

Pfizer Research Grant RFP

Transthyretin Amyloid Cardiomyopathy (ATTR-CM) Research

Competitive Grant Program – using Expert Review Panel



Overview

This competitive program seeks to support research in the United States that advances medical knowledge in the understanding, diagnosis, and treatment of ATTR Amyloidosis.



Geographic Scope

United States



Project Types and Area of Interest

Pfizer is interested in supporting proposals that advance our understanding of the basic science and early diagnosis and treatment of ATTR cardiac amyloidosis through research. See **Area of Interest** section of RFP for further details.



Key Milestones

- Application submission deadline: **April 27, 2023**
- Anticipated decision notification date: **July 1, 2023**
- Anticipated project start date: **December 1, 2023**



Funding Range and Project Length

Individual projects requesting up to \$75,000 USD/year for 1 to 2 years will be considered.

I. Eligibility

Geographic Scope:

- United States

Applicant Eligibility Criteria

- 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.

II. Requirements

Date RFP Issued

- February 22, 2023

Clinical Area

- TTR Amyloidosis

Area of Interest for this RFP:

Pfizer is interested in supporting research proposals that advance our understanding of the basic science and early diagnosis and treatment of ATTR cardiac amyloidosis through research focused in the following areas:

- **Approaches for the early identification and follow up of ATTR amyloidosis patients**
 - Multidisciplinary approaches to diagnosis and care
 - Multimodality imaging approaches to diagnosis including Artificial Intelligence (AI) and Machine Learning (ML)
 - New diagnostic algorithms
 - Non-invasive diagnostic techniques (e.g. biomarkers, use of AI)
 - Risk factors for disease penetrance
 - Definition and measurement of disease progression and natural history studies
 - New outcomes measures (Quality of life; patient reported outcomes, imaging)
- **Real-world (RW) efficacy and safety of tafamidis in the clinical setting for the management of ATTR amyloidosis**
 - Effect of Tafamidis on conduction disorders (i.e. arrhythmias, atrial fibrillation)
 - Effect of Tafamidis on echo, MRI or PET measures and hemodynamics
 - Effect of Tafamidis on amyloid burden
 - Effect of Tafamidis on quality of life
 - Changes in serum TTR, biomarker analysis
 - Evaluating existing databases for clinical outcomes
- **Evaluation of patients with ATTR-CM presenting with a mixed phenotype (e.g. cardiomyopathy and polyneuropathy)**
 - Real-world treatment of mixed phenotype patients with Tafamidis 61mg including examination of both cardiac and neurological outcomes
 - Case control and cross-sectional studies
 - Evaluating existing databases for clinical outcomes

- **Gender/sex related differentiation**
 - Delineate factors which contribute to under recognition, under diagnosis and treatment management of ATTR-CM in women
 - Characterize ATTR-CM gender specific differences
 - Risk factors and comorbidities
 - Demographics and clinical characteristics in wild type and hereditary
 - Characterize differences in the clinical assessment and/or the diagnostic approach when evaluating women at risk for ATTR-CM (i.e./ appropriate ECG and echo parameters for women, biomarkers, etc.)
 - Analyze the current prevalence/penetrance of ATTR-CM in women
 - Identify and understand the impact of sex/gender on the pathophysiological response to ATTR-CM

- **Pathophysiology:**
 - Mechanistic studies to advance the basic science of amyloid formation and deposition including studies of the:
 - Functional role of TTR
 - Long term impact of TTR knockdown
 - Amyloidogenesis
 - Tissue tropism of amyloid deposits
 - Proteolytic cleavage

Note: Pfizer will not supply formulated study drug nor pure substance

Expected Approximate Monetary Range of Grant Applications:

- Individual projects requesting up to \$75,000 USD/year for 1 to 2 years will be considered.
- Award amounts include direct costs, institutional overhead costs (capped at 28% per Pfizer policy), and indirect costs
- 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: 2/22/2023
- Proposal Due Date: 4/27/2023
- Anticipated Notification Date: July 2023
- Anticipated Project Timeline: up to 2 years
- Anticipated Project Start Date: December 2023
- **NOTE:** Grants will be distributed following a fully executed agreement and submission of Final Protocol, documentation of IRB/IEC approval, regulatory approval (if applicable), exemption or waiver.

How to Submit:

Note: Please read this section carefully since applications submitted not following these instructions will not be accepted and will be cancelled

- Please go to <http://www.cybergrants.com/pfizer/Research> and sign in. First-time users should click "Create your password". *[Note: there are individual portals for each grant application type. Please be sure to use the URL above.]*
- Click the "Start a New Research Grant Application" button.
- In the application:
 - For the question "Competitive Grant?" select Yes
 - Select the following Competitive Grant Program Name: **2023 RD US ATTR Amyloidosis Research**
- Requirements for submission:
 - Complete all required sections of the online application. See **Appendix** for additional details
- 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 after the due date will not be reviewed.

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 "2023 RD US ATTR Amyloidosis Research."
- 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.
- The agreement is expected **to be signed by both parties within 2023 and without change**.
- 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.
- This RFP is supported by Pfizer Inc. and, if approved, payment will be sent from the United States.
- Payment will only be made to requesting Institution.

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.

About Pfizer Global Medical Grants

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 general Request for Proposal (RFP) that provides detail regarding a general 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 research gaps 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.

Appendix

Specific RFP Submission Requirements

Applications will be accepted via the online portal listed in the [How to Submit](#) section. Project Proposals/Protocols should be single-spaced using Calibri 12-point font and 1-inch margins. Note there is a 15-page limit exclusive of references. When uploading your Full Proposal please ensure it addresses the following sections:

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.

Anticipated Project Timeline

- Provide an anticipated timeline for your project including project start/end dates
 - 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
- 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:
 - 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.
 - 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.