Pfizer Announces a Research Grant RFP

2022 Hemophilia ASPIRE#- Africa Middle East, Asia-Pacific, & Latin America

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.

#ASPIRE: Advancing Science and Patient care through Innovative Research and Education

Competitive Grant Program Eligibility

Geographic Scope	• Africa Middle East, Asia-Pacific, and/or Latin America
Applicant Eligibility Criteria	To be eligible: • 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. • The applicant (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. • Applicant must be affiliated with a host institution

Requirements

Date RFP Issued	• 10 November 2021
Clinical Area	• Hemophilia
Area of Interest Focus	Projects that will be considered for Pfizer support will focus on the following areas: **<u>Basic and Clinical Science of Gene Therapy for Hemophilia:</u>** 1. What are the mechanisms determining tropism, transduction, safety, and tolerability of vectors for gene therapy? 2. What is the prevalence and impact of AAV neutralizing antibodies? Which strategies can be used to circumvent pre-existing antibodies, with the ultimate goal of either re-dosing or expanding potential eligibility for gene therapy? 3. What mechanisms underpin hepatic and/or immunologic adverse effects of gene therapy? What management strategies can be used to mitigate risk or treat adverse responses (e.g., immunosuppressive regimens)? 4. What mechanisms influence the durability and/or interpatient variability of response to gene therapy? What factors predict response and are there biomarkers that can be identified to guide decision-making?

5. With a focus on optimal long-term surveillance, what innovative approaches can be used to provide long-term follow-up in persons receiving gene therapy (e.g., digital approaches; optimized registry design, maintenance of engagement)?
6. What are the improvement measures required for gene therapy access and affordability in developing countries? What are parameters for site readiness for gene therapy?

Basic and Clinical Science of Tissue Factor Pathway Inhibitor (TFPI) and anti-TFPI monoclonal antibodies:

1. What are the mechanisms involved in the interaction and cross-talk between TFPI, protein C, antithrombin III and protein S?
2. What is the impact of concomitant treatments (e.g., antifibrinolytics and hemostatic treatments used in combination with anti-TFPI) on hemostasis?
3. What is the role of TFPI in pathological states associated with enhanced thrombogenesis? How can laboratory investigation be optimized?
4. What is the potential role of anti-TFPI in bleeding disorders other than hemophilia A &B?

Burden of disease: Clinical Hemophilia A and B:

1. What is the natural history of hemophilia in the modern era, where prophylaxis has gained broad adoption (including low-dose and high dose regimens)? What gaps remain with respect to optimal treatment and adherence? Natural history of hemophilia with inhibitors?
2. What unmet need remains with respect to arthropathy in the current treatment era? What is the clinical burden, impact, and natural history of arthropathy?
3. What unmet needs remain with current standard of care treatment? What is the impact on patient-relevant outcomes such as quality of life, treatment preference, work productivity, and quality of care? What is the unmet need in patients with inhibitors?
4. With a focus on optimal long-term surveillance, what innovative approaches can be used to provide long-term follow-up in persons receiving hemophilia treatment (e.g., digital approaches; optimized registry design, maintenance of engagement)?
5. What are the safety considerations for blood born emerging pathogens and how has COVID19 impacted the hemophilia community?

Note: Pfizer will not supply any study drug

Expected Approximate Monetary Range of Grant Applications	• Individual **basic or clinical research projects taking place in Africa Middle East, Asia-Pacific, and/or Latin America** requesting up to $50,000/year for 1 to 2-year projects will be considered. Pfizer anticipates awarding up to 1 grant Please note: • Overhead rates of up to 28% of the total proposed project budget may be supported by Pfizer. This must be included in the grant amounts noted above. Please click here for details. • 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: 10 November 2021 • Proposal Deadline: 1 March 2022 • Review of Full Proposals by ERP: April 2022 • Anticipated Full Proposal Notification Date: May 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 RD EM Hemophilia Research- AfME, APAC, LATAM** • 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, Amanda Stein (amanda.j.stein@pfizer.com), with the subject line "2022 Hemophilia Research AfME, APAC, LATAM" • 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

References:

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
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:
	  ○ Institutional overhead and indirect costs may be included within the grant request. Examples include human resources department costs, payroll processing and accounting costs, janitorial services, utilities, property taxes, property and liability insurance, and building maintenance as well as additional project expenses such as costs for publication, IRB / IEC review fees, software license fees, and travel. Please note: Pfizer does not provide funding for capital equipment.
	  ○ The inclusion of these costs cannot cause the amount requested to exceed the budget limit set forth in the RFP.
	  ○ It should be noted that grants awarded through GMG cannot be used to purchase therapeutic agents (prescription or non-prescription).
	• Pfizer maintains a maximum allowed overhead rate of 28% for independent grant projects. Please click here for details.

References	• Bibliography of relevant references.