

Pfizer Independent Research Grant Request for Proposals

Competitive Grant Program – Pfizer Internal Review Process

Real World Evidence on the Impact of Early and Appropriate Use of Aztreonam-Avibactam (ATM-AVI)



Overview

This Request For Proposals (RFP) invites research proposals aimed at assessing outcomes associated with the early and appropriate use of Aztreonam-Avibactam (ATM-AVI), **guided by actionable rapid diagnostic results**, in real world clinical settings.

In scope are adult patients with suspected or documented infections due to carbapenem-resistant *Enterobacterales* (CRE) and *Stenotrophomonas maltophilia*, treated with ATM-AVI.



Geographic Scope

Australia, Brazil, Chile, India, Italy, South Africa, Spain, and United Kingdom. Proposals from North America (USA, Canada) are out of scope for this project.

**Proposals from institutions already participating in Pfizer-sponsored or funded, overlapping ATM-AVI RWE study will be considered out of scope. Proposals involving studies on patients that have received ATM-AVI via pre-approval or pre-launch expanded access routes will be considered out of scope.*



Project Types and Area of Interest

Potential applicants are requested to submit research proposals to study all the below outcomes following the **impact of diagnostic workflow on earlier selection of appropriate therapy ATM-AVI for adult patients** with suspected or documented infections due to either CRE or *Stenotrophomonas maltophilia*.

- Time to appropriate therapy
- Antibiotic Escalation / De-escalation Rates
- Clinical effectiveness with ATM-AVI
- Microbiological outcomes with ATM-AVI
- Health Economic outcomes with ATM-AVI (in addition to any of the above)



Key Milestones



Funding Range and Project Length

Individual projects requesting up to \$50,000 USD will be considered. The total budget for this RFP is \$100,000 USD.

Maximum project length is 18 months.

I. Eligibility

Geographic Scope:

Countries where ATM-AVI is available and used in clinical practice at the time of RFP release, including but not limited to Australia, Brazil, Chile, India, Italy, South Africa, Spain, and United Kingdom.* Proposals from North America (USA, Canada) are out of scope for this project.

*Proposals from institutions already participating in Pfizer sponsored or funded, overlapping ATM-AVI RWE studies would be considered out of scope. Proposals involving studies on patients that have received ATM-AVI via pre-approval or pre-launch expanded access routes would be considered out of scope.

Applicant Eligibility Criteria:

- The institution and Principal Investigator (PI) must be based in one of the eligible countries noted above.
- Only organizations are eligible to receive grants, not individuals or medical practice groups (i.e., an independent group of physicians not affiliated with a hospital, academic institution, or professional society).
- If the project involves multiple departments within an institution and/or between different institutions / organizations / associations, all institutions must have a relevant role and the requesting organization must have a key role in the project.
- The PI must have a medical or postdoctoral degree (MD, PhD, or equivalent), an advanced nursing degree (BSN with a MS/PhD), or a degree in Pharmacy, Microbiology.
- The applicant must be the PI or an authorized designee of such individual (e.g., PI's research coordinator).
- The PI must be an employee or contractor of the requesting organization.
- Requesting organization must be legally able to receive award funding directly from Pfizer Inc. We strongly recommend that applicants confirm this with their organization or institution prior to submitting an application. Grants awarded to organizations that are subsequently found to be unable to accept funding directly from Pfizer Inc. may be subject to rescission.
- For grant requests submitted from India, a valid Foreign Contribution Regulation Act (FCRA) certificate is required for an organization to be eligible to receive funding. Applicants are encouraged to familiarize themselves with FCRA requirements, procedures, and associated timelines before submitting a grant application.

II. Requirements

Primary Area of Interest:

Infectious Disease - Bacterial - RES

General Area of Interest for this RFP:

The intent of this Request for Proposals (RFP) is to invite research proposals aimed at assessing **impact of diagnostic workflow on earlier selection of appropriate therapy^a** with Aztreonam-Avibactam (ATM-AVI) in real world clinical settings, in adult patients with suspected or documented infections due to either carbapenem-resistant *Enterobacteriales* CRE or *Stenotrophomonas maltophilia*.

- Required: Time to appropriate therapy
- Required: clinical effectiveness with ATM-AVI
- Strongly encouraged: Measurement of antibiotic escalation / de-escalation rates based on diagnostic test results

- Strongly encouraged: proposals that include microbiological outcomes with ATM-AVI
- Optional/add-on: health economic outcomes with ATM-AVI (in addition to any of the above)

^a Definition of early and appropriate treatment within this context: Appropriate therapy for the initiation of a systemic antibacterial regimen with suspected or confirmed in vitro activity against the causative CRE or *Stenotrophomonas maltophilia* organism; with treatment decisions concordant with the actionable rapid diagnostic result, with activity confirmed by carbapenemase genotype and/or reference AST.¹ For CRE infections where active targeted therapy depends on microbiology, early and appropriate therapy is defined as active therapy initiated within the range of ≤24 hours of culture collection/clinical recognition for high-risk CRE infection, and no later than 48 hours from index culture collection in patients when prior active therapy has not been given.²

Expected Approximate Monetary Range of Grant Applications:

IMPORTANT: Grants will be distributed following a fully executed agreement and submission of Final Protocol, Documentation of IRB/IEC Approval, Regulatory Approval (if applicable), Exemption or Waiver.

Individual projects requesting up to \$50,000 USD will be considered. The estimated total available budget related to this RFP is \$100,000 USD. A total of 2-3 projects will be awarded.

Award amounts include direct costs, institutional overhead costs (capped at 28% per Pfizer policy), and indirect costs.

Note: grant requests for drug/compound are not in scope of this RFP. Pfizer will not supply formulated study drug nor pure substance.

Key Dates:



IMPORTANT: Be advised applications submitted after the due date will not be reviewed.

*Please note the deadline is 23:59 Eastern Standard Time (e.g., New York, GMT -5)

How to Submit:

IMPORTANT: Please read this section carefully since applications submitted not following these instructions will not be accepted and will be cancelled.

Click [here](#) to navigate to this Competitive Grant Program's unique Program Application Form.

- First-time users should create a Requester Portal account by clicking **Not a member?**

OR

- Navigate to: <https://pfizermarcie.my.site.com/pfzrequester> and sign in.
- In the upper navigation bar, click **Grant Programs** to see all available programs.

- Select **Research**
- Click **Apply** on the **2027 I&I G RWE on ATM-AVI RES** to open the Program Application Form.
- Requirements for submission:
 - Complete all required sections of the online application
 - **IMPORTANT: Upload proposal (see Appendix) in the Proposal/Protocol field.**

For more information on navigating Pfizer's new grant management system (MARCIE), please refer to this helpful [User Guide](#).

Questions:

- Please click [here](#) to view "Frequently Asked Questions" regarding the Competitive Grant Program.
- If you have questions regarding this RFP, please direct them in writing to the Grant Officer, **Talita Honorato-Rzeszewicz** (Talita.Honorato-Rzeszewicz@pfizer.com), with the subject line "2027 I&I G RWE on ATM-AVI RES".

Review and Approval Process:

Grant requests received in response to a general RFP are reviewed by Pfizer to make final grant decisions.

Mechanism by which Applicants will be Notified:

All applicants will be notified via email by the dates noted above.

Applicants may be asked for additional clarification during the review period.

Grant Agreements:

If your grant is approved, your institution will be required to enter into a written grant agreement with Pfizer. Please click [here](#) to view the core terms of the agreement.

Under Pfizer's competitive grant program, modifications to grant agreements will not be reviewed unless a genuine conflict exists as between applicable law and the terms of the relevant grant agreement. Applicant is encouraged to share the core terms with counsel for approval prior to submitting an application.

Except where prohibited by applicable law and, in any case, subject to review by Pfizer Legal, payment of grant funding may only be paid to the grantee organization.

This RFP is supported by Pfizer Inc. and, if approved, payment will be sent from the United States.

References:

1. Tamma PD, Heil EL, Justo JA, Mathers AJ, Satlin MJ, Bonomo RA. **IDSA 2024 Guidance on the Treatment of Antimicrobial-Resistant Gram-Negative Infections.** *Clinical Infectious Diseases*. 2024;79(3):e91-e116. doi:10.1093/cid/ciae403.
2. Bassetti M, Kanj SS, Kiratisin P, Rodrigues C, Van Duin D, Villegas MV, Yu Y. **Early appropriate diagnostics and treatment of MDR Gram-negative infections.** *JAC-Antimicrobial Resistance*. 2022;4(5):dlac089. doi:10.1093/jacamr/dlac089.

About Pfizer Grants:

Pfizer supports the global healthcare community's independent initiatives (e.g., research, quality improvement or education) to improve patient outcomes in areas of unmet medical need that are aligned with Pfizer's medical and/or scientific strategies.

Pfizer's competitive grant program involves a publicly posted general Request for Proposal (RFP) that provides detail regarding a general area of interest, sets timelines for review and approval, and uses an internal Pfizer review process to make final grant decisions. Organizations are invited to submit an application addressing the research gaps as outlined in the specific RFP.

For all Investigator Sponsored Research (ISRs) and general research grants, the grant requester (and ultimately the grantee) is responsible for the design, implementation, sponsorship, and conduct of the independent initiative supported by the grant, including compliance with any regulatory requirements. Pfizer must not be involved in any aspect of study protocol or project development, nor the conduct or monitoring of the research program. An ISR grant request cannot be submitted for a study that has already commenced and was not originally supported by Pfizer.

Appendix

IMPORTANT: RFP Submission Requirements

Applications will be accepted via the online portal listed in the How to Submit section. Project Proposals/Protocols should be single-spaced using Calibri 12-point font and 1-inch margins. Note there is a **15-page limit**, exclusive of references. When uploading your Full Proposal please ensure it addresses the following sections:

Goals and Objectives

Provide the main goal of the study and the study population (if applicable). Provide a detailed definition that is directly linked to the primary objective.

Assessment of Need for the Project

This should reflect your study rationale. Provide a brief description of the medical/scientific question and the rationale of how this trial or study addresses the question.

Target Audience

Describe the primary audience(s) targeted for this project. For Investigator Sponsored Clinical Trials, please specify the age, gender and other demographic information for trial population.

Also indicate whom you believe will directly benefit from the project outcomes. Describe the overall population size as well as the size of your sample population.

Project Design and Methods

Describe concisely the research design and methods for achieving the stated goals. For a clinical interventional study, include inclusion/exclusion criteria, treatment plan and statistical plan.

Innovation

Explain what measures you have taken to assure that this project idea is original and does not duplicate other projects. Describe how this project builds upon existing work, pilot projects, or ongoing projects developed either by your institution or other institutions related to this project.

Evaluation and Outcomes

Specify type and frequency of safety, efficacy, and/or outcome measures. Also indicate the method(s) used to assess measures.

Provide a publication plan describing intended submission of abstracts to (a) congress(es) or intended submission of (a) publication(s) to peer-reviewed journals.

Anticipated Project Timeline

Provide an anticipated timeline for your project including project start/end dates.

An ISR grant request cannot be submitted for a study that has already commenced and was not originally supported by Pfizer.

Additional Information

If there is any additional information you feel Pfizer should be aware of concerning the importance of this project, please summarize here.

Early-career applicants: Letter(s) of support from mentor(s) and collaborators describing how the award will advance the applicant's career.

Organization Detail

This information is used to assess the capability of the organizational resources available to perform the effort proposed. Identify the facilities to be used [laboratory, animal, clinical and "other"]. If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project.

Budget Detail

The budget amount requested must be in U.S. dollars (USD).

While estimating your budget please keep the following items in mind:

General organizational running costs such as legal fees, insurance, heating, and lighting etc. should be included in an Institutional Overhead (if required). These costs are not specific to a grant request and therefore, should not appear as line items in budgets. However, costs that are specific to the study (e.g., some countries require insurance to be taken out on a per-study basis for clinical research) would be acceptable to be included as line items.

The inclusion of these costs cannot cause the amount requested to exceed the budget limit set forth in the RFP.

Pfizer does not provide funding for capital purchases (infrastructure expenses such as equipment, purchases of software or software licenses, technology or bricks and mortar). Equipment hire/leasing is acceptable and may be included in project budget.

It should be noted that grants awarded through GMGP cannot be used to purchase Pfizer therapeutic agents (prescription or non-prescription).

Pfizer maintains a company-wide, maximum allowed overhead rate of 28% for independent studies and projects. Please [click here](#) for details.

Required Documents

- Project Plan or Proposal
- Initial Study Protocol
- Organizations must obtain approval from an Institutional Review Board (IRB) for their proposal to be eligible to receive the grant award. It is not mandatory to have IRB approval at the time of proposal submission. However, organizations are anticipated to secure an IRB evaluation subsequent to the award notification and must ensure that the approval is in place prior to 01 June 2027 or project start date.