Pfizer Announces

Establishment of System for Early Detection of Atrial Fibrillation and Prevention of Cardiogenic Embolism

Competitive Grant Program – using Expert Review Panel

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Note this RFP is also available in Japanese for your convenience

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	Applications are invited from organizations such as, o Universities, university hospitals, regional core hospitals, and other medical educational institutions o Medical societies, research groups, etc. o Medical foundations and NPO, etc. (Corporations, patient associations, patient support groups engaged in activities related to the field of disease) o Medical, Pharmacist, and Dental Associations o Other organizations engaged in medical education. (Publishing companies that provide medical education information, etc.) o Only organizations are eligible to receive grants, not individuals or medical practice groups. o 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 projects offering continuing education credit, the requesting organization must be accredited.

III. Requirements

Date RFP Issued	February 22, 2021
Clinical Area	Atrial fibrillation (AF) and cardiogenic embolism
Specific Area of Interest for this RFP:	It is our intent to support projects that promote behavioral change of healthcare providers to improve situations such as i) medical and scientific knowledge are not put into practice, ii) medical and scientific knowledge are put into practice but do not exert sufficient results. Therefore, projects including construction of a system/organization to put the knowledge into practice and/or to lead to results would be eligible for the support. Note that educational projects aiming for an enhancement of knowledge s out of scope of this program. Examples of proposals are as follows, • A project to promote a regional healthcare partnership to improve medical adherence of anticoagulants.

	• A project to develop a regional partnership system to promote early detection and treatment of undiagnosed AF • A project to promote developing and disseminating of a healthcare partnership system and screening method aiming for diagnosis rate improvement for AF • A project to develop a healthcare partnership system to lead AF patients/ AF-suspected patients from a medical check up to specialists. • A project to develop a system promoting appropriate anticoagulant therapy to prevent cardiogenic embolism. It is not our intent to support clinical research projects. Projects evaluating the efficacy of therapeutic or diagnostic agents will not be considered. Information on how to submit requests for support of clinical research projects can be found at Investigator Sponsored Research More information can be found at Quality Improvement Grants
Target Audience:	For primary care providers, allied healthcare professionals (i.e., nurses or pharmacists), Specialists (e.g., cardiologists, hematologists, internists, neurologists, neurosurgeons, nephrologists, geriatricians), and other healthcare professionals involved in the care of patients with CV disease. *NOTE: Projects whose target is "Patients only" are not eligible.*
Disease Burden Overview:	Stroke is the fourth leading cause of death and about 6% of Japan's total medical expenses are spent on treatment.[1, 2] Furthermore stroke has a risk of after-effects such as a movement disorder and a cognitive disorder and is the biggest cause of bedridden and long-term care.[3] The number of patients with cerebrovascular disease has been decreasing[4], but total number of stroke patients is 1.11 million[5] and annual healthcare cost is 1.8 trillion, which is more than 4 % of total annual healthcare cost, at 2017.[6] Among cerebral infarctions which account for 60% in stroke, cardiogenic embolism has a high mortality rate because of its large infarct size, and often results in severe aftereffects. Since 75% of the causes of cardiogenic embolism are AF and aging is a factor of increasing AF prevalence, prevention of cardiogenic embolism caused by AF is very important in the aging society today[7]. Half of the AF is asymptomatic AF, and early detection ad diagnosis by a pulse check and an electrocardiopgram is important to prevent cerebral infarction caused by AF.[8] However, a recent study reported that only about half of the patients with AF received anticoagulant therapy, even though NVAF had been detected.[9] Additionally, optimal adherence to anticoagulant therapy is important to achieve prevention of stroke in NVAF patients and poor medication adherence is potentially harmful for NVAF patients due to the unfavorable influence on stroke severity.[10, 11]
Recommendations and	Related Guidelines and Recommendations

Target Metrics:	• JCS/JHRS 2020 Guideline on Pharmacotherapy of Cardiac Arrhythmias • Japanese Guidelines for the Management of Stroke 2015 • 2019 AHA/ACC/HRS focused update of the 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. • Heart Rhythm. 2019 Aug;16(8): e66-e93. • 2020 ESC Guidelines for the diagnosis and management of atrial fibrillation developed in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS) • Screening for Atrial Fibrillation: A Report of the AF-SCREEN International Collaboration. Circulation. 2017 May 9;135(19):1851-1867
Barriers:	• Among general public, understanding about AF is still low which results in no visit even after noticing irregular pulse, and understanding about a self pulse check is also low.[12] It is important to improve understanding of patients and general public about AF, and it helps healthcare providers to make their activities more effective. • Implementation status of an electrocardiopgram at each local government varies since electrocardiopgram is not a mandatory item performed at specific health checkups which is for 65 years old and health checkups for latter-stage elderly which is for over 75 years old.[13] • Half of the patients with acute cerebral infarction were not diagnosed as AF before they developed the infarction, and there were some patients who haven't treated with appropriate anticoagulant therapy even though they were diagnosed as AF.[14]
Current National Efforts to Reduce Gaps:	• Ministry of Health, Labor and Welfare (MHLW) Based on "the Basic Act On Stroke, Heart Disease, and Other Cardiovascular Disease Measures for Extending Healthy Longevity", "Stroke and Cardiovascular Disease Measure Promotion Plans" are set as a basis of measures against cardiovascular disease settled by regional governments. • The Japan Stroke Association/Japanese Heart Rhythm Society Conduct activities to raise awareness about the symptoms of atrial fibrillation and the risk of cerebral infarction, medical management to prevent cerebral infarction. • The Japan Stroke Association In addition to collaborative activity with Japanese Heart Rhythm Society, conduct activities to disseminate and raises awareness of basic knowledge about stroke. • The Japan Stroke Society/The Japanese Circulation Society Collaborated with the 19 related academic societies and issued the "5-year

	Plan for Overcoming Stroke and Cardiovascular Disease" to clarify the goals and strategies for overcoming stroke and cardiovascular disease. • Local government Conduct AF screening projects to prevent cardiogenic embolism are ongoing in several municipalities.
Expected Approximate Monetary Range of Grant Applications:	The total available budget related to this RFP is 10,000,000 JPY. Individual projects requesting up to 10,000,000 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.
Key Dates:	• RFP release date: February 22, 2021 • LOI due date: May 31, 2021 Please note the deadline is midnight Eastern Time (New York, GMT -5). • Review of LOIs by External Review Panel: July 2021 • Anticipated LOI Notification Date: August 2021 • Full Proposal Deadline: September 2021* *Only accepted LOIs will be invited to submit full proposals • Review of Full Proposals by External Review Panel: September 2021 • Anticipated Full Proposal Notification Date: October 2021 • Grants distributed following execution of fully signed Letter of Agreement • Anticipated Project Start and End Dates: January 2022 – December 2023
How to Submit:	• Please go to www.cybergrants.com/pfizer/loi and sign in. First-time users should click "Create your password". • In the application: o Select the following Project Type: "*Quality Improvement*". o Select the following Primary Area of Interest: "*CVM-anti-coagulation (AFIB, VTE)*" o Select the following Competitive Grant Program Name: "*2021 IM L-Establishment of system for early detection of Atrial Fibrillation and prevention of cardiogenic embolism*" • 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 click the "Technical Questions" link at the bottom of the page. **IMPORTANT:** Be advised applications submitted through the wrong

	application type and/or submitted after the due date will not be reviewed by the committee.
Questions:	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 "*2021 IM L- Establishment of system for early detection of Atrial Fibrillation and prevention of cardiogenic embolism*."
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.
Review and Approval Process:	• A specific grant program RFP uses an expert review panel (ERP) to make final grant decisions. • The panels are comprised of 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, continuing professional development or quality improvement
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 or to make a summary presentation during the review period.

References:

1. Vital Statistics 2019（MHLW）
2. Estimates of National Medical Care Expenditure 2018 (MHLW)
3. Comprehensive Survey of Living Conditions 2019
4. Annual Health, Labour and Welfare Report 2018 (MHLW)
5. Patient Survey 2017 (MHLW)
6. Estimates of National Medical Care Expenditure 2017 (MHLW)
7. 5-year Plan for Overcoming Stroke and Cardiovascular Disease 2016 (The Japan Stroke Society/The Japanese Circulation Society)
8. Senoo K, et al. Circ J. 2012;76(4):1020-3
9. Yamashita Y, et al. Chest. 2016 Feb;149(2):401-412.
10. Yamashiro K, et al. J Stroke Cerebrovasc Dis. 2019 Jun;28(6):1773-1780.
11. Raparelli V,et al. Thromb Haemost. 2017 Jan 26;117(2):209-218.
12. Y Taguchi, Stroke 37: 228–231, 2015
13. Specific Health Checkups and Specific Health Guidance, version 3 (MHLW)
14. Toyoda K, et al. Circ J. 2015;79(2):307-9.

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	• 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 *overall* 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	• 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 *your* 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	• 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	• 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	• 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	• 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.

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
Organization Detail	• 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.
Budget Detail	• 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: o 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. o The inclusion of these costs cannot cause the amount requested to exceed the budget limit set forth in the RFP. o It should be noted that grants awarded through GMG cannot be used to purchase therapeutic agents (prescription or non-prescription). o Consumption tax should be included in your budget. • Pfizer maintains a company-wide, maximum allowed overhead rate of 28% for independent studies and projects.