



Pfizer Announces a **Research Grant RFP**

# ***Transthyretin Amyloid Cardiomyopathy (ATTR-CM) Research***

***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 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 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 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.

## II. Eligibility

<b>Geographic Scope:</b>	United States
<b>Applicant Eligibility Criteria</b>	<ul style="list-style-type: none"> <li>• The institution and principal investigator (PI) must be based in one of the eligible countries noted above.</li> <li>• Only organizations are eligible to receive grants, not individuals or medical practice groups.</li> <li>• 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.</li> <li>• Applicant must be affiliated with a host institution</li> </ul>

## III. Requirements

<b>Date RFP Issued</b>	<ul style="list-style-type: none"> <li>• March 1, 2022</li> </ul>
<b>Clinical Area</b>	<ul style="list-style-type: none"> <li>• Transthyretin Amyloid Cardiomyopathy</li> </ul>
<b>General Area of Interest for this RFP:</b>	<p>Research projects that will be considered for support include:</p> <ul style="list-style-type: none"> <li>• Early identification, evaluation, diagnosis, prognosis &amp; treatment</li> <li>• Natural history</li> <li>• Epidemiology             <ul style="list-style-type: none"> <li>○ Prevalence of TTR amyloidosis among at-risk populations (e.g. carpal tunnel syndrome, aortic stenosis, hypertrophic cardiomyopathy, lumbar spinal stenosis, hip &amp; knee arthroplasty, atrial fibrillation)</li> <li>○ Changing epidemiology of cardiac amyloid subtypes (hereditary vs wild-type)</li> </ul> </li> <li>• Scintigraphy             <ul style="list-style-type: none"> <li>○ Use of scintigraphy for diagnosis of early disease and/or monitoring disease progression</li> <li>○ Phenotype and management of patients with Perugini Grade 1 uptake</li> </ul> </li> <li>• New methodology to accelerate appropriate ATTR CM patient identification including Machine learning/ Artificial Intelligence and new biomarkers</li> <li>• Study of hereditary ATTR genotypes and phenotypes             <ul style="list-style-type: none"> <li>○ Non-Val30Met genotypes</li> <li>○ Val122Ile, Thr60Ala, Val30Met, and others</li> </ul> </li> <li>• Mixed phenotypic manifestations (e.g. polyneuropathy and cardiomyopathy)</li> <li>• Use of tafamidis in the clinical setting (i.e. real world evidence)</li> </ul>

<p><b>Expected Approximate Monetary Range of Grant Applications:</b></p>	<ul style="list-style-type: none"> <li>Individual projects requesting up to \$75,000 will be considered.</li> </ul>
<p><b>Key Dates:</b></p>	<ul style="list-style-type: none"> <li>RFP release date: March 1, 2022</li> <li>Grant Application due date: May 5, 2022 Please note the deadline is 23:59 Eastern Standard Time (e.g. New York, GMT -5).</li> <li>Anticipated Grant Award Notification Date: July 2022</li> <li>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</li> <li>Anticipated Project Start Date: after September 2022</li> </ul>
<p><b>How to Submit:</b></p>	<ul style="list-style-type: none"> <li>Please go <a href="http://www.cybergrants.com/pfizer/Research">www.cybergrants.com/pfizer/Research</a> and sign in. First-time users should click “Create your password”. <i>[Note: there are individual portals for each grant application type. Please be sure to use the URL above.]</i></li> <li>Click the “Start A New Research Grant Application” button.</li> <li>In the application:             <ul style="list-style-type: none"> <li>For the question “Competitive Grant?” select Yes</li> <li>Select the following Competitive Grant Program Name: <b>2022 RD US ATTR-CM Research</b></li> <li>Select the following Primary Area of Interest: TTR Amyloidosis</li> </ul> </li> <li>Requirements for submission: Complete all required sections of the online application and upload your project proposal (see Appendix) in the Proposal/Protocol field.</li> <li>If you encounter any technical difficulties with the website, please click the “Technical Questions” link at the bottom of the page.</li> </ul> <p><b>IMPORTANT:</b> Be advised applications submitted after the due date will not be reviewed.</p>
<p><b>Questions:</b></p>	<ul style="list-style-type: none"> <li>If you have questions regarding this RFP, please direct them in writing to the Grant Officer, Amanda Stein (<a href="mailto:amanda.j.stein@pfizer.com">amanda.j.stein@pfizer.com</a>), with the subject line “2022 RD US ATTR-CM Research”</li> <li>Please click <a href="#">here</a> to view Frequently Asked Questions regarding the Competitive Grant Program</li> </ul>

<b>Grant Agreements:</b>	<ul style="list-style-type: none"><li>• If your grant is approved, your institution will be required to enter into a written grant agreement with Pfizer. Please click <a href="#">here</a> to view the core terms of the agreement.</li><li>• 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.</li></ul>
<b>Review and Approval Process</b>	<ul style="list-style-type: none"><li>• Grant requests received in response to a general RFP are reviewed by Pfizer to make final grant decisions.</li></ul>
<b>Mechanism by which Applicants will be Notified:</b>	<ul style="list-style-type: none"><li>• All applicants will be notified via email by the dates noted above.</li><li>• Applicants may be asked for additional clarification during the review period.</li></ul>

## 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 10-page limit exclusive of references. Please include the following:**

<b>Goals and Objectives</b>	<ul style="list-style-type: none"> <li>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</li> </ul>
<b>Assessment of Need for the Project</b>	<ul style="list-style-type: none"> <li>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</li> </ul>
<b>Target Audience</b>	<ul style="list-style-type: none"> <li>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</li> <li>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</li> </ul>
<b>Project Design and Methods</b>	<ul style="list-style-type: none"> <li>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</li> <li>Please describe how the project submitted supports diversity, equity, and inclusion either through the study population targeted or through the project team that is directly involved</li> </ul>
<b>Innovation</b>	<ul style="list-style-type: none"> <li>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</li> </ul>
<b>Evaluation and Outcomes</b>	<ul style="list-style-type: none"> <li>Specify type and frequency of safety, efficacy, and/or outcome measures. Also indicate the method(s) used to assess measures</li> <li>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</li> </ul>
<b>Anticipated Project Timeline</b>	<ul style="list-style-type: none"> <li>Provide an anticipated timeline for your project including project start/end dates                             <ul style="list-style-type: none"> <li>An ISR grant request cannot be submitted for a study that has already commenced and was not originally supported by Pfizer.</li> </ul> </li> </ul>

<p><b>Additional Information</b></p>	<ul style="list-style-type: none"> <li>• If there is any additional information you feel Pfizer should be aware of concerning the importance of this project, please summarize here</li> <li>• Early-career applicants: Letter(s) of support from mentor(s) and collaborators describing how the award will advance the applicant’s career.</li> </ul>
<p><b>Organization Detail</b></p>	<ul style="list-style-type: none"> <li>• 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</li> </ul>
<p><b>Budget Detail</b></p>	<ul style="list-style-type: none"> <li>• While estimating your budget please keep the following items in mind:             <ul style="list-style-type: none"> <li>○ 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.</li> <li>○ The inclusion of these costs cannot cause the amount requested to exceed the budget limit set forth in the RFP.</li> <li>○ It should be noted that grants awarded through GMG cannot be used to purchase Pfizer therapeutic agents (prescription or non-prescription).</li> </ul> </li> <li>• Pfizer maintains a company-wide, maximum allowed overhead rate of 28% for independent studies and projects. Please <a href="#">click here</a> for details.</li> </ul>
<p><b>References</b></p>	<ul style="list-style-type: none"> <li>• Bibliography of relevant references.</li> </ul>