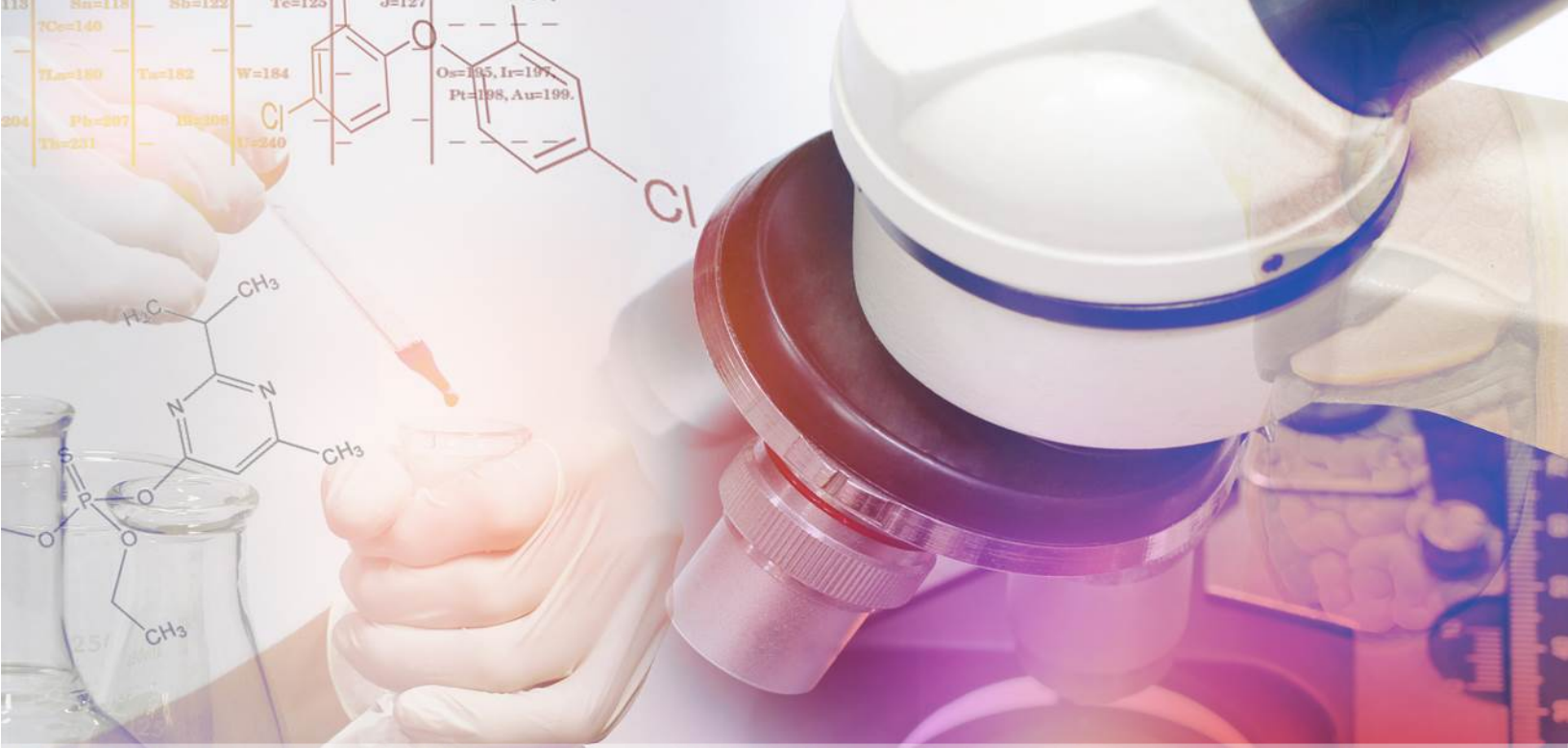

Pfizer Announces a Research Grant RFP

Junior Investigator Transthyretin Amyloid Cardiomyopathy (ATTR-CM) Research

Competitive Grant Program- using Expert Review Panel

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 research, practice or care 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.

Competitive Grant Program Eligibility

Geographic Scope	• All countries except for the United States
Applicant Eligibility Criteria	To be eligible: • The applicant (PI) must be a junior investigator with a professional terminal degree (MD and/or PhD and/or PharmD or equivalent). Applicants enrolled in a residency, fellowship or postdoctoral program are encouraged to apply. **Applicants must have obtained their terminal degree less than 10 years ago**. • 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 2021 Expert Review Panel and 2020 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 principal investigator (PI) and institution must be based outside of the United States. • Applicant must be affiliated with a host institution

Requirements

Date RFP Issued	• January 15, 2021
Clinical Area	• Transthyretin Amyloid Cardiomyopathy (ATTR-CM)
Area of Interest Focus	Projects that will be considered will aim to improve the understanding of the epidemiology, basic science, early diagnosis and treatment of ATTR-CM through research focused in the following areas: **Epidemiologic evaluations for ATTR-CM** • Global or regionally focused evaluations • Studies of prevalence of ATTR-CM within enriched patient populations (e.g. patients with valvular disorders or post-valve replacements, HCM, spinal stenosis, carpal tunnel syndrome, etc.) • Gender analysis – prevalence, natural history, etc.

Approaches for the early identification and follow up of ATTR-CM patients

- Multidisciplinary approaches to appropriate diagnosis and care
- Multimodality imaging approaches to appropriate 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
- Markers of disease progression and natural history studies
- New staging systems
- New outcomes measures (Quality of life; patient reported outcomes, Imaging)
- Genetic screening programs for families
- Genetic counseling patient support tools

RW efficacy and safety of tafamidis in the clinical setting for the management of ATTR-CM (*Note: Pfizer will not supply formulated study drug)*

- Effect of Tafamidis on conduction disorders (i.e. arrhythmias, atrial fibrillation)
- Effect of Tafamidis on ECHO or MRI 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 or treatment Information
    - Phenotype or genomic factors

Evaluation of patients with ATTR-CM presenting with a mixed phenotype (e.g. cardiomyopathy and polyneuropathy)

- RW treatment of mixed phenotype patients with Tafamidis 61mg including examination of both cardiac and neurological outcomes

	• Case Control and Cross-Sectional Studies
	  • Includes examination of phenotype and genotype relationships
	• Evaluating Existing Databases for:
	  • Clinical outcomes or treatment information
	  • Phenotype or genomic factors
	Longitudinal evaluations of neurologic manifestations in patients with ATTR-CM including wild type
	
	Mechanistic studies to advance the basic science of amyloid formation and deposition on the heart and including studies of the:
	  ○ Functional role of TTR
	  ○ Long term impact of TTR knockdown
	Characteristics of ATTR-CM in post-organ transplant patients, including natural course of disease progression
	
	European country specific early access program data collection

Expected Approximate Monetary Range of Grant Applications	• Individual projects requesting up to $75,000/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
Key Dates	• RFP release date: January 15, 2021 • Proposal Deadline: *March 22, 2021 *Please note the deadline is 23:59 Eastern Time (New York, GMT -5). • Anticipated Notification Date: July 2021 • Anticipated Project Timeline: up to 2 years • Anticipated Project Start Date: December 2021 • NOTE: Pfizer support will be distributed following execution of fully signed agreement and receipt of all required information according to grant type (e.g. IRB/IEC approval).
How to Apply	• Please go to www.cybergrants.com/pfizer/Research and sign in. First-time users should click “Create your password.” Requirements for submission: • For the question “Competitive Grant?” select Yes

	• Select the following Competitive Grant Program Name: 2021 RD G-Transthyretin Amyloid Cardiomyopathy (ATTR-CM) Research
	• Complete all required sections of the online application. See Appendix A for additional details
	  ○ When uploading your Full Proposal/Protocol please use the following template which can be downloaded by clicking here.
	  ○ The study budget will be collected within the online application and **must be entered in US Dollars (USD)**.
	• If you encounter any technical difficulties with the website, please click the "Technical Questions" link at the bottom of the page

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-CM Research RFP." • Please click here to view Frequently Asked Questions regarding the Competitive Grant Program
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 panel is comprised of external 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
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. • The agreement is expected to be signed by both parties within 2021 and without change.
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

Appendix A
Full Proposal/Protocol

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) The study budget will be collected within the online application and **must be entered in US Dollars (USD)**.

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

(c) 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.