

Pfizer Announces

Efforts for early detection of atrial fibrillation and cardioembolic stroke prevention

Competitive Grant Program

日本語版はこちらをクリックしてください。

Note this RFP is also available in <u>Japanese</u> 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, Universities, university hospitals, regional core hospitals, and other medical educational institutions
	 Medical societies, research groups, etc.
	 Medical foundations and NPO, etc. (Corporations, patient associations, patient support groups engaged in activities related to the field of disease)
	 Medical, Pharmacist, and Dental Associations
	 Other organizations engaged in medical education. (Publishing companies that provide medical education information, etc.)
	Grants can only be awarded to organizations, not individuals.
	For programs offering credit, the requesting organization must be the accredited grantee.

III. Requirements

Date RFP Issued	February 4, 2020
Clinical Area	Atrial fibrillation / Cardioembolic stroke
Specific Area of Interest for this RFP:	Projects related to improve early detection of atrial fibrillation to prevent cardioembolic stroke will be supported by this program.
	Examples of proposals are as follows,
	 A project to promote early diagnosis of atrial fibrillation by raising awareness of the importance of autologous pulse and electrocardiography through education and awareness activities for atrial fibrillation.
	 A project to build a collaboration system within or among hospitals to improve the diagnosis rate of atrial fibrillation.
	 A project to promote medical collaboration between cardiologists and non- cardiologists to ensure that patients suspected of atrial fibrillation found by non-specialist or at the regular medical checkups are examined by specialists.
	 A project to disseminate the significance of anticoagulant therapy for the prevention of cardioembolic stroke.
	• A project to improve medication adherence of anticoagulants.

	Based on General Methodologies to Improve Systems, following projects, for example, will be given high priority,
	 Projects should be such that changes in the behavior of health care providers ultimately can be expected to close the practice gap, rather than simply creating educational programs and materials to fill the knowledge gap.
	 Projects should use innovative, not conventional nor already tried, approaches to achieve the goal
	 Projects are preferable if multiple departments and multiple medical institutions are involved, or if the results are expected to have a significant impact on multiple departments and multiple medical institutions.
	 Projects are preferable if they are not a single-shot and could have continuous positive impacts on clinical practice in Japan over the future.
	 Projects should have a SMART (specific, measurable, attainable, relevant, and time-bound) goal.
	Past examples of quality improvement reports in the same disease area are as follows,
	 Adherence to Guideline-Directed Stroke Prevention Therapy for Atrial Fibrillation is Achievable: First Results from Get With The Guidelines-Atrial Fibrillation (GWTG-AFIB). Circulation. 2019 Mar 19;139(12):1497-1506.
	 Improving the quality of care for patients with or at risk of atrial fibrillation: an improvement initiative in UK general practices. Open Heart. 2019 Oct 15;6(2): e001086.
	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 <u>Investigator Sponsored Research</u>
	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/or other healthcare professionals involved in the care of patients with CV disease. Projects whose target is "Patients only" are not eligible
	Charles in the biggest equal of bodyidden and laws torre care, and should 400/ of
Disease Burden Overview:	Japan's total medical expenses are spent on treatment. Stroke is the third leading cause of death. ^{1,2}
	The onset of stroke has become a major social problem, leading to family

	About 60% of stroke caused by cerebral infarctions, and cardioembolic stroke accounts for 20 to 30% in cerebral infarctions 6
	Cardioembolic stroke has a high mortality rate because of its large infarct size.
	and often results in severe aftereffects. ⁷
	Since 75% of the causes of cardioembolic stroke are atrial fibrillation, prevention of cardioembolic stroke caused by atrial fibrillation is very important.
	Appropriate use of oral anticoagulants can reduce cerebral infarction in about 60% of patients with atrial fibrillation. ^{9,10}
	However, a recent study reported that only about half of patients with atrial fibrillation received anticoagulant therapy, even though NVAF had been detected. ^{11,12} Additionally, optimal adherence to OAC 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. ^{13,14}
	Carrying out early detection and medical checkups such as pulse taking and electrocardiography are important to prevent cerebral infarction, because the half of atrial fibrillation patients are asymptomatic. ¹⁵
Recommendations and	Related Guidelines and Recommendations
Target Metrics:	 Atrial fibrillation treatment (drug) guidelines (revised version 2013)
	 Stroke treatment guidelines 2015 (Supplement 2017)
	 Stroke treatment guidelines 2015 (Supplement 2017) 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.
	 Stroke treatment guidelines 2015 (Supplement 2017) 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.
	 Stroke treatment guidelines 2015 (Supplement 2017) 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. 2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS.
	 Stroke treatment guidelines 2015 (Supplement 2017) 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. 2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS. Europace. 2016 Nov;18(11):1609-1678.
	 Stroke treatment guidelines 2015 (Supplement 2017) 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. 2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS. Europace. 2016 Nov;18(11):1609-1678. Screening for Atrial Fibrillation: A Report of the AF-SCREEN International Collaboration.
	 Stroke treatment guidelines 2015 (Supplement 2017) 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. 2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS. Europace. 2016 Nov;18(11):1609-1678. Screening for Atrial Fibrillation: A Report of the AF-SCREEN International Collaboration. Circulation. 2017 May 9;135(19):1851-1867.

	important to raise awareness to the disease among patients and citizens. ¹⁶
	Electrocardiogram examination is not an essential item in specific health checkups for national health insurance subscribers nor in annual health checkups for people aged 75 and over. Therefore, it is likely that many local governments do not include electrocardiography in the medical checkups as essential item. ¹⁷
	There are many patients with acute cerebral infarction who had not been diagnosed with atrial fibrillation. Even if diagnosed, there are still many patients who are not treated with appropriate anticoagulant therapy. ¹⁸
Current National Efforts to Reduce Gaps:	The Japan Stroke Association and The Japanese Heart Rhythm Society are conducting 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 disseminates and raises awareness of basic knowledge about stroke. The Japan Stroke Society and the Japanese Cardiovascular Society cooperated 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. AF screening projects to prevent cardioembolic stroke are ongoing in several municipalities. ¹⁹
Expected Approximate Monetary Range of	The total available budget related to this RFP is 15,000,000 JPY. Individual projects requesting up to 10,000,000 JPY will be considered.
Grant Applications:	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 4, 2020
	• LOI due date: May 31, 2020 Extended Due Date: June 7, 2020
	Please note the deadline is midnight Eastern Time (New York, GMT -5).
	Review of LOIs by External Review Panel: July 2020
	Anticipated LOI Notification Date: August 2020
	Full Proposal Deadline: September 2020*
	*Only accepted LOIs will be invited to submit full proposals
	Review of Full Proposals by External Review Panel: September 2020
	Anticipated Full Proposal Notification Date: October 2020
	Grants distributed following execution of fully signed Letter of Agreement
	Project start: January 2021
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: Select the following Project Type: "Quality Improvement". Select the following Primary Area of Interest: "CVM-anti-coagulation (AFIB, VTE)" Select the following Competitive Grant Program Name: "Atrial fibrillation and cardioembolic stroke prevention 2020" 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.
	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 "Efforts for early detection of atrial fibrillation and prevent cardio embolic stroke."
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. Overview of the basic survey on Japanese citizens' life in Heisei 28th (Ministry of Health, Labor and Welfare)
- 2. Demographic statistics in Heisei 29th (Ministry of Health, Labor and Welfare)
- 3. Overview of the basic survey on Japanese citizens' life in Heisei 25th (Ministry of Health, Labor and Welfare)
- 4. Estimates of National Medical Care Expenditure in Heisei 27th (Ministry of Health, Labor and Welfare)
- 5. Comprehensive research project for health science "The study on the quality evaluation of medical treatment for stroke using regional stroke registration: The summary and assignment study report in Heisei 17th"
- 6. Kubo M, et al. Neurology 2006; 66: 1539-44
- 7. Ken Okumura, Electrocardiogram. 2011; 31: 292-296.
- 8. Masahiro Yasaka. Patients who was diagnosed with acute cerebral infarction in National Hospital Organization Kyushu Medical Center from 2009 to 2010
- 9. Hart RG, et al. Ann Intern Med. 2007;146:857-867
- 10. Albers GW, et al. Arch Intern Med 1994; 154: 1443-8
- 11. Hirokazu Bokura, et al. Stroke Data Bank. 57: 2015
- 12.Yamashita Y, et al. Chest. 2016 Feb;149(2):401-412.
- 13.Yamashiro K, et al. J Stroke Cerebrovasc Dis. 2019 Jun;28(6):1773-1780.
- 14.Raparelli V,et al. Thromb Haemost. 2017 Jan 26;117(2):209-218.
- 15.Senoo K, et al. Circ J. 2012;76(4):1020-3.
- 16. Yoshiharu Taguchi, Stroke. 37: 228–231, 2015
- 17. The guideline for smooth implementation of specific health examinations and specific health guidance-the 3rd edition (Ministry of Health, Labor and Welfare)
- 18. Toyoda K, et al. Circ J. 2015;79(2):307-9.
- 19. Proposal for Stroke Prevention-Aiming to Control Cardiogenic Cerebral Embolism- the 4th edition (Japan Stroke Association)

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 <u>here</u> 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 <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	• 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	• 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:
	 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).
	 Consumption tax should be included in your budget.
	 Pfizer maintains a company-wide, maximum allowed overhead rate of 28% for independent studies and projects.

