Pfizer Research Grant Request for Proposals Research on Diagnostic and Treatment of Invasive Mold Disease

Competitive Grant Program – Pfizer Internal Review Process

Overview

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Invasive mold disease (IMD) has become a serious threat to public health around the world and in China, with high mortality and morbidity¹⁻⁴. However, it is difficult to early diagnosis IMD which leads to the high misdiagnosis rate of IMD both IA and IM, compounded with the low quality of prescription antifungals and the high incidence of adverse events (AE) associated with IMD treatment, resulting in lengthy hospitalization, low clinical response, and high disease burden, which have become serious challenges in China clinical practice⁷⁻¹². It is imperative to kick off antifungal treatment at right time with the right use of antifungal drugs for the right patient.

This competitive program seeks to encourage organizations to submit grant applications for research focused on diagnostic and treatment of invasive mold disease (IMD).

Geographic Scope/Location of Project

China

Project Types and Area of Interest

Potential applicants are encouraged to identify and address the clinical unmet needs for the diagnostic and treatment of invasive mold disease (IMD) to early identify suspicious IMD patients, early kick off antifungal treatment and give appropriate antifungal drugs to improve patient outcomes and the prognosis of IMD, reduce treatment relevant AE and improve outcomes. Also leverage healthcare professionals' awareness and management of IMD.

Key Milestones

- Application submission deadline: May 22, 2025
- Anticipated decision notification date: Aug 8, 2025
- Anticipated project start date: Nov 26, 2025

Funding Range and Project Length

Individual projects requesting up to \$80,000 will be considered. The estimated total available budget related to this RFP is \$434,000.

Maximum project length is 3 years.



I. Eligibility

Geographic Scope/Location of Project/Study:

China

Applicant Eligibility Criteria

- The institution and Principal Investigator (PI) must be based in China.
- 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), or a degree in Pharmacy.
- 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 Investment Co., Ltd. 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 Investment Co., Ltd. may be subject to rescission.

II. Requirements

Date RFP Issued

Mar 13, 2025

Clinical Area

Invasive Mold Disease

General Area of Interest for this RFP:

Invasive mold disease (IMD) has become a serious threat to public health around the world and in China, with high mortality and morbidity¹⁻⁴. Multiple studies have shown that among patients with hematological malignancies, the mortality rate of Invasive Aspergillus (IA) exceeds 50%, and the mortality rate of aspergillosis in HSCT patients is even nearly 90%⁵. For invasive mucormycosis (IM), mucormycosis-associated 90-day mortality remains high (41%) despite the use of antifungals, and the mortality rate of IM is about 70%~90% with central nervous system (CNS) involvement⁶. However, it is difficult to early diagnosis IMD which leads to the high misdiagnosis rate of IMD both IA and IM, compounded with the low quality of prescription antifungals and the high incidence of adverse events (AE) associated with IMD treatment, resulting in lengthy hospitalization, low clinical response, and high disease burden, which have become serious challenges in China clinical practice⁷⁻¹². It is imperative to kick off antifungal treatment at right time with the right use of antifungal drugs for the right patient.

This competitive program seeks to encourage organizations to submit grant applications for research focused on diagnostic and treatment of invasive mold disease (IMD).



- Projects that will be considered for Pfizer support will focus on research:
 - Disease burden of invasive mold disease (IMD)
 - Disease burden of invasive mold disease (IMD) in Pediatric population.
 - Disease burden of Central nervous system invasive mold disease (CNS-IMD) and Isavuconazole as first line therapy for CNS-IMD and long-term outcomes.
 - Invasive mold disease (IMD) treatment in adult population
 - Isavuconazole and others antifungal agents in terms of effectiveness and safety in different population (hematology malignancies, chronic obstructive pulmonary diseases, immunosuppressant use, pos-viral infections, intensive care, solid organ transplant, etc).
 - Isavuconazole as first line therapy for invasive mucormycosis (IM) and IA & IM co-infection in different population (hematology malignancies, chronic obstructive pulmonary diseases, immunosuppressant use, pos-viral infections, intensive care, solid organ transplant, etc).
 - Drug to drug interactions management in real world with Isavuconazole in different population (hematology malignancies, immunosuppressant use, pos-viral infections, intensive care, solid organ transplant, etc).
 - Therapeutic drug concentration monitoring (TDM) value for Isavuconaozle in special population.

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

Expected Approximate Monetary Range of Grant Applications:

- Individual projects requesting up to \$80,000 will be considered. The estimated total available budget related to this RFP is \$434,000.
- Award amounts include direct costs, institutional overhead costs (capped at 28% per Pfizer policy), and indirect costs.

Key Dates:

- RFP release date: Mar 13, 2025
- Grant Application due date: May 22, 2025

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

- Anticipated Grant Award Notification Date: Aug 8, 2025
- 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.
- Anticipated Project Start and End Dates: Nov 26, 2025 to Nov 26, 2028

How to Submit

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

- Please go to <u>www.cybergrants.com/pfizer/Research</u> and sign in. First-time users should click "Create your password". [Note: there are individual portals for each grant application type. Please be sure to use the URL above.]
- Click the "Start a New Research Grant Application" button.
- In the application:
 - For the question "Competitive Grant?" select Yes
 - Select the following Competitive Grant Program Name: 2025 HOS CN Invasive Mold Disease RES



- Select the following Primary Area of Interest: Infectious Disease Fungal RES
- Requirements for submission:
 Complete all required sections of the online application and upload your project proposal (see Appendix) in the Proposal/Protocol field.
- If you encounter any technical difficulties with the website, please click the "Technical Questions" link at the bottom of the page.

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

Questions:

- If you have questions regarding this RFP, please direct them in writing to the Grant Officer, Juan Liu (<u>GMGChina@pfizer.com</u>), with the subject line "2025 HOS CN Invasive Mold Disease RES - Mar 13, 2025"
- Please click <u>here</u> to view Frequently Asked Questions regarding the Competitive Grant Program.

Grant Agreements:

- If your grant is approved, your institution will be required to enter into a written grant agreement with Pfizer. Please click <u>here</u> 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.

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.

References

- 1. WHO fungal priority pathogens list to guide research, development and public health action. Geneva: World Health Organization; 2022. Licence: CC BY-NC-SA 3.0 IGO.
- 2. Sun Y, Meng F, Han M, et al. Epidemiology, management, and outcome of invasive fungal disease in patients undergoing hematopoietic stem cell transplantation in China: a multicenter prospective observational study [J]. Biol Blood Marrow Transplant, 2015, 21 (6): 1117-1126. DOI: 10.1016/j.bbmt.2015.03.018.
- 3. Kontoyiannis DP, Marr KA, Park BJ, et al. Prospective surveillance for invasive fungal infections in hematopoietic stem cell transplant recipients, 2001- 2006: overview of the Transplant Associated Infection Surveillance Network (TRANSNET) Database [J]. Clin Infect Dis, 2010, 50 (8): 1091- 1100. DOI: 10.1086/651263.
- 4. Garcia-vidal C, Upton A, Kirby KA, et al. Epidemiology of invasive mold infections in allogeneic stem cell transplant recipients: biological risk factors for infection according to time after transplantation [J]. Clin Infect Dis, 2008, 47 (8) : 1041- 1150. DOI: 10.1086/591969.



- 5. Nicolle MC, et al. Invasive aspergillosis in patients with hematologic malignancies: incidence and description of 127 cases enrolled in a single institution prospective survey from 2004 to 2009. Haematologica. 2011 Nov;96(11):1685-91. doi: 10.3324/haematol.2011.044636.
- 6. Wirawan Jeong et al. Contemporary management and clinical outcomes of mucormycosis: A systematic review and meta-analysis of case reports. Int J Antimicrob Agents. 2019 May;53(5):589 597. doi:10.1016/j.ijantimicag.2019.01.002. Epub 2019 Jan 10.
- 7.Zhu K, Feng H, Xu Y, et al. An analysis of 60 years of autopsy data from Zhejiang university in Hangzhou, China. PLoS One 2014;9:e112500.
- 8. Zeng X, Ye S, Liu M. Investigation of the usage of hospitalized patients using antifungal agents in the respiratory medicine department of a hospital. Chinese Journal of Antibiotics 2017;42:600-3.
- 9. de Souza MC, Santos AG, Reis AM. Adverse Drug Reactions in Patients Receiving Systemic Antifungal Therapy at a High-Complexity Hospital. J Clin Pharmacol 2016;56:1507-15.
- 10. Andes D, Azie N, Yang H, et al. Drug-Drug Interaction Associated with Mold-Active Triazoles among Hospitalized Patients. Antimicrob Agents Chemother 2016;60:3398-406.
- 11. Ueno R, Nishimura S, Fujimoto G, et al. Healthcare resource utilization and economic burden of antifungal management in patients with hematologic malignancy in Japan: a retrospective database study. Curr Med Res Opin 2021;37:1121-34.
- 12. Firacative C. Invasive fungal disease in humans: are we aware of the real impact? Mem Inst Oswaldo Cruz . 2020 Oct 9;115:e200430.

About Pfizer Global Medical Grants & Partnerships

Pfizer Global Medical Grants & Partnerships (GMGP) 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 GMGP 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.



General 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 Chinese Yuan (CNY).
- 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 <u>click here</u> for details.

