



Pfizer Announces

Patient Registries In ATTR-CM

Competitive Grant Program

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 Request for Proposal (RFP) that provides detail regarding a specific area of interest, sets timelines for review and approval, and uses an external review panel (ERP) to make final grant decisions. Organizations are invited to submit an application addressing the specific gaps in practice as outlined in the specific RFP.

For all quality improvement grants, the grant requester (and ultimately the grantee) is responsible for the design, implementation, and conduct of the independent initiative supported by the grant. Pfizer must not be involved in any aspect of project development, nor the conduct or monitoring of the quality improvement program.



II. Eligibility

Geographic Scope:	Japan
Applicant Eligibility Criteria	<ul style="list-style-type: none"> ● The following may apply: medical, nursing, allied health, and/or pharmacy professional schools; healthcare institutions (both large and small); professional associations; and other entities with a mission related to healthcare improvement. ● More information on organizations eligible to apply directly for a grant can be found at http://www.pfizer.com/files/IGLC_OrganizationEligibility_effJuly2015.pdf. ● Collaborations within institutions (e.g., between departments and/or inter-professional), as well as between different institutions / organizations / associations, are encouraged. Please note all partners must have a relevant role and the requesting organization must have a key role in the project. ● For programs offering credit, the requesting organization must be the accredited grantee.

III. Requirements

Date RFP Issued	February 12, 2020
Clinical Area	Cardiology : ATTR-CM (transthyretin amyloidosis - cardiomyopathy)
Specific Area of Interest for this RFP:	<ul style="list-style-type: none"> ● It is our intent to support projects that focus on enhancing infrastructure of nationwide registry for ATTR-CM, contributing to quality improvements of research and treatment environment for ATTR-CM. The Grantee would establish and maintain this registry. Extensions to existing ATTR-CM registries will also be considered. ● <i>It is not our intent to support clinical research projects. Projects evaluating the efficacy of therapeutic or diagnostic agents will not be considered.</i> Information on how to submit requests for support of clinical research projects can be found at www.Pfizer.com/iir.
Target Audience:	Facilities or organizations that can diagnose and treat ATTR-CM patients.
Disease Burden	ATTR-CM is a type of amyloidosis caused by tissue deposition of amyloid derived from transthyretin (TTR), and is a disease that mainly

<p>Overview:</p>	<p>causes dysfunction due to amyloid deposition in the myocardium. Regardless of the presence or absence of TTR gene mutations, it is known to show typical symptoms of restrictive heart disease and conduction abnormalities including bundle branch block, atrioventricular block and atrial fibrillation, and the prognosis is generally poor. Patients die due to sudden cardiac death, congestive heart failure, myocardial infarction, etc.</p>
<p>Recommendations and Target Metrics:</p>	<ul style="list-style-type: none"> ● Related Guidelines and Recommendations <ul style="list-style-type: none"> ○ JCS 2018 Guideline on Diagnosis and Treatment of Cardiomyopathies http://www.j-circ.or.jp/guideline/pdf/JCS2018_tsutsui_kitaoka.pdf ○ Japan Intractable Disease Information Center http://www.nanbyou.or.jp/entry/45 ○ All about Amyloidosis-Clinical Practice Guidelines 2017 and Q & A (Ishiyaku Publishers, Inc.,2017)
<p>Gaps Between Actual and Target, Possible Reasons for Gaps:</p>	<p>The prevalence, clinical features, and clinical course in Japanese ATTR-CM patients have not been clarified. The disease registry for ATTR-CM is expected to elucidate them by collecting information from patient data. In addition, it is expected that appropriate early diagnosis will be possible through detailed clinical feature will be clarified. In order to achieve these goals, it is considered essential to ensure continuity that enables long-term operation and maintenance of the disease registry.</p>
<p>Barriers:</p>	<ul style="list-style-type: none"> ● Phenotypic variability and non–disease-specific symptoms often delay diagnosis and lead to misdiagnosis.⁴ It is expected that a registry of ATTR-CM will be established, and that data will be used to clarify patient profiles and accelerate early diagnosis. ● A nationwide survey on systemic wild-type ATTR (ATTRwt) amyloidosis in Japan was conducted using a questionnaire.⁵⁻⁷ Therefore, the survey based on patient data have not yet been performed.
<p>Current National Efforts to Reduce Gaps:</p>	<p>A nationwide survey on the wild-type ATTR(ATTRwt) was conducted to elucidate the frequency, background and possible diagnostic issues of ATTRwt in Japan. In this survey, the number of ATTRwt patients is 51.⁵</p>

<p>Expected Approximate Monetary Range of Grant Applications:</p>	<ul style="list-style-type: none"> ● Individual projects requesting up to 15,000,000 JPY will be considered. ● The amount of the grant Pfizer will be prepared to fund for any project will depend upon the external review panel’s evaluation of the proposal and costs involved and will be stated clearly in the approval notification.
<p>Key Dates:</p>	<ul style="list-style-type: none"> ● RFP release date: February 12, 2020 ● LOI due date: March 20, 2020 Please note the deadline is midnight Eastern Time (New York, GMT -5). ● Review of LOIs by External Review Panel: April 2020 ● Anticipated LOI Notification Date: April 2020 ● Full Proposal Deadline: *May 2020 *Only accepted LOIs will be invited to submit full proposals Please note the deadline is midnight Eastern Time (New York, GMT -5). ● Review of Full Proposals by External Review Panel: June 2020 ● Anticipated Full Proposal Notification Date: July 2020 ● Grants distributed following execution of fully signed Letter of Agreement ● Period of Performance: October 2020 to November 2023
<p>How to Submit:</p>	<ul style="list-style-type: none"> ● Please go to www.cybergrants.com/pfizer/loi and sign in. First-time users should click “Create your password”. ● In the application: <ul style="list-style-type: none"> ○ Select the following Project Type: “Quality Improvement”. ○ Select the following Primary Area of Interest: “TTR Amyloidosis” ○ Select the following Competitive Grant Program Name: “Patient Registries In ATTR-CM” ● Requirements for submission: Complete all required sections of the online application and upload the completed LOI template (see Appendix). ● If you encounter any technical difficulties with the website, please

	<p>click the “Technical Questions” link at the bottom of the page.</p> <p>IMPORTANT: Be advised applications submitted through the wrong application type and/or submitted after the due date will not be reviewed by the committee.</p>
Questions:	<ul style="list-style-type: none">• If you have questions regarding this RFP, please direct them in writing to the Grant Officer, Akihiro Kamina (meg.japan@pfizer.com), with the subject line “<i>Patient Registries In ATTR-CM.</i>”
Mechanism by which Applicants will be Notified:	<ul style="list-style-type: none">• All applicants will be notified via email by the dates noted above.• Applicants may be asked for additional clarification or to make a summary presentation during the review period.

References:

1. T J Smith, et al Mayo Clin Proc 1984; 59: 547-55
2. R A Kyle, et al. Am J Med 1996; 101: 395-400
3. Gonzalez-Lopez E, et al. European heart journal. 2017 Jun 21;38(24):1895-1904.
4. Lousada I, et al. Journal of the American College of Cardiology. 2018;71(11 Supplement):A890
5. Y. Sekijima, et al. Amyloid 2018;25(1):8-10
6. K. Marume, et al. Circ J 2019;83:1698-1708
7. Y. Tsutsui, et al. Circ Rep 2019;1:277-285

IV. Terms and Conditions

Please take note every Request for Proposal (RFP) released by Pfizer Independent Grants for Learning & Change (IGLC), as well as a RFP released jointly with a Partner(s), is governed by specific terms and conditions. Click [here](#) to review these terms and conditions.

Appendix A

Letter of Intent Requirements

The Letter of Intent (LOI) will be accepted via the online application. When answering the LOI questions in the application please keep the following in mind:

Goals and Objectives	<ul style="list-style-type: none"> ● Briefly state the overall goal of the project. Also describe how this goal aligns with the focus of the RFP and the goals of the applicant organization(s). ● List the <i>overall</i> objectives you plan to meet with your project both in terms of learning and expected outcomes. Objectives should describe the target population as well as the outcomes you expect to achieve as a result of conducting the project.
Assessment of Need for the Project	<ul style="list-style-type: none"> ● Please include a quantitative baseline data summary, initial metrics (e.g., quality measures), or a project starting point (please cite data on gap analyses or relevant patient-level data that informs the stated objectives) in <i>your</i> target area. Describe the source and method used to collect the data. Describe how the data was analyzed to determine that a gap existed. If a full analysis has not yet been conducted, please include a description of your plan to obtain this information.
Target Audience	<ul style="list-style-type: none"> ● Describe the primary audience(s) targeted for this project. 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	<ul style="list-style-type: none"> ● Describe the planned project and the way it addresses the established need. ● If your methods include educational activities, please describe succinctly the topic(s) and format of those activities
Innovation	<ul style="list-style-type: none"> ● Explain what measures you have taken to assure that this project idea is original and does not duplicate other projects or materials already developed. ● 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	<ul style="list-style-type: none"> ● In terms of the metrics used for the needs assessment, describe how you will determine if the practice gap was addressed for the target group. Describe how you expect to collect and analyze the data. ● Quantify the amount of change expected from this project in terms of your target audience. ● Describe how the project outcomes will be broadly disseminated.

<p>Anticipated Project Timeline</p>	<ul style="list-style-type: none"> ● Provide an anticipated timeline for your project including project start/end dates
<p>Additional Information</p>	<ul style="list-style-type: none"> ● If there is any additional information you feel Pfizer should be aware of concerning the importance of this project, please summarize here
<p>Organization Detail</p>	<ul style="list-style-type: none"> ● Describe the attributes of the institutions / organizations / associations that will support and facilitate the execution of the project and the leadership of the proposed project. Articulate the specific role of each partner in the proposed project. Letters of support from partner organizations will be required at the Full Proposal stage only and should not be included with the LOI.
<p>Budget Detail</p>	<ul style="list-style-type: none"> ● A total amount requested is the only information needed for the LOI stage. Full Budget is not required. This amount can be adjusted at the Full Proposal stage as applicable. ● The budget amount requested must be in Japanese YEN (JPY). ● While estimating your budget please keep the following items in mind: <ul style="list-style-type: none"> ○ Institutional overhead and indirect costs may be included within the grant request. Examples include human resources department costs, payroll processing and accounting costs, janitorial services, utilities, property taxes, property and liability insurance, and building maintenance as well as additional project expenses such as costs for publication, IRB / IEC review fees, software license fees, and travel. Please note: Pfizer does not provide funding for capital equipment. ○ 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