Pfizer Research Grant RFP

Junior Investigator Global ATTR Cardiac Amyloidosis Research

Competitive Grant Program – using Expert Review Panel

Overview

This competitive grant program seeks to support research proposals from Junior Investigators that advance our understanding of the early diagnosis and treatment of ATTR Cardiac amyloidosis.

Geographic Scope/Location of Project

France, Italy, Spain, Germany, Japan, Canada, Australia and South Korea

Project Types and Area of Interest

Research focused in the following areas:

- Approaches for the early identification and follow up of ATTR Cardiac Amyloidosis patients
- RW efficacy and safety of tafamidis in the clinical setting for the management of ATTR Cardiac Amyloidosis
- Evaluation of patients with ATTR Cardiac Amyloidosis presenting with a mixed phenotype (e.g. cardiomyopathy and polyneuropathy)

Key Milestones

- Application submission deadline: **6 May 2024**
- Anticipated decision notification date: **August 2024**
- Anticipated project start date: **after November 2024**

Funding Range and Project Length

- Individual projects requesting up to $100,000 will be considered.
- Expected project duration is 1 to 2 years.

I. Eligibility

Geographic Scope:

- France, Italy, Spain, Germany, Japan, Canada, Australia and South Korea

Applicant Eligibility Criteria

- The institution and Principal Investigator (PI) must be based in one of the eligible countries noted above.
- 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 Cardiac Amyloidosis.
- **Applicant must have a mentor or senior investigator participate as a co-investigator.**
  - **The Junior Investigator must be listed as the PI in the application and the Mentor must be listed as the co-PI**
- Members of the 2024 Expert Review Panel and 2023 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).
- Applicant must be affiliated with a host institution.
- Requesting organization must be legally able to receive award funding directly from Pfizer Inc. We strongly recommend that applicants confirm this with their organization or institution prior to submitting an application. Grants awarded to organizations that are subsequently found to be unable to accept funding directly from Pfizer Inc. may be subject to rescission.

II. Requirements

Date RFP Issued

- 18 March 2024

Clinical Area

- ATTR Cardiac Amyloidosis

Specific Area of Interest for this RFP:

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

- **Approaches for the early identification and follow up of ATTR Cardiac Amyloidosis patients**
  - Multidisciplinary approaches to diagnosis and care.
  - New diagnostic algorithms.
  - Non-invasive diagnostic techniques (e.g. biomarkers, use of AI)
  - Measurement disease progression and new staging systems.
  - New outcomes measures (Quality of life; patient reported outcomes, Imaging, biomarkers)

- **RW efficacy and safety of tafamidis in the clinical setting for the management of ATTR Cardiac Amyloidosis**
  - Effect of Tafamidis on ECHO, MRI or PET measures and hemodynamics.

- Effect of Tafamidis on amyloid burden.
- Evaluating existing Databases for Clinical outcomes.

- **Evaluation of patients with ATTR Cardiac Amyloidosis presenting with a mixed phenotype (e.g. cardiomyopathy and polyneuropathy)**
  - Retrospective analysis of real word data (RWD) of mixed phenotype patients treated with Tafamidis 61mg including examination of both cardiac and neurological outcomes.

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

Expected Approximate Monetary Range of Grant Applications:

- Individual projects requesting up to $100,000 will be considered. Pfizer anticipates funding up to 4 projects.
- 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, and will be stated clearly in the grant agreement.

Key Dates:

- RFP Release Date: **18 March 2024**
- Proposal Due Date: **6 May 2024**
- Review of Full Proposals by ERP: **June 2024**
- Anticipated Full Proposal Notification Date: **August 2024**
- 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 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: 2024 RD G ATTR Cardiac 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 "ATTR Research 2024."
- 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 2024 and without change**.
- Under Pfizer's competitive grant program, **modifications to grant agreements will not be reviewed** unless a genuine conflict exists as between applicable law and the terms of the relevant grant agreement. Applicant is encouraged to share the core terms with counsel for approval prior to submitting an application.
- Except where prohibited by applicable law and, in any case, subject to review by Pfizer Legal, payment of grant funding may only be paid to the grantee organization.
- This RFP is supported by Pfizer Inc. and, if approved, payment will be sent from the United States.

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 sited 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.