Pfizer Announces a Research Grant RFP

2021 Global Hemophilia ASPIRE#

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 external 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	• Global
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. • For the Young Investigator award, the PI must have received this degree within the last 7 years. • Applicant must be affiliated with a host institution

Requirements

Date RFP Issued	• December 2, 2020
Clinical Area	• Hemophilia
Area of Interest Focus	Projects that will be considered for Pfizer support will focus on the following areas: 1. Basic and Clinical Science of Gene Therapy for Hemophilia • Basic science, tropism, transduction efficiency & tolerability of viral vectors • AAV antibody seroprevalence, titer assessment, reduction and tolerance • Role of immunosuppression in managing immune response and potential retreatment • Effect of Gene Therapy on liver biology • Impact on patient's lifestyle (e.g. reproduction, alcohol consumption, level of physical activity)

	2. Basic and Clinical Science of Tissue Factor Pathway Inhibitor (TFPI) and anti-TFPI monoclonal antibodies • Basic biology of TFPI interactions with Protein C, ATIII & Protein S • Cross talk among regulators (e.g., Protein S being a co-factor for both Protein C and TFPI) • Impact of concomitant treatments (antifibrinolytics and hemostatic treatments) added to anti-TFPI on the physiology of hemostasis • Role of TFPI in pathological states associated with enhanced thrombogenesis and their laboratory investigation. • Potential role of anti-TFPI in bleeding disorders other than hemophilia A and B 3. Burden of disease: Clinical Hemophilia A and B • Natural history of hemophilia and adherence to current standard of care • Arthropathy: presence, development, clinical burden & joint damage in hemophilia • Patient experiences with hemophilia, Quality of Life, unmet needs, treatment preferences and goals, and quality of care • Quality of Life/Work analysis and cost of care in Hemophilia • Strategies to promote long-term follow-up of patients ***Note: Pfizer will <u>not</u> supply any study drug***
Expected Approximate Monetary Range of Grant Applications	• Individual **basic science** project requesting up to $90,000/year for 1 to 2-year projects will be considered. Pfizer anticipates awarding up to 1 grant • Individual **clinical science** projects requesting up to $70,000/year for 1 to 2-year projects will be considered. Pfizer anticipates awarding up to 1 grant • **Young Investigator basic or clinical projects** requesting up to $70,000/year for 1 to 2-year projects will be considered. Pfizer anticipates awarding up to 1 grant • 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. • 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.

Key Dates	• RFP release date: December 2, 2020 • Submission Deadline: March 1, 2021* *Please note the deadline is 23:59 Eastern Time (New York, GMT -5). • Anticipated Full Proposal Notification Date: May 2021
How to Apply	• Please go to www.cybergrants.com/pfizer/Research and sign in. First-time users should click "Create your password". Requirements for submission: • Select the following Competitive Grant Program Name: **2021 RD G - Global Hemophilia ASPIRE** • 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 "Gene & Anti-TFPI Therapies in Hemophilia RFP." • Please click here to view Frequently Asked Questions regarding the Competitive Grant Program
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
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
References	• Bibliography of relevant references.