Treatment outcomes from Retrospective Analysis of patient Charts for AztrEonam/Avibactam (TRACE)

First published: 14/08/2026

Last updated: 17/08/2026

Study Finalised

Administrative details

EU PAS number

EUPAS1000000956

Study ID

1000000956

DARWIN EU® study

No

Study countries

France

Greece

Italy

Romania

Saudi Arabia

Spain

United Kingdom

Study description

ATM-AVI offers broad-spectrum activity against β-lactamase-producing bacteria, including MBL producers and provides optimized ATM and AVI exposure.14,22 While clinical studies have established ATM-AVI's pharmacokinetics/pharmacodynamics profile, effectiveness and safety, data from routine clinical practice is scarce – particularly with regards to patient characteristics and clinical outcomes.23-28 The ASSEMBLE study specifically evaluated ATM-AVI activity against MBL-producing pathogens.21 Although the study's results suggest a promising role for ATM-AVI in treating serious infections caused by MBL-producing Gram-negative bacteria,21 the study's relatively small sample size limits the generalizability of these findings.

Assessing the real-world performance of ATM-AVI and understanding its utilization for approved indications are therefore critical from a public health perspective, providing insights into the drug's performance across diverse patient populations and clinical settings and complementing findings from controlled clinical trials. This information is valuable for highlighting the therapeutic value of ATM-AVI in combatting MDR GNB infections, which pose a significant growing public health threat.29 Furthermore, understanding the specific clinical scenarios in which ATM-AVI is prescribed can directly inform healthcare policy and resource allocation, enabling public health authorities to monitor the emergence of resistance patterns and ensuring that ATM-AVI remains a viable treatment option. In summary, evaluating the real-world application of ATM-AVI is critical, as it informs clinical practice, supports effective healthcare planning and contributes to the global effort against antimicrobial resistance. This evidence gap will be addressed by conducting an

international, multi-center, descriptive retrospective medical chart review to comprehensively describe the real-world clinical outcomes associated with the use of ATM-AVI in adult patients.

Study status

Finalised

Research institutions and networks

Institutions

Pfizer

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Kristi Kuper

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 24/03/2026

Actual: 16/03/2026

Study start date
Planned: 10/08/2026

Actual: 16/03/2026

Data analysis start date
Planned: 24/02/2028

Actual: 16/03/2026

Date of interim report, if expected
Planned: 31/12/2026

Actual: 16/03/2026

Date of final study report
Planned: 01/06/2028

Actual: 16/03/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

pfizer

Study protocol

C3601019_TRACE Study Protocol_V1.0_Redacted_05AUG2026_Redacted.pdf
(801.03 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Healthcare resource utilisation

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

This study is a non-interventional, exposure-based retrospective chart review intended to describe patient characteristics and real-world clinical outcomes associated with ATM-AVI use in hospitalized adults.

Main study objective:

To estimate the clinical cure rate (proportion) of hospitalized adult patients receiving ATM-AVI for infections caused by multi-drug-resistant Gram-negative organisms.

Study Design

Non-interventional study design

Case-only

Study drug and medical condition

Medicinal product name

EMBLAVEO

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

AZTREONAM

AVIBACTAM

Anatomical Therapeutic Chemical (ATC) code

(J01DF51) aztreonam and beta-lactamase inhibitor

aztreonam and beta-lactamase inhibitor

Medical condition to be studied

Infection

Additional medical condition(s)

To estimate the clinical cure rate (proportion) of hospitalized adult patients receiving ATM-AVI for infections caused by multi-drug-resistant Gram-negative organisms.

Population studied

Short description of the study population

Indication for antibiotic use: Individual ≥18 years of age, hospitalized with a suspected or documented Gram-negative bacterial infection , and received ATM-AVI for at least 72 hours

Microbiological sampling: Patient underwent microbiological sampling prior to or on the same day of initiation of ATM-AVI

Treatment timeline: Record of receiving ATM-AVI treatment between September 1, 2024, or the earliest date ATM-AVI is commercially available in each country, and October 31, 2027.

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)

- Elderly (≥ 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)

Study design details

Setting

This study is an international study intended to be conducted in selected hospitals/sites in Europe and Saudi Arabia based on the results of feasibility assessment performed between July and December 2025. This assessment provided important insights into the feasibility of the planned study to describe real-world clinical outcomes associated with ATM-AVI in adult patients with Gram-negative bacterial infections.

Outcomes

Patient demographics, clinical history, comorbidities, index infection characteristics, microbiological results, ATM-AVI use patterns, clinical cure/failure, healthcare resource utilization including length of stay (LOS), Intensive Care Unit (ICU) LOS, and readmissions within 30 days, in hospital all cause mortality

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Data analysis plan

Continuous variables will be summarized using descriptive statistics such as number of observations (N), mean, SD, median, first and third quartile, minimum and maximum values. Categorical data will be summarized with the N and percentage (%) of patients in each category. Missing observations will be presented in tables as a separate category. The calculation of percentages will not include the missing category. Missing values in this study will not be

imputed. All statistical tests performed are 2-sided with a significance level of 5%. No adjustment for multiple
testing is performed. Detailed methodology for summary and statistical analyses of data collected in this study will be documented in a SAP which will be dated, filed and maintained by the sponsor. The SAP may modify
the plans outlined in the protocol; any major modifications of primary endpoint definitions or their analyses would be reflected in a protocol amendment. For primary endpoint, the frequency and proportion of clinical cure will be calculated. The Clopper Pearson exact method will be used to calculate the 95% confidence interval. For the secondary and exploratory endpoints, descriptive summary will be performed as appropriate. Survival analysis using the Kaplan–Meier method will be applied for time-to-event outcomes (e.g. mortality and cure), accounting for differing follow-up times and censoring. Cox proportional hazards regression will be conducted to analyze the impact of multiple covariates (e.g., antimicrobial genotypic/phenotypic resistance, specific pathogens, infection sites, potential risk factors for resistance and marker of disease severity) on the time it takes for mortality or cure. The first dose of ATM-AVI therapy will be defined as time 0 for survival analysis.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s), other

The data source for this study will be patient medical records and hospital laboratory information management systems for detailed microbiological results data. The data generated in participating sites will be collected by trained site personnel and entered into the research platform through electronic case report forms (eCRFs). Data will be abstracted from patient medical charts (either electronic or hard copies) after treatment completion and records of hospital readmissions will be identified up to 30 days post discharge for the index hospitalization. Censoring events will be tracked by Investigator sites during data abstraction activities. The clinical outcomes will be obtained from investigator assessments.

Data sources (types)

Non-interventional study

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No