Pfizer Independent Research Grant Request for Proposals

Competitive Grant Program – Pfizer Internal Review Process

Invasive Mold Infections (IMI) - Real-World Evidence from Treatment Outcomes with Isavuconazole

Overview

This competitive program aims to support research proposals that address data gaps concerning Invasive Mold Infectionsin in real-world settings. This initiative seeks to advance clinical understanding of isavuconazole within the treatment landscape.

The goal is to address critical knowledge gaps and develop evidence-based strategies to optimize treatment with isavuconazole, improve patient outcomes, and reduce morbidity and mortality associated with these infections.

Geographic Scope

Australia, Germany, Israel, Italy, Spain, and Switzerland

Project Types and Area of Interest

Proposals with the following areas of interest will be considered:

- Isavuconazole as first line therapy and the burden of IMI disease in adutl and pediatric settings in onco-hematology, solid organ transplant, immunosuppressant usage, post-viral infections, intensive care settings, chronic obstructive pulmonary diseases, CAR-T cell therapy, and presence of co-infections between Invasive Aspergillosis and Invasive Mucormycosis
- Isavuconazole usage outcomes for mould infections in the Central Nervous System (CNS)
- Isavuconazole use and therapeutic dosage monitoring (TDM) in severely ill patients and special populations
- Drug-drug interactions management in real world settings
- Breakthrough infections after azol treatment

Key Milestones

Submission Deadline	Anticipated Grant Award Notification	Anticipated Project Start Date/Duration
29 July 2025	October 2025	January 2026

Funding Range and Project Length

Individual projects requesting up to $30,000 USD will be considered.

Maximum project length is 10 months.

I. Eligibility

Geographic Scope:

Australia, Germany, Israel, Italy, Spain, and Switzerland

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, Physiotherapy, or Social Work.
- 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.

II. Requirements

Primary Area of Interest:

Infectious Disease - Fungal - RES

General Area of Interest for this RFP:

Projects to be considered for Pfizer support will focus on the following areas:

- Real-world evidence studies leveraging quality data sources for description and analysis of Isavuconazole treatment outcomes. Data sources can be: demographics data, surveillance systems, electronic health records, clinical and lab registries, patient reported clinical outcomes, wearables, or any other good quality data types able to provide reliable results.
- The burden of the disease across different populations, including onco-hematology, solid organ transplant, immunosuppressant usage, post-viral infections, intensive care settings, chronic obstructive pulmonary diseases, and presence of co-infections between Invasive Aspergillosis and Invasive Mucormycosis.
- Isavuconazole as first line therapy in onco-hematology, solid organ transplant, immunosuppressant usage, post-viral infections, intensive care settings, chronic obstructive pulmonary diseases, CAR-T cell recipients, etc.) and presence of co-infections between Invasive Aspergillosis and Invasive Mucormycosis.
- Isavuconazole and Central Nervous System (CNS) infections and outcomes.
- Isavuconazole and therapeutic dosage monitoring in severely ill patients and special populations such as, but not restricted to: ECMO, Renal replacement therapy, obese, hypoalbuminemic patients, pediatric (efficacy and safety beyond plasma levels).

- Drug-drug interactions management with isavuconazole in real-world settings in adult and pediatric settings.
- Breakthrough infections after azol treatment.

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 $30,000 USD will be considered. The estimated total available budget related to this RFP is $100,000 USD.
- Award amounts include direct costs, institutional overhead costs (capped at 28% per Pfizer policy), and indirect costs.

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.

Please go to: www.cybergrants.com/pfizer/Research and sign in.

Note: there are individual portals for each grant application type. Please be sure to use the URL above.

First-time users should click “Create your password”.

Click the “Start A New Research Grant Application” button.

Requirements for submission:

Complete all required sections of the online application

IMPORTANT: Upload proposal (see Appendix) in the Proposal/Protocol field.

In the application:

For the question “**Competitive Grant?**” select “**Yes**”

Select the following Primary Area of Interest: **Infectious Disease - Fungal - RES**

Select the following Competitive Grant Program Name: **2025 I&I G Invasive Mold Infections Real World Evidence RES**

Questions:

- If you encounter any technical difficulties with the website, please click here or the "Technical Questions" link at the bottom of the page in Cybergrants.
- 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 "***Invasive Mold Diseases (IMD) - Real World Evidence from Treatment Outcomes 2025***"

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:

- Bitar D et al. Emerg Infect Dis. 2014;20:1149-1155; 2. Webb BJ et al. Open Forum Infect Dis. 2018;5:ofy187; 3. Skiada A et al. J Fungi (Basel). 2020;6:265; Bongomin F et al. J Fungi (Basel). 2017;3:57; 2. Bitar D et al. Emerg Infect Dis. 2014;20:1149-1155; 3. Prakash H, Chakrabarti A. J Fungi (Basel). 2019;5:26; 4. Denning DW. Lancet Infect Dis. 24;7:428-438
- Liu, F., Panagiotakos, D. Real-world data: a brief review of the methods, applications, challenges and opportunities. *BMC Med Res Methodol* **22**, 287 (2022). https://doi.org/10.1186/s12874-022-01768-6

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. 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.

Study Population

- Describe the study population for this project. Please specify all clinically relevant characteristics, including the age, gender and other demographic information for the study 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. Describe the data source, potential sources of bias in the data and methods to deal with bias or missing data; inclusion/exclusion criteria, sample size, 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, if the study design requires IRB approval. 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 19 December 2025.