



National Medical Association and Pfizer Announce a **Quality Improvement Grant RFP**

Quality Improvement Initiatives to Address Healthcare Barriers for Cardiac Amyloidosis

Competitive Grant Program

I. Introduction

This Request for Proposals (RFP) is for initiatives that span multiple rare disease areas. The National Medical Association (NMA) and Pfizer Global Medical Grants (GMG) are collaborating to offer a new competitive grant opportunity focused on supporting Quality Improvement projects which address significant barriers that contribute to geographic and racial healthcare disparities disproportionately impacting minority populations potentially affected by Cardiac Amyloidosis

About the National Medical Association (NMA):

The NMA mission is to advance the art and science of medicine for people of African descent through education, advocacy, and health policy to promote health and wellness, eliminate health disparities, and sustain physician viability. NMA will provide training, technical assistance and support to grantees, and establish 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 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 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.

*The National Medical Association will offer a virtual, interactive cultural humility training to **all applicants** of this RFP free of cost. The overarching objective of the training is to improve patient outcomes by equipping applicants with awareness, knowledge, skills, and competencies that will enable them to grasp and potentially deliver culturally competent care to minority populations.*

II. Eligibility

Geographic Scope:	United States
Applicant Eligibility Criteria	<ul style="list-style-type: none">• Only organizations are eligible to receive grants, not individuals or medical practice groups.• Collaborations within institutions (e.g., between departments and/or inter-professional), as well as between different institutions / organizations / associations, are encouraged. Please note all partners must have a relevant role and the requesting organization must have a key role in the project. <p><i>For programs offering education credit, the requesting organization must be the accredited grantee.</i></p>

III. Requirements

Date RFP Issued	December 22, 2022
Clinical Area	Cardiac Amyloidosis
Specific Area of Interest for this RFP:	<p>It is our intent to support independent Quality Improvement (QI) initiatives which focus on one or both of the following:</p> <ul style="list-style-type: none">• Identify significant barriers that contribute to geographic and racial healthcare disparities disproportionately impacting minority populations potentially affected by Cardiac Amyloidosis (inclusive of hereditary transthyretin amyloid cardiomyopathy) and addressing these challenges to increase earlier diagnosis, quality care and improved patient outcomes through innovative and sustainable approaches. <p style="text-align: center;">AND/OR</p> <ul style="list-style-type: none">• Improve and help advance already established coordinated partnerships with local organizations (e.g., religious groups, local businesses) and local community healthcare centers to better address at least one social determinant of health (SDoH) and signs and symptoms of potential cardiac amyloidosis. <p>All projects ultimately supported must have a focus on data collection and analysis, specifically how the changes and improvements will be measured. The measurements should be tailored to the individual project and the specific data collection capabilities of the grantee.</p> <p>Proposals coming from community engaged programs such as academic-community partnerships and local community organizations (barber shops,</p>

	<p>beauty salons, religious groups, non-profit organizations, etc.) are encouraged and will be prioritized.</p> <p><i>It is not our intent to support clinical research projects. Projects evaluating the efficacy of therapeutic or diagnostic agents will not be considered. Projects that involve the creation or support of a patient registry are also not eligible.</i></p>
<p>Target Audience:</p>	<p>Underserved populations with Cardiac Amyloidosis in the United States</p>
<p>Disease Burden Overview:</p>	<p>Black/African Americans are disproportionately affected with heart disease more than other ethnic or racial groups.^{1,2}</p> <p>Heart failure is a clinical syndrome that affects >6.5 million Americans, with an estimated 550,000 new cases diagnosed each year. The complexity of heart failure management is compounded by the number of patients who experience adverse downstream effects of the social determinants of health (SDoH).³</p> <p>Cardiac amyloidosis, a group of diseases characterized by extracellular deposition of mis-folded proteins in the heart, that leads to heart failure, reduced quality of life and death, is often misdiagnosed and/or diagnosed at a late stage in the disease course due to lack of disease awareness or insufficient screening. It is considered rare, but the true prevalence is challenging to estimate because it is frequently underrecognized.^{4, 5, 6, 7}</p> <p>Hospitalization for cardiac amyloidosis is costly, with high rates of readmission and mortality.⁸</p> <p>The lack of higher reported mortality rates in states with a greater proportion of black residents suggests underdiagnosis of amyloidosis, including cardiac forms of the disease, in many areas of the United States.⁹</p> <p>Although nine types of cardiac amyloidosis are known, AL (composed of monoclonal immunoglobulin light chains) and ATTR [transthyretin, either variant/hereditary (ATTRv/hATTR) or acquired/senile/wild-type (ATTRwt) forms] currently account for the vast majority of cardiac amyloidosis.⁴</p> <p>Transthyretin amyloid cardiomyopathy (ATTR-CM) is an important cause of heart failure that disproportionately affects people of African descent.¹⁰</p> <p>There is an increased risk of HF among African Americans who carry the most common mutation associated with hATTR (Val122Ile, where isoleucine substitutes for valine at position 122 p.V142I and has an autosomal dominant inheritance pattern). This mutation is present in 3.4% of African Americans, with 1.5 million individuals in the United States being allele carriers, although not all individuals with the Val122Ile mutation develop symptoms of hereditary ATTR-CM.¹¹⁻¹⁷</p>

	<p>Diagnosis in the early stages of hereditary transthyretin (ATTR) amyloidosis is imperative to support timely disease management.¹⁸</p>
<p>Recommendations and Target Metrics:</p>	<p>Related Guidelines/Expert Consensus, Position/Scientific Statements and Recommendations</p> <p><u>Guideline/Expert Consensus</u></p> <ul style="list-style-type: none"> • 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines (Section 7.8 Cardiac Amyloidosis)¹⁹ • Expert Consensus Recommendations for the Suspicion and Diagnosis of Transthyretin Cardiac Amyloidosis²⁰ <p><u>Position/Scientific Statements</u></p> <ul style="list-style-type: none"> • Diagnosis and treatment of cardiac amyloidosis: a position statement of the ESC Working Group on Myocardial and Pericardial Diseases⁴ • Cardiac Amyloidosis: Evolving Diagnosis and Management: A Scientific Statement from the American Heart Association²¹ <p><u>Recommendations</u></p> <ul style="list-style-type: none"> • Screening for Transthyretin Amyloid Cardiomyopathy in Everyday Practice⁶

<p>Gaps Between Actual and Target, Possible Reasons for Gaps:</p>	<p>The Amyloidosis Research Consortium (ARC) conducted a national survey that was translated to increase the range of targeted populations to survey. The survey objective was to gain insight into patient experiences with delays and errors in the diagnostic pathway for cardiac amyloidosis.</p> <p>Patient and caregiver surveys were created by ARC and posted on ARC's website and distributed to the Amyloidosis Foundation, Amyloidosis Support Groups, and individual physicians for distribution to individuals affected by cardiac amyloidosis.²²</p> <p>The ARC survey findings showed that:</p> <ul style="list-style-type: none"> • Patients with cardiac amyloidosis are commonly misdiagnosed. Physicians who misdiagnose tend to focus on treating presenting symptoms individually, which causes delays in diagnosis and patients to receive incorrect treatments, typically for their cardiac involvement, that can worsen symptoms and reduce survival. • Diagnosis by cardiologists is increasing over time, however, patients still frequently see five or more doctors before they are diagnosed correctly. • A high percentage of hereditary ATTR-CM went undiagnosed after the start of symptoms. This illustrates there is a demand for better understanding and awareness across the health care provider and patient community. • Physician and patient education about initial symptoms is vital in facilitating earlier diagnosis. Understanding of early signs, such as carpal tunnel, and early symptoms are crucial to improving diagnosis and care.
<p>Barriers:</p>	<ul style="list-style-type: none"> • Patients identified travel as the greatest challenge to accessing care at amyloidosis centers.²³ • Patients and patient advocates indicate that problems related to insurance coverage were obstacles to receiving treatment for amyloidosis.²³
<p>Current National Efforts to Reduce Gaps:</p>	<p>National Professional Associations, such as American Society of Nuclear Cardiologists, have highlighted creative ways members are raising awareness of this condition among people who may not have heard of it but could be at risk. Additionally, there are a number of organizations, such as the Amyloidosis Support Group, Amyloidosis Research Consortium, Amyloidosis Foundation, National Organization for Rare Disorders (NORD), MacKenzie's Mission, that have created 24-hour hotline, a highly informative websites, support groups on Facebook, various informative multilingual educational video & print materials for patients & providers to increase awareness, and promote earlier suspicion, diagnosis & treatment.</p>

<p>Expected Approximate Monetary Range of Grant Applications:</p>	<ul style="list-style-type: none"> Selected individual projects requesting up to \$50,000 will be considered. The total available budget related to this RFP is \$150,000. In addition, the National Medical Association will offer a virtual, interactive cultural humility training to all applicants of this RFP free of cost. The overarching objective of the training is to improve patient outcomes by equipping applicants with awareness, knowledge, skills, and competencies that will enable them to grasp and potentially deliver culturally competent care to minority populations.
<p>Key Dates:</p>	<ul style="list-style-type: none"> RFP release date: December 22, 2022 Full Proposal Deadline Extended: March 16, 2023 Review of Full Proposals by External Review Panel: April 2023 Anticipated Full Proposal Notification Date: May 2023 Grants distributed following execution of fully signed Letter of Agreement Anticipated Project Start a Date: June 2023
<p>How to Submit:</p>	<ul style="list-style-type: none"> Please go to www.cybergrants.com/pfizer/QI and sign in. First-time users should click “REGISTER NOW”. <i>[Note: there are individual portals for each grant application type. Please be sure to use the URL above.]</i> 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 US - NMA SDoH Cardiac Amyloidosis 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. <p>IMPORTANT: Be advised applications submitted through the wrong application type and/or submitted after the due date will not be reviewed by the committee.</p>
<p>Questions:</p>	<ul style="list-style-type: none"> 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 “2023 RD US - NMA SDoH Cardiac Amyloidosis.”
<p>Grant Agreements:</p>	<ul style="list-style-type: none"> 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.

	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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:	<ul style="list-style-type: none"> • All applicants will be notified via email by the dates noted above. • Applicants may be asked for additional clarification during the review period.

References:

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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	<ul style="list-style-type: none">• 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 <i>overall</i> 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	<ul style="list-style-type: none">• 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 <i>your</i> 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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Provide an anticipated timeline for your project including project start/end dates
Additional Information	<ul style="list-style-type: none"> • If there is any additional information you feel Pfizer should be aware of concerning the importance of this project, please summarize here
Organization Detail	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • While estimating your budget please keep the following items in mind: <ul style="list-style-type: none"> ○ 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.