

Hereditary Transthyretin Amyloidosis Research in China 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

| Geographic Scope: | China |
|-----------------------------------|---|
| Applicant Eligibility Criteria | The institution and principal investigator (PI) must be based in China. Only organizations are eligible to receive grants, not individuals or medical practice groups. The applicant (PI) must be a healthcare professional. Applicant must be affiliated with a host institution. |

III. Requirements

| Date RFP Issued | • February 25, 2022 |
|--|--|
| Clinical Area | Hereditary Transthyretin Amyloidosis |
| General Area of Interest for this RFP: | Projects that will be considered for Pfizer support will focus on Hereditary Transthyretin Amyloidosis (hATTR) clinical studies in China. Aspects for consideration include but not limited to: |
| | • Early identification, evaluation, diagnosis, prognosis & treatment: genetic screening of family members, the monitoring and evaluation of asymptomatic TTR gene mutation carriers, the early identification of disease onset, the timing of initiation of treatment, etc. |
| | Natural history: the natural history of Chinese hATTR patients. |
| | Study of hereditary ATTR genotypes and phenotypes: the characteristics of Chinese hATTR patients in different areas. |
| | Mixed phenotypic manifestations: evaluation of cardiac involvement in hATTR patients. |
| | Use of tafamidis in the clinical setting: the efficacy and safety of treatment, etc. |
| | Note: Pfizer will not supply any study drug |





| Expected Approximate Monetary Range of Grant Applications: | Individual projects requesting up to \$20,000 will be considered. 5-6 projects will be supported in total. |
|--|--|
| Key Dates: | RFP release date: February 25,2022 Grant Application due date: May 20, 2022 Please note the deadline is 23:59 Eastern Standard Time (e.g., New York, GMT -5). Anticipated Grant Award Notification Date: June 30, 2022 Grants will be distributed following a fully executed agreement. Anticipated Project Start and End Dates: Aug 2022 to Aug 2024 |
| How to Submit: | Please go <u>https://www.cybergrants.com/pfizer/Research</u> and sign in. First-time users should click "Create your password". 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: 2022-RD-CN: Hereditary Transthyretin Amyloidosis Research in China Select the following Primary Area of Interest: Hereditary Transthyretin Amyloidosis 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. 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, Juan Liu (juan.liu7@pfizer.com), with the subject line "Hereditary Transthyretin Amyloidosis Research in China-April 13, 2022". 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 |
| | An ISR grant request cannot be submitted for a study that has already commenced and was not originally supported by Pfizer. |
| 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 |
| Budget Detail | • The budget amount requested must be in Chinese Yuan (CNY). |
| | While estimating your budget please keep the following items in mind: |
| | 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. |
| | The inclusion of these costs cannot cause the amount requested to exceed the budget limit set forth in the RFP. |
| | It should be noted that grants awarded through GMG cannot be used to purchase therapeutic agents (prescription or non- prescription). |
| | Pfizer maintains a company-wide, maximum allowed overhead rate of 28% for independent studies and projects |
| References | Bibliography of relevant references. |



