International Pharmaceutical Federation (FIP) and Pfizer Announce a Quality Improvement Grant RFP

Gene Therapy Site-Preparedness

Competitive Grant Program

I. Introduction

This Request for Proposals (RFP) is for initiatives that span multiple rare disease areas. The International Pharmaceutical Federation (FIP) and Pfizer Global Medical Grants are collaborating to offer a new competitive grant opportunity focused on Pharmacy teams and the integration of gene therapy into the treatment armamentarium for patients with a Rare Disease. The focus is the roles of pharmacy in ensuring gene therapy site preparedness in the management of rare diseases, and then by sharing learnings and experiences more widely.

About the International Pharmaceutical Federation (FIP):

The FIP mission is to support global health by enabling the advancement of pharmaceutical practice, sciences and education. Our vision is for a world where everyone benefits from access to safe, effective, quality and affordable medicines and health technologies, as well as from pharmaceutical care services provided by pharmacists, in collaboration with other healthcare professionals. Evaluating the role that pharmacists play to ensure site preparedness in this important area of gene therapy in rare disease is an important development, to provide guidance, toolkits and support for the profession in the logistics required in this area. FIP will provide technical assistance and support to grantees, establishing a learning community for grantees.

About Pfizer Global Medical Grants (GMG):

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 programme 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 practice as outlined in the specific RFP.

For all quality improvement grants, the grant requester (and ultimately the grantee) is responsible for the design, implementation, and conduct of the independent initiative supported by the grant. Pfizer must not be involved in any aspect of project development, nor the conduct or monitoring of the quality improvement program.

II. Eligibility

Geographic Scope:	Global
Applicant Eligibility Criteria	• Applicant must be a FIP Member Organization or collaborate with a FIP Member Organization or constituency. • Only organizations are eligible to receive grants, not individuals or medical practice groups.

III. Requirements

Date RFP Issued	15 November 2022
Clinical Area	Gene Therapy- Rare Disease
Specific Area of Interest for this RFP:	• Projects that will be considered for support will focus on operationally preparing and/or optimizing Institutional Pharmacists for the integration of recombinant Adeno-Associated Virus (rAAV) gene therapy into the treatment armamentarium for patients with a Rare Disease. • Support is available for the development of initiatives that will result in operational preparedness, needs-assessment, development of leadership, standards of care, best practices, SOP development, site readiness, support and/or operational training of pharmacists to improve the site's readiness for rAAV gene therapy delivery. • Proposals should be related to rAAV gene therapy operational quality improvement that is therapeutic area and disease area agnostic (i.e., not related to a specific rare disease or group of rare diseases) • Proposals tailored to a specific rare disease or group of rare diseases will **not** be considered. • Proposals that are primarily related to gene therapy medical and scientific education will **not** be considered. *It is not our intent to support clinical research projects. Projects evaluating the efficacy of therapeutic or diagnostic agents will not be considered.*

Target Audience:	Pharmacists / pharmaceutical scientists.
Background:	Pharmacists have a key role in the proper handling and general management of gene replacement therapies, identifying risk level, establishing infrastructure, and developing adequate policies and protocols.[1, 2]
Expected Approximate Monetary Range of Grant Applications:	• Individual projects requesting up to $50,000 will be considered. The estimated total available budget related to this RFP is $150,000. • 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 grant agreement.
Key Dates:	• RFP release date: 15 November 2022 • Application Deadline: 18 January 2023 • Review of Applications by Expert Review Panel: February 2023 • Anticipated Full Proposal Notification Date: March 2023 • Grants distributed following execution of fully signed Grant Contract • Anticipated Project Start Date: May 2023
How to Submit:	• Please go to www.cybergrants.com/pfizer/QI and sign in. First-time users should click "REGISTER NOW". *[Note: there are individual portals for each grant application type. Please be sure to use the URL above.]* • Click the "Start A New Quality Improvement Application" button. • For the question "Competitive Grant?" select Yes • Select the following Competitive Grant Program Name: **2023 RD G - FIP Gene Tx Site Preparedness QI** • Requirements for submission: Complete all required sections of the online application (see Appendix). • 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 through the wrong application type and/or submitted after the due date will not be reviewed by the committee.
Questions:	• If you have questions regarding this RFP, please direct them in writing to the Pfizer Grant Officer, Amanda Stein (amanda.j.stein@pfizer.com) or to Carola van der Hoeff (carola@fip.org) at FIP.

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	• A specific grant program RFP uses 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:

1. Petrich J, Marchese D, Jenkins C, Storey M, Blind J. Gene Replacement Therapy: A Primer for the Health-system Pharmacist. *Journal of Pharmacy Practice*. 2020;33(6):846-855. doi:10.1177/0897190019854962
2. Myers CJ. Preparing pharmacists to manage gene therapies. J Am Pharm Assoc (2003). 2021;61(3):e78-e82. doi:10.1016/j.japh.2020.11.018

Appendix A

Proposal Requirements

Applications will be accepted via the online portal. The main section of the full proposal document should be no longer than 12 pages in length (12-point font and 1-inch margins) excluding Organization Detail, References, and Budget Narrative. The full proposal should be uploaded in the portal as a single document.

Goals and Objectives	• Briefly state the overall goal of the project. Also describe how this goal aligns with the focus of the RFP and the goals of the applicant organization(s). • List the *overall* objectives you plan to meet with your project both in terms of learning and expected outcomes. Objectives should describe the target population as well as the outcomes you expect to achieve as a result of conducting the project.
Assessment of Need for the Project	• Please include a quantitative baseline data summary, initial metrics (e.g., quality measures), or a project starting point (please cite data on gap analyses or relevant patient-level data that informs the stated objectives) in *your* target area. Describe the source and method used to collect the data. Describe how the data was analyzed to determine that a gap existed. If a full analysis has not yet been conducted, please include a description of your plan to obtain this information.
Target Audience	• Describe the primary audience(s) targeted for this project. 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 the planned project and the way it addresses the established need. • If your methods include educational activities, please describe succinctly the topic(s) and format of those activities • Please describe how the project submitted supports diversity, equity, and inclusion either through the study population targeted or through the project team that is directly involved
Innovation	• Explain what measures you have taken to assure that this project idea is original and does not duplicate other projects or materials already developed. • 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	• In terms of the metrics used for the needs assessment, describe how you will determine if the practice gap was addressed for the target group. Describe how you expect to collect and analyze the data. • Quantify the amount of change expected from this project in terms of your target audience. • Describe how the project outcomes will be broadly disseminated.
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
Organization Detail	• Describe the attributes of the institutions / organizations / associations that will support and facilitate the execution of the project and the leadership of the proposed project. Articulate the specific role of each partner in the proposed project. Letters of support from partner organizations will be required at the Full Proposal stage only and should not be included with the LOI.

Budget Detail	• While estimating your budget please keep the following items in mind:
	  ○ 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. The inclusion of these costs cannot cause the amount requested to exceed the budget limit set forth in the RFP.
	  ○ 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 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.