

Transthyretin Amyloid Cardiomyopathy (ATTR-CM) Research – U.S.

Competitive Grant Program - internal Pfizer review process

I. Background

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, scientifice and/or research interest(s)

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 internal Pfizer review process to make final grant decisions. Organizations are invited to submit an application addressing the research gaps as outlined in the specific RFP.

For all 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.

II. 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

III. Requirements

Date RFP Issued	• April 7, 2021
Clinical Area	Transthyretin Amyloid Cardiomyopathy (ATTR-CM)
General Area of Interest for this RFP:	 Projects that will be considered for Pfizer support will focus on several or one specified area: Early identification, evaluation, diagnosis, prognosis & treatment Study of hereditary ATTR genotypes and phenotypes Non-Val30Met genotypes Val122Ile, Thr60Ala, Val30Met, and others Mixed phenotypic manifestations (e.g. polyneuropathy and cardiomyopathy) Use of tafamidis in the clinical setting (i.e. real-world evidence)
Expected Approximate Monetary Range of Grant Applications:	 Individual projects requesting up to \$75,000 will be considered.





Key Dates:	RFP release date: April 7, 2021
	Grant Application due date: June 9, 2021
	Please note the deadline is 23:59 Eastern Standard Time (e.g. New York, GMT -5).
	Anticipated Grant Award Notification Date: July 2021
	 Grants will be distributed following a fully executed agreement, receipt of IRB/IEC Approval and Final Protocol
	Anticipated Project Start: on or after October 2021
How to Submit:	 Please go to <u>http://www.cybergrants.com/pfizer/Research</u> and sign in. First-time users should click "Create your password".
	In the application:
	 For the question "Are you replying to a Request for Proposal as part of the Competitive Grant Program?" select Yes
	 Select the following Competitive Grant Program Name: 2021 RD L ATTR-CM Research US
	 Select the following Primary Area of Interest: Transthyretin Amyloid Cardiomyopathy (ATTR-CM)
	Requirements for submission:
	Complete all required sections of the online application and upload your project proposal (see Appendix) in the Proposal/Protocol field.
	 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 (<u>amanda.j.stein@pfizer.com</u>), with the subject line "ATTR-CM Research RFP."
	 Please click <u>here</u> 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 <u>here</u> 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.
Review and Approval Process	 Grant requests received in response to a general RFP are reviewed by Pfizer to make final grant decisions.
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 General RFP Submission Requirements

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. Please include the following:

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. All publications must follow ICH guidelines
Anticipated Project Timeline	 Provide an anticipated timeline for your project including project start/end dates
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
References	Bibliography of relevant references.



