

Pfizer Research Grant RFP

Junior Investigator Global ATTR Amyloidosis Research ASPIRE

Competitive Grant Program – using Expert Review Panel



Overview

This competitive grant program seeks to support research conducted by Junior Investigators that advances medical knowledge in the understanding, diagnosis and treatment of ATTR Amyloidosis.



Geographic Scope

All countries except for the United States



Project Types and Area of Interest

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



Key Milestones

- Application submission deadline: **March 21, 2023**
- Anticipated decision notification date: **July 31, 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:

- All countries except for the United States

Applicant Eligibility Criteria

- The applicant (PI) must be a junior investigator with a professional terminal degree (MD and/or PharmD or equivalent). Applicants **must have obtained their terminal degree* less than 10 years ago.**
**Terminal degree: end of training (i.e. residency/fellowship). The 10 years will begin after someone completes their training and begin a real teaching or patient care-focused job*
- Applicant must be developing their research careers in ATTR Amyloidosis.
- **Applicant must have a mentor or senior investigator participate as a co-investigator**
- Members of the 2023 Expert Review Panel (ERP) and 2022 ASPIRE awardees are not eligible to apply or serve as mentors or collaborating investigators on applications from other investigators (this includes applications from junior investigators).
- The Junior Investigator must be listed as the PI in the application and the Mentor must be listed as the co-PI
- The principal investigator (PI) and institution must be based outside of the United States.
 - Applicant must be affiliated with a host institution

II. Requirements

Date RFP Issued

- January 19, 2023

Clinical Area

- TTR Amyloidosis

Area of Interest for this RFP:

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

- **Epidemiologic evaluations for ATTR amyloidosis**
 - Global or regionally-focused evaluations
 - Gender analysis – prevalence, natural history, etc.
- **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
 - New diagnostic algorithms
 - Non-invasive diagnostic techniques (e.g. biomarkers, use of AI)
 - Risk factors for disease penetrance
 - Definition and measurement disease progression and natural history studies
 - New staging systems
 - New outcomes measures (Quality of life; patient reported outcomes, Imaging)
 - Management of cardiac complications

- **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
 - Use of tafamidis post-organ transplant
- **Evaluation of patients with ATTR-CM presenting with a mixed phenotype (e.g. cardiomyopathy and polyneuropathy)**
 - RW treatment of mixed phenotype patients with Tafamidis 61 mg including examination of both cardiac and neurological outcomes
 - Longitudinal evaluations of neurologic manifestations in patients with ATTR-CM including wild type
 - Case Control and Cross-Sectional Studies
 - Evaluating Existing Databases for clinical outcomes
- **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: 1/19/2023
- Proposal Due Date: 3/21/2023
- 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 G - Global ATTR Amyloidosis Research**
- Requirements for submission:
 - Complete all required sections of the online application. See **Appendix** for additional details
 - When uploading your Full Proposal/Protocol please use the following template which can be downloaded by clicking [here](#).
 - The Junior Investigator must be listed as the PI in the application and the Mentor must be listed as the co-PI
- 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 G - Global 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

Applications will be accepted via the online portal. When uploading your Full Proposal/Protocol please use the following template which can be downloaded by clicking [here](#).

PLEASE UPLOAD STUDY PROTOCOL (12-page max limit) and MANDATORY OTHER ITEMS AS A SINGLE DOCUMENT. DO NOT SUBMIT MULTIPLE DOCUMENTS. READ CAREFULLY BELOW FOR HOW TO PREPARE THIS SECTION OF YOUR APPLICATION.

- General Notes about Study Protocol Requirements and Organization
 - The content for this portion of the application should be organized as detailed below and is mandatory.
 - The study protocol itself must not exceed 12 pages: minimum 12 pt. font with 1' margins around (not including references or itemized budget). **Study protocols that exceed this 12-page limit will not be reviewed.**
 - Following the study protocol, include these sections in the same document which are not part of the 12-page limit noted above: Reference list, Description of the Overall Research Environment, and Qualifications to Conduct the Proposed Research, Study Budget Narrative.
 - **All protocols are to be organized as noted below. Please do not deviate from this outline in preparing your study protocol and accompanying information and review the instructions carefully. A protocol submission template is provided [here](#). Use of this protocol template is required to ensure your submission is fully compliant with the study protocol requirements and organization.**

PREPARING THE STUDY PROTOCOL:

LIST THE TITLE OF YOUR APPLICATION AT THE TOP OF THE FIRST PAGE, THEN ORGANIZE THE PROTOCOL AS FOLLOWS:

Section I. Study Protocol

(1) BACKGROUND:

(a) Objectives

- (i) We suggest about 4 paragraphs to discuss the objectives of your proposed research.

(b) Specific Aims and Hypotheses

- (i) List each separate Specific Aim and how the hypothesis for that aim will be tested.

(2) RELEVANCE OF PROPOSED STUDY TO PROGRAM MISSION (up to 3 brief paragraphs suggested)

(3) PRELIMINARY DATA IN SUPPORT OF THE PROPOSAL (up to 2 pages suggested or longer if needed)

- (a) Review data generated by your or your collaborator's laboratories or clinical programs that support the proposed research and specific aims.

(4) METHODS: a general schema for preparing this section of your application follows. Some sections may not apply to your research. All applicable sections should be included and other appropriate

sections added as applicable to your proposal. Any figures and tables must be included in the body of the text.

(a) Experimental Design

(i) Population to be tested, sample size and recruitment plan:

1. Inclusion criteria
2. Exclusion criteria

(b) Study Procedures

(i) State specifically how each Specific Aim will be accomplished by providing a detailed review of the methods for the proposed research.

1. What type of study design will be used (e.g. open label prospective study, cross-sectional study, retrospective chart review, etc).
2. State how the primary and secondary outcomes measures will be collected (e.g. discuss the dependent measures to be used).
 - a. Review all outcome measures and their collection in sufficient detail to allow the review committee to determine whether the measures and schedule for collection of them is sufficient to allow for meaningful conclusions to be drawn from the proposed research.
3. Provide justification for the involvement of human subjects.

(c) Data Analysis Plan: Discuss all endpoints and outcome measures and specifically how these data will be managed.

- (i) Include sample size and power calculations
- (ii) Discuss how any variability and bias will be controlled as applicable
- (iii) Describe the actual statistical methods to be employed
- (iv) Review the anticipated results

(5) Milestones and Study Timeline

(a) Briefly describe (1 paragraph), or use a table to illustrate, how the specific aims will be completed within 12-months or 24-months of funding. Indicating the timing for any training of investigators and research personnel, subject recruitment, laboratory assessments, data analysis and manuscript preparation. These are just examples. Your timeline should include details for achieving all milestones relevant to your proposed research.

(6) Potential Limitations and Considerations

(a) In a few paragraphs, discuss possible issues to obtaining the primary outcome measure(s) and management plans should they not be feasible. Other limitations, depending on the research proposed, could include managing delays in subject recruitment, underestimating sample sizes needed, or unforeseen issues with study methodologies proposed.

(b) The purpose of this section is to demonstrate to the review committee that you have planned for potential hurdles in completing the proposed research.

Section II. Mandatory Other Items

At the end of the study protocol, include the following mandatory items. These are excluded from the 12-page maximum page count for the study protocol but must be included as part of the same document (i.e. 1 file should contain all the information above for your study protocol plus the sections noted below).

(1) Reference List for any literature cited in the study protocol.

(2) Description of the Overall Research Environment.

(a) Briefly describe the overall resources available to you in support of the proposed research. If you have collaborators on the proposed research, include similar descriptions for any resources their collaboration brings to the research.

(3) Qualifications to conduct the proposed research

(a) Prepare a paragraph for the committee explaining what uniquely qualifies you (and your collaborators, if applicable) to conduct the proposed research.

(b) Junior investigators should include some discussion of how mentors or collaborators involved can help to ensure the successful completion of the proposed work.

(4) Budget Narrative

(a) Please refer to the “Expected Approximate Monetary Range of Grant Applications” section above for funding limits.

(b) This section of the protocol can be used to provide a description/narrative of your budget

(5) Overlap

(a) If applicable, list any other research support with a description of overlap. Otherwise state: NO OTHER RESEARCH SUPPORT OR OVERLAP.