Pfizer Announces a Research Grant RFP

2022 HBU RE-BRIEF-IT

REal World Data (RWD) in the management of Gram-negative Multidrug-Resistant (MDR) BacteRial severe InfEctions and invasive Fungal disease, ITalian experiences

Competitive Grant Program - using Expert Review Panel

Pfizer Global Medical Grants (GMG) 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 GMG competitive grant program involves a publicly posted Request for Proposal (RFP) that provides detail regarding a specific area of interest, sets timelines for review and approval, and uses an expert review panel (ERP) to make final grant decisions. Organizations are invited to submit an application addressing the specific gaps in research, practice or care 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.

Competitive Grant Program Eligibility

Geographic Scope	• Italy
Applicant Eligibility Criteria	To be eligible: • The institution and principal investigator (PI) must be based in the eligible country noted above. • Only organizations are eligible to receive grants, not individuals or medical practice groups. • The applicant (PI) must have a medical or postdoctoral degree (MD, PhD, or equivalent). • Applicant must be affiliated with the host institution • Both early career and experienced investigators are encouraged to apply and consideration will be given to all proposals meeting the selection criteria

Requirements

Date RFP Issued	• March 1st 2022
Clinical Area	• Gram-negative multidrug-resistant (MDR) bacterial severe infections and invasive fungal disease
Area of Interest Focus	• The aim of this RFP is to generate new, local Italian, Real World Data (RWD) in the management of Gram-negative MDR bacterial severe infections and invasive fungal disease in order to fill knowledge gaps in specific settings and clinical conditions which have been less extensively investigated. • We would like to support ISRs (Investigator Sponsored Research), which is independent research study where the investigator or organization is the sponsor of the study and where Pfizer provides financial support for the development or refinement of specific and defined medical knowledge relating to a Pfizer asset. • Research projects to be supported should be observational and mainly prospective. We would encourage innovative aspects to be included. • The projects should not exceed 24 months • Multicenter protocols will be preferred, with an exclusive focus on RWD

	in relation to the following topics: ○ Use of ceftazidime-avibactam in specific settings such as Solid Organ Transplant (SOT), critically ill, pediatric or immunocompromised patients ○ Use of ceftazidime-avibactam in clinical conditions such as pneumonia or complicated intra-abdominal infections (including cholangitis) or any other subset within the approved indications of the drug ○ Use of isavuconazole in specific settings such as: Blood Marrow Transplant, Solid Organ Transplant (SOT), critically ill patients or patients developing Invasive Fungal Infection (IFI) regardless to their immune status ○ Use of isavuconazole in clinical conditions such as liver disease (including liver toxicity induced by other antifungals) or in the presence of co-morbidities that require other treatments where there could be possible drug-drug interactions (DDI).
Expected Approximate Monetary Range of Grant Applications	• Individual projects requesting up to a maximum of 80,000 EUR will be considered. Pfizer anticipates awarding up to 3 or 4 grants, depending on requested budgets. The estimated total available budget related to this RFP is 200,000 EUR. • The amount of the grant Pfizer will be prepared to fund for any project will depend upon the expert review panel's evaluation of the proposal and costs involved and will be stated clearly in the approval notification.
Key Dates	• RFP release date: March 1st, 2022 • Full proposals deadline: April 28th, 2022 [Please note the deadline is 23:59 Eastern Time (New York, GMT -5).] • Review of Full Proposals by ERP: June 2022 • Anticipated Full Proposal Notification Date: July 2022
How to Apply	• Please go to www.cybergrants.com/pfizer/Research and sign in. First-time users should click "Create your password" • Click the "Start A New Research Grant Application" button. Requirements for submission: • For the question "Competitive Grant?" select Yes • Select the following Competitive Grant Program Name: **2022 HBU IT: RE-BRIEF-IT** Real World Data (RWD, ITalian experiences • Complete all required sections of the online application. See Appendix A for additional details • If you encounter any technical difficulties with the website, please click

	the "Technical Questions" link at the bottom of the page
Questions:	• If you have questions regarding this RFP, please direct them in writing to the Grant Officer, Ai Ping Lee (AiPingLee@pfizer.com), with the subject line "2022 HBU IT RE-BRIEF-IT Real World Data (RWD) in the management of Gram-negative MDR bacterial severe infections and invasive fungal disease,ITalian experiences" • Please click here 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 here to view the core terms of the agreement. • Pfizer has drafted the terms of these agreements to be balanced and reasonable and to further the goals of both parties. Negotiating grant agreements requires significant resources, so please ensure that your institution (including your legal department) is able and willing to abide by these terms before proceeding with submission of your application as they will need to be accepted in their entirety.
Review and Approval Process	• Grant requests received in response to a specific RFP are reviewed by an expert review panel (ERP) to make final grant decisions. • The panels are comprised of professionals from the medical community with advanced degrees and expertise in particular clinical areas, or specific needs of a geographic region/learner group, or expertise in research, continuing professional development or quality improvement
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

Appendix A
Full Proposal/Protocol

Applications will be accepted via the online portal. Full Proposal/Protocol documents should be no longer than 10-15 pages in length (12-point font and 1-inch margins) excluding Organization Detail and References. When uploading your Full Proposal/Protocol please ensure it addresses the following:

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. All publications must follow ICH guidelines
Anticipated Project Timeline	• Provide an anticipated timeline for your project including project start/end dates o 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

Global Medical Grants

	• 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	• A total amount requested is the only information needed for the LOI stage. Full Budget is not required. This amount can be adjusted at the Full Proposal stage as applicable.
	
	• The budget amount requested must be in U.S. dollars (USD).
	
	• While estimating your budget please keep the following items in mind:
	
	   o General organizational running costs such as insurances, heating, lighting, rent, building maintenance may be included. 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.
	
	   o The inclusion of these costs cannot cause the amount requested to exceed the budget limit set forth in the RFP.
	
	   o It should be noted that grants awarded through GMG 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

References	• Bibliography of relevant references.