	xx
Timing of death (if patient died)[1]					
n (%)	xx	xx	xx	xx	xx
During Index hospitalization	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Within 30 days of discharge	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Within 60 days of discharge	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	xx	xx	xx	xx	xx
Total in-hospital mortality rate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
95% CI	xx.x; xx.x	xx.x; xx.x	xx.x; xx.x	xx.x; xx.x	xx.x; xx.x
Cumulative mortality rate at 30 days post-discharge [2]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
95% CI	xx.x; xx.x	xx.x; xx.x	xx.x; xx.x	xx.x; xx.x	xx.x; xx.x
Cumulative mortality rate at 60 days post-discharge [3]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
95% CI	xx.x; xx.x	xx.x; xx.x	xx.x; xx.x	xx.x; xx.x	xx.x; xx.x

FAS72+ analysis set has all patients exposed to ceftazidime-avibactam ≥ 72 hours.
[1] The post-discharge timing of death are from 1-30 days and is 31-60 days, inclusive.
[2] Cumulative mortality up to 30 days post-discharge, including in-hospital mortality
[3] Cumulative mortality up to 60 days post-discharge, including in-hospital mortality

Table 33.1 Vital Status and Mortality Rates by Indication in Patients Infected by *Escherichia Coli* Overall (FAS72+)

For all tables 35.1 through 35.6: add the footnotes:
FAS72+ analysis set has all patients exposed to ceftazidime-avibactam ≥ 72 hours.
[1] The post-discharge timing of death are from 1-30 days and is 31-60 days, inclusive.
[2] Cumulative mortality up to 30 days post-discharge, including in-hospital mortality
[3] Cumulative mortality up to 60 days post-discharge, including in-hospital mortality

Table 33.2 Vital Status and Mortality Rates by Indication in Patients Infected by *Klebsiella* spp. Overall (FAS72+)

Table 33.3 Vital Status and Mortality Rates by Indication in Patients Infected by *Enterobacter* spp. Overall (FAS72+)

Table 33.4 Vital Status and Mortality Rates by Indication in Patients Infected by *Pseudomonas* spp. Overall (FAS72+)

Table 33.5 Vital Status and Mortality Rates by Indication in Patients Infected by Other Gram-negative Bacteria Overall (FAS72+)

Table 33.6 Vital Status and Mortality Rates by Indication by no Pathogen Identified Overall (FAS72+)

Table 34 Vital Status and Mortality Rates in Patients with Ceftazidime-Avibactam Exposure <72 Hours by Indication Overall (FAS72-)

	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Patient status at date of last available record					
n(%)	xx	xx	xx	xx	xx
Alive	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Patient Died	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing	xx	xx	xx	xx	xx
Total in-hospital mortality rate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
95% CI	xx.x; xx.x	xx.x; xx.x	xx.x; xx.x	xx.x; xx.x	xx.x; xx.x

FAS72- analysis set has all patients exposed to ceftazidime-avibactam < 72 hours.
SD- Standard deviation, Q1- Quartile one, Q3- Quartile three, Min- Minimum, Max- Maximum.
[1] Percentages computed among the total number of patients by Country.
[2] Date of death - Date of treatment initiation.
[3] Percentages computed among the total number of patients within the category.

Table 35 Antibiotic Therapy After Ceftazidime-Avibactam During the Index Hospitalization by Indication Overall (FAS72+)

First create Overall table. Repeat table for each of Gram-Negative/ Gram-Positive/ Anaerobic/ other (include antifungal, antiviral, other)	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Any antibiotic(s) used for current infection after Ceftazidime-avibactam, n (%)[1]					
n	xx	xx	xx	xx	xx
Yes	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing, n	xx	xx	xx	xx	xx
Antibiotic class and name (generic name, n(%) [2]					
n	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Therapeutic class 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 3 etc.	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Therapeutic class 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 2 etc.	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Therapeutic class 3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 2 etc.	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Therapeutic class 4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 2 etc.	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Therapeutic class 5	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Antibiotic 2 etc.	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
… …					
Total duration of antibiotics used for current infection after Ceftazidime-avibactam [3]					
n	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x

First create Overall table. Repeat table for each of Gram-Negative/ Gram-Positive/ Anaerobic/ other (include antifungal, antiviral, other)	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Missing, n	xx	xx	xx	xx	xx
n	xx	xx	xx	xx	xx
Reason for initiating per antibiotic, n(%)[2]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
n	xx	xx	xx	xx	xx
Clostridium difficile	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
De-escalation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Disease progression	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Empiric treatment	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Failure of antimicrobial therapy	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Infection	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Microbiology	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Prophylaxis	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Relapse	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing, n	xx	xx	xx	xx	xx
Reason for discontinuation per antibiotic, n(%) [2]					
n	xx	xx	xx	xx	xx
AE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Perceived clinical failure/disease progression	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Isolation of a resistant pathogen	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preference for empiric coverage	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Secondary infection requiring regimen change	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Switch to oral therapy	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
De-escalation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Cure	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Death	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Missing, n	xx	xx	xx	xx	xx

FAS72+ analysis set has all patients exposed to ceftazidime-avibactam ≥ 72 hours.
AE - Adverse event, SD - Standard deviation, Q1- Quartile one, Q3 - Quartile three. Min - minimum, Max - Maximum
[1] Percentages computed among the total number of patients by Country.
[2] Percentages computed among the total number of patients within the category.
[3] Duration of Antibiotic = [Stop Date of Antibiotic – Start Date of Antibiotic]

Table 36 Adverse Events by Indication Overall (FAS)

	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Any adverse event					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Any adverse event leading to discontinuation of ceftazidime-avibactam					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Any serious adverse event					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Any fatal serious adverse event					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Any non-fatal serious adverse event					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Any serious adverse event leading to discontinuation of ceftazidime-avibactam					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx

The full analysis set (FAS) has all eligible patients.

Table 36.1 Adverse Events Related to Ceftazidime-Avibactam by Indication Overall (FAS)

	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Any adverse event					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Any adverse event leading to discontinuation of ceftazidime-avibactam					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Any serious adverse event					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Any fatal serious adverse event					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Any non-fatal serious adverse event					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Any serious adverse event leading to discontinuation of ceftazidime-avibactam					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx

The full analysis set (FAS) has all eligible patients.

Table 37 Adverse Events by System Organ Class by Indication Overall (FAS)

System organ class	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Any adverse event					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
System organ class 1					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 1					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 2					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 3					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
System organ class 2					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 1					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 2					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 3					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Etc…					

The full analysis set (FAS) has all eligible patients.

Table 37.1 Adverse Events Related to Ceftazidime-Avibactam by System Organ Class by Indication Overall (FAS)

System organ class	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Any adverse event					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
System organ class 1					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 1					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 2					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 3					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
System organ class 2					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 1					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 2					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 3					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Etc…					

The full analysis set (FAS) has all eligible patients.

Table 38 Serious Adverse Events by System Organ Class by Indication Overall (FAS)

System organ class	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Any serious adverse event					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
System organ class 1					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 1					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 2					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 3					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
System organ class 2					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 1					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 2					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 3					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Etc…					

The full analysis set (FAS) has all eligible patients.

Table 38.1 Serious Adverse Events Related to Ceftazidime-Avibactam by System Organ Class by Indication Overall (FAS)

System organ class	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Any serious adverse event					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
System organ class 1					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 1					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 2					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 3					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
System organ class 2					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 1					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 2					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 3					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Etc…					

The full analysis set (FAS) has all eligible patients.

Table 39 Adverse Events Leading to Death by System Organ Class by Indication Overall (FAS)

System organ class	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Any adverse event					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
System organ class 1					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 1					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 2					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 3					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
System organ class 2					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 1					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 2					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 3					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Etc…					

The full analysis set (FAS) has all eligible patients.

Table 39.1 Adverse Events Leading to Death Related to Ceftazidime-Avibactam by System Organ Class by Indication Overall (FAS)

System organ class	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Any adverse event					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
System organ class 1					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 1					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 2					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 3					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
System organ class 2					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 1					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 2					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 3					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Etc…					

The full analysis set (FAS) has all eligible patients.

Table 40 Adverse Events Leading to Discontinuation of Ceftazidime-Avibactam by System Organ Class by Indication Overall (FAS)

System organ class	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Any adverse event					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
System organ class 1					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 1					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 2					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 3					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
System organ class 2					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 1					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 2					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 3					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Etc…					

The full analysis set (FAS) has all eligible patients.

Table 40.1 Adverse Events Related to Ceftazidime-Avibactam Leading to Discontinuation of Ceftazidime-Avibactam by System Organ Class by Indication Overall (FAS)

System organ class	cIAI (N=xx)	cUTI (N=xx)	HAP/VAP (N=xx)	Other (N=xx)	TOTAL (N=xx)
Any adverse event					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
System organ class 1					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 1					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 2					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 3					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
System organ class 2					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 1					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 2					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Preferred term 3					
Patients, n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Events, n	xx	xx	xx	xx	xx
Etc…					

The full analysis set (FAS) has all eligible patients.

List of Listings

Listing 1.1. Site Characteristics (1)

Site	Physician specialty/ Other, specify	Care level	Hospital type	Total number of beds	Total number of ICU beds	Is the percentage of Gram-negative isolates that exhibit resistance to 3rd generation cephalosporins known?	If, Yes/ Rate	Time period start date/Time period end date
xxxxx	xx	xx	xx	xx	xx	xx	xx	xx

Listing 1.2. Site Characteristics (2)

Site	Is the percentage of Gram-negative isolates that exhibit resistance to carbapenems known?	If, Yes/ Rate	Time period start date/Time period end date	Is the percentage of Gram-negative isolates that exhibit resistance to 3rd generation cephalosporins and carbapenems known?	If, Yes/ Rate	Time period start date/Time period end date	Is the percentage of Gram-negative isolates that exhibit resistance to colistin known?	If, Yes/ Rate	Time period start date/Time period end date
xx	xx	xx	xx	xx	xx	xx	xx	xxx	xx

Listing 2. Demographic

Subjid	Date of informed consent /Did the patient pass all eligibility criteria?	Age/Sex	Height (cm)	Weight(kg)	BMI(kg/m^2)	Current employment status
xx	xx	xx	xx	xx	xx	xx

Listing 3.1. Indication Diagnosis of UTI (ENR)

Subjid	Age/Sex	Source of infection	Diagnosis of UTI Primary diagnosis	Diagnosis of UTI Secondary diagnosis	Symptoms	Date of sampling	Positive dipstick for leukocyte esterase and/or nitrite	Date of diagnosis	Patient have a secondary bacteremia	Did the patient test positive for COVID-19 at admission or during hospitalization?
xx	xx/F	xx	xx			DDMMMYYYY		DDMMMYYYY	No	

Listing 3.2. Indication Clinical Diagnosis of IAI

Subjid	Age/Sex	Source of infection	Diagnosis of IAI Primary diagnosis	Diagnosis of IAI Secondary diagnosis	Symptoms	Date of diagnosis	Patient have a secondary bacteremia	Did the patient test positive for COVID-19 at admission or during hospitalization?
xx	xx/F	xx				DDMMMYYYY	Yes	

Listing 3.3. Indication Nosocomial Pneumonia (NP) HAP- Hospital Associated Pneumonia (HAP)/ Ventilator-Associated Pneumonia (VAP)

Subjid	Age/Sex	Source of infection	HAP Diagnosis	VAP Diagnosis	Symptoms	Date of diagnosis	Explain other; initial site of infection (organ)	Patient have a secondary bacteremia	Did the patient test positive for COVID-19 at admission or during hospitalization?
xx	xx/F	xx	xx	xx	xxxxx	DDMMMYYYY	xxxxxxxxx	xxxx	

[1] CAI: Community-Acquired Infection; HAI: Hospital-Acquired Infection; HCAI: Healthcare-Associated Infection

Listing 3.4. Indication Other

Subjid	Age/Sex	Source of infection	Indication for ceftazidime-avibactam other	Symptoms	Explain other; initial site of infection (organ)	Patient have a secondary bacteremia	Did the patient test positive for COVID-19 at admission or during hospitalization?
xx	xx/F	xx	xx	xxxxx	xxxxxxxxx	xxxx	

Listing 4. Subject with Comorbidities

Subjid	Age/Sex	Comorbidities	Deyo-Charlson score calculated	Diagnosis	Diagnosis date	Chemotherapy received in the last 3 months?	Indwelling devices that the patient had at the time of the infection diagnosis
xx	xx/F	xx	XX	xx	Dd/mmm/yy	xx	xxxx

Listing 5. Prior Antibiotic Therapy

Subjid	Age/Sex	Any antibiotic(s) used within 90 days prior to date of admission for the current hospitalization?	Antibiotic/ other	Start date/ Stop date	Reason for treatment
xx	xx/F	xx	xx	xx	xxxxxxxxxx

Listing 6. Prior Hospitalization

Subjid	Age/Sex	Any prior hospitalizations within 90 days prior to date of admission for the current hospitalization?	Date of admission	Date of discharge	Primary diagnosis at discharge SOC	Primary diagnosis at discharge: Preferred Term
xx	xx/F	xx	xx	xx	xxxxxxxx	xxxxxxxx

Listing 7. Healthcare Procedures within 30 days prior to ceftazidime-avibactam initiation

Subjid	Age/Sex	Any prior healthcare procedures within 30 days prior to ceftazidime-avibactam initiation?	Date of healthcare procedure	Type of healthcare procedure	Other, specify
xx	xx/F	xx	xx	xx	xxxxxxxxx

Listing 8. Additional Risk Factors

Subjid	Age/Sex	Has the patient travelled to any foreign country in the last 3 months? / Country	Start date/ Return date	Was subject hospitalized during travel?	Is the patient pregnant?	Number of weeks of gestation since last menstrual period	Does the patient drink alcohol? / Number of drinks per week	Tobacco use
xx	xx/F	xx	xx	xx				

Listing 9. Antibiotic Therapy: Prior Lines of Treatment

Subjid	Age/Sex	Any antibiotic(s) used for current infection before ceftazidime-avibactam initiation?	Antibiotic/ other	Start date/ stop date	Dose/ unit	Frequency	Route of administration	Reason for initiating	Reason for discontinuation
xx	xx/F	xx		xx	xx				

Listing 10. Pattern of use of Ceftazidime-Avibactam

Subjid	Age/Sex	Use of Ceftazidime-avibactam reported in patient records?	Start date/ stop date	Dose/ unit	Frequency	Duration of Administration (hours)	Route of administration	Reason for initiating	Reason for discontinuation
xx	xx/F	xx		xx					

Listing 11. Concomitant Antibiotic Therapy

Subjid	Age/Sex	Any antibiotic(s) used concurrently with ceftazidime-avibactam?	Antibiotic	Start date / stop date	Dose / unit	Frequency	Duration of Administration (days)	Route of administration	Reason for initiating	Reason for discontinuation
xx	xx/F	xx			xx					

Listing 12. Antibiotic Treatment After Ceftazidime-Avibactam

Subjid	Age/Sex	Any antibiotic(s) used directly after ceftazidime-avibactam?	Antibiotic	Start date / stop date	Dose / unit	Frequency	Duration of Administration (days)	Route of administration	Reason for initiating	Reason for discontinuation
xx	xx/F	xx			xx					

Listing 13. Initial Hospitalization

Subj id	Age/Sex	Date of hospital admission	Mode of admission	Source of admission/ Other	Ward admitted for initial hospitalization	Date of initial hospitalization admission	Diagnosis at admission	Wards admitted/transferred to during hospital stay	Was the patient discharged by the end of the study period (30 Jun 2019)?	Date of hospital discharge	Diagnosis at discharge
xx	xx/F	xx			xx						

Listing 13.1. Disease Severity

Subjid	Age/Sex	Was the patient admitted to the ICU	If yes, was APACHE II completed?	Score	If yes, was another disease severity score completed?/ Type of Score	Score
xx	xx/F	Yes/NO	xx	xxx		xx

Listing 14.1. Healthcare Resource Utilization During Hospitalization (1)

Subjid	Age/Sex	Healthcare resource utilized	Mechanical ventilation Start date / Stop date	Hemodialysis (including intermittent or continuous renal replacement therapy)	Start date / Stop date / Number of episodes	CT/MRI date/ Tracheostomy date
xx	xx/F			xx		

Listing 14.2. Healthcare Resource Utilization During Hospitalization - Percutaneous procedures (2)

Subjid	Age/Sex	Percutaneous procedures SOC	Percutaneous procedures SOC/ Preferred term	Was percutaneous procedure performed to control infection?	Procedure/Date of procedure/Other	Was other procedure performed to control infection?
xx	xx/F	xx	xx	xx	xx	xx

Listing 14.3. Healthcare Resource Utilization During Hospitalization – Surgical Interventions(3)

Subjid	Age/Sex	Surgical intervention date	Surgical Type	Surgical Indication SOC	Surgical Indication Preferred term	Was surgical procedure performed to control infection?
xx	xx/F	xxx	xx	xxx	xxx	xx

Listing 15. Hospital Readmissions

Subjid	Age/Sex	Was the patient readmitted to hospital within 60 days post-initial discharge?	Patient readmitted within 30 days of initial discharge or 60 days?	Date of readmission/ Date of discharge	Reason for readmission	Specify infection
xx	xx/F	xx	xx	xxx	xxxx	xxxxx

Listing 16 Treatment Evaluation for Initial Hospitalization and at 60-Days Post-Discharge

Subjid	Age/Sex	Period	Date of evaluation	Clinical success	Reason for success	Clinical failure	Reason for failure	Clinical Indeterminate	Reason for indeterminate
xx	xx/M	Initial hospitalization 60 days post-discharge	xx	xxx	xxx	xxx	xxx	xxx	xxx
xx	xx/M	Initial hospitalization 60 days post-discharge	xx	xxx	xxx	xxx	xxx	xxx	xxx
xx	xx/M	Initial hospitalization 60 days post-discharge	xx	xxx	xxx	xxx	xxx	xxx	xxx

Listing 17. Microbiology Sample Taken

Subjid	Age/Sex	Sample taken?	Date of identification	Timing of sample collection	Number of bacterial pathogen(s) identified in specimens sampled	Was a fungal pathogen identified?	Type of specimen
	xx/F						

Listing 18. Microbiology Bacterial Pathogens Identified in Specimen Sampled

Subjid	Age/Sex	Ceftazidime-avibactam start date	Infection type	Date of identification – sample time	Sample type	Pathogen Identified	Does the bacteria present any beta-lactamase?	How many were identified?	Ambler's class	Type
	xx/F									
	xx/F									
	xx/F									

Footnote
[1] **ST1: Sample Time 1 – ST2: Sample Time 2 – ST3: Sample Time 3 – ST4: Sample Time 4 – ST5: Sample Time 5**
Sample time 1: Before initial antibiotic therapy - Sample time 2: After initial antibiotic therapy but before ceftazidime - avibactam therapy - Sample time 3: After initiation or during ceftazidime-avibactam therapy - Sample time 4: After end of ceftazidime-avibactam therapy - Sample time 5: After end of any antibiotic therapy.

Listing 18.1. Pathogen Susceptibility

Subjid	Age/Sex	Ceftazidime-Avibactam start and stop dates	Pathogen/date	Date of identification	Class of antibiotic tested	Antibiotic tested	Susceptibility
xx	xx/F						

Listing 19. Mortality and Cumulative Mortality in-Hospital,30-Days and 60-Days Post Discharge

Subjid	Period	Age/Sex	Did the patient die during the hospitalization or within 60 days post discharge?	Date of last ceftazidime avibactam administration	Date of hospital discharge	Date of death	Cause of death SOC	Cause of death Preferred term
xx	Initial hospitalization 30-days post-discharge 60 days post-discharge	xx/F	xxx	xx	xx	xx	xxx	xxx
xx	Initial hospitalization 30-days post-discharge 60 days post-discharge	xx/F	xxx	xx	xx	xx		xxx
xx	Initial hospitalization 30-days post-discharge	xx/F	xxx	xx	xx	xx		xxx
xx	60 days post-discharge	xx/F	xxx	xx	xx	xx		xxx

[1] Cumulative mortality up to 30 days post-discharge, including in-hospital mortality
[2] Cumulative mortality up to 60 days post-discharge, including in-hospital mortality

Listing 20. Adverse Events

Subjid	Age/Sex	AE SOC	AE preferred term	Start date /End date / days	If, After treatment initiation but before hospital discharge	Date of death	Relationship	AE Serious? Criteria for seriousness	Outcome	Action taken
xxx	xx/F	xxxxxxx	xxxxxxx							

Listing 21. Serious Adverse Events

Subjid	Age/Sex	AE SOC	AE term	Start date /End date / days	If, After treatment initiation but before hospital discharge	Date of death	Relationship	Criteria for seriousness	Outcome	Action taken
xxx	xx/F	xxxxxxx	xxxxxxx							

Listing 22. Adverse Events Leading to Discontinuation of Ceftazidime-Avibactam

Subjid	Age/Sex	AE SOC	AE term	Start date /End date / days	If, After treatment initiation but before hospital discharge	Date of death	Relationship	AE Serious? Criteria for seriousness	Outcome	Action taken
xxx	xx/F	xxxxxxx	xxxxxxx							

Subjid	Age/Sex	AE SOC	AE term	Start date /End date / days	If, After treatment initiation but before hospital discharge	Date of death	Relationship	AE Serious? Criteria for seriousness	Outcome	Action taken

Listing 23. Patient Disposition

Subjid	Age/Sex	Date of first dose of Ceftazidime/avibactam (Date of enrollment)	Date of Data extraction	Date of ICF signature	Met eligibility criteria	If no, inclusion /exclusion criteria not met	FAS72+	FAS72-	Reason for exclusion from FAS
xxx	xx/F			DD-MMM-YYYY NA as per local regulation	Y N	I1 I2 I3 I4 I5 E1 E2 E3	Y N	Y N	

Listing 24. End of Chart Review

Subjid	Age/Sex	Was patient followed through medical records up to 60 days after hospital discharge?	If No, reason	Other, specify	Date of end of chart review	Date of death
xxx	xx/F					