



## **Pfizer Announces**

**- Efforts for early detection of atrial fibrillation and prevent cardio embolic stroke -**

## **Competitive Grant Program**

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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

<b>Geographic Scope:</b>	Japan
<b>Applicant Eligibility Criteria</b>	<ul style="list-style-type: none"> <li>• Applications are invited from organizations such as             <ol style="list-style-type: none"> <li>1. Medical, nursing, allied health, and/or pharmacy professional schools</li> <li>2. Health care institutions, medical organizations, associations, or government agencies</li> <li>3. Other entities with a mission related to healthcare improvement.</li> </ol> </li> <li>• Grants can only be awarded to organizations, not individuals.</li> <li>• For programs offering credit, the requesting organization must be the accredited grantee.</li> </ul>

## III. Requirements

<b>Date RFP Issued</b>	February 20, 2019
<b>Clinical Area</b>	Atrial fibrillation
<b>Specific Area of Interest for this RFP:</b>	<p>Projects related to early detection of atrial fibrillation to prevent cardio embolic stroke are eligible for support by this program.</p> <p>Examples of proposals are as follows,</p> <ul style="list-style-type: none"> <li>○ A project to promote early diagnosis of atrial fibrillation by raising awareness to the importance of self-diagnosis and routine electrocardiogram examination through multi-channel disease educational activities.</li> <li>○ A project to build a collaboration system within or among hospitals to improve the diagnosis rate of atrial fibrillation.</li> <li>○ A project to establish and distribute a method to screen for atrial fibrillation.</li> <li>○ 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 within local areas.</li> <li>○ A project to prepare materials to be used for improving patients' understanding of the importance of self-pulse taking anti-coagulant therapies.</li> <li>○ A project to promote the dissemination of the importance of antithrombotic therapy based on evidence and the guidelines for</li> </ul>

prevention of cardiogenic cerebral embolism.

Based on the "5-year plan to overcome a stroke and cardiovascular disease" (prepared jointly by Japanese Circulation Society and Japanese Stroke Society) and related Japanese guidelines, following projects, for example, may be important,

- 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.

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 [www.Pfizer.com/iir](http://www.Pfizer.com/iir).

**Target Audience:**

Healthcare providers interested in early detection of atrial fibrillation to prevent cardio embolic stroke

**Disease Burden Overview:**

As Japanese elderly population increases, the number of patients with atrial fibrillation and its prevalence have risen. As a result, incidence of cardiogenic cerebral embolism is also increasing. In Japan, there are reports that there are about 800,000 patients who have been diagnosed with atrial fibrillation by electrocardiography, and it is estimated that there may be more than 1 million patients including potential patients yet undiagnosed<sup>1</sup>. The cardiogenic cerebral embolism caused by atrial fibrillation is generally more severe than other types of cerebral infarctions and patients with cardiogenic stroke often die or suffer from aftereffects of the disease. It has been reported that only about 50% of the patients could be reintegrated into society<sup>2</sup>. Stroke is one of the leading causes of high-level nursing care, which results in severe burdens not only for patients but also caregiving families. In addition, higher medical costs associated with the disease have become a social problem.

The Japan Stroke Association and the Japanese Circulation Society prepared "5-year plan to overcome a stroke and cardiovascular diseases" and promote early detection of atrial fibrillation and appropriate antithrombotic therapy as

	<p>two major pillars to prevent cardiogenic stroke<sup>5</sup>. In order to achieve the goals, it is necessary to build a system that every people is routinely screened for atrial fibrillation leading to an appropriate anti-thrombotic therapies by taking advantage of opportunities of annual medical checkups and/or practice at local general practitioners<sup>5</sup>. It is thought that pulse taking is also effective for early detection of atrial fibrillation. Although educational activities have been carried out by academic societies alone or jointly with healthcare companies<sup>6</sup>, pulse taking is not yet common in general practice.</p>
<p><b>Recommendations and Target Metrics:</b></p>	<p>Related Guidelines and Recommendations</p> <ul style="list-style-type: none"> <li>○ Atrial fibrillation treatment (drug) guidelines (revised version 2013).</li> <li>○ Stroke treatment guidelines 2015 (Supplement 2017).</li> <li>○ 2014 AHA / ACC / HRS Guideline for the Management of Patients With Atrial Fibrillation.</li> <li>○ 2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS.</li> <li>○ Screening for Atrial Fibrillation: A Report of the AF-SCREEN International Collaboration.</li> </ul>
<p><b>Barriers:</b></p>	<p>There are many patients with cardio embolic stroke who had not been diagnosed with atrial fibrillation. Even if diagnosed, there are still many patients who are not treated with anti-coagulants. According to the reports from Fukuoka Stroke Registry, 45.9% of patients with cardio embolic stroke had not been diagnosed with atrial fibrillation before incidence of the stroke. Patients with atrial fibrillation may sometimes have symptoms such as palpitation, shortness of breath, chest pain or discomfort, but about 50% are asymptomatic. Therefore, it is thought that there are significant numbers of undiagnosed patients with atrial fibrillation even if they regularly visit hospitals. Since it is difficult to find atrial fibrillation from subjective symptoms, pulse taking or electrocardiography in patients at higher risk may be important.</p> <p>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.</p> <p>Awareness to the disease is still low among general citizen in Japan. This may be one of reasons why they do not consult a cardiologist even if they notice abnormal pulse. In order to make efforts of medical staff more effective, it is also important to raise awareness to the disease among patients and citizens.</p> <p>Anticoagulant therapy to prevent cardio embolic stroke based on assessment of both cerebral infarction risk and bleeding risk is important. Disease education for the patients, assessment of medication adherence and comorbid disease management are also important factor associated with anticoagulant therapy.</p> <p>However, it has been reported that about 50% of patients with NVAF to be</p>

	<p>treated with an anticoagulant are not actually treated (“under used”) and many patients, even if treated, are prescribed sub-optimal doses of anticoagulants (“under dosed”) in Japan. Anticoagulation therapy based on the guidelines is highly expected.</p>
<p><b>Current National Efforts to Reduce Gaps:</b></p>	<ul style="list-style-type: none"> <li>• Activities to raise awareness to atrial fibrillation by a joint executive committee of The Japan Stroke Association and The Japanese Heart Rhythm Society.</li> <li>• The Japan Stroke Association cooperates with pharmaceutical companies to raise awareness of the disease, which include preparation of materials for citizens and doctors, lectures for doctors and citizens, television broadcasting and so on.</li> <li>• Preparation of "5-year plan to overcome stroke and cardiovascular disease" through cooperation between the Japanese Stroke Association and the Japanese Circulation Society.</li> <li>• In the Guidance for preparation plan for Specific Health Checkups etc. (Third Edition), criteria for selecting subjects for electrocardiography has been revised. (It recommends that those who have systolic blood pressure of 140 mmHg or higher and/or diastolic blood pressure of 90 mmHg or higher, or those suspected of arrhythmia based on subjective symptoms and objective symptoms should be examined by electrocardiography.)</li> <li>• In order to raise the detection rate of atrial fibrillation, electrocardiogram examination has performing for all examinees of health examination. (Izumisano city, Osaka prefecture etc.)</li> </ul>
<p><b>Expected Approximate Monetary Range of Grant Applications:</b></p>	<p>Individual projects requesting up to 7,000,000 Yen (JPY) will be considered.</p> <p>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>
<p><b>Key Dates:</b></p>	<ul style="list-style-type: none"> <li>• RFP release date: February 20, 2019</li> <li>• LOI due date: June 13, 2019</li> </ul> <p>Please note the deadline is midnight Eastern Time (New York, GMT -5).</p> <ul style="list-style-type: none"> <li>• Review of LOIs by External Review Panel: August 2019</li> <li>• Anticipated LOI Notification Date: August 2019</li> <li>• Full Proposal Deadline: September 2019*</li> </ul> <p>*Only accepted LOIs will be invited to submit full proposals</p> <p>Please note the deadline is midnight Eastern Time (New York, GMT -5).</p> <ul style="list-style-type: none"> <li>• Review of Full Proposals by External Review Panel: October, 2019</li> <li>• Anticipated Full Proposal Notification Date: October, 2019</li> </ul>

	<ul style="list-style-type: none"> <li>Grants distributed following execution of fully signed Letter of Agreement</li> <li>Period of Performance: January, 2020</li> </ul>
<b>How to Submit:</b>	<ul style="list-style-type: none"> <li>Please go to <a href="http://www.cybergrants.com/pfizer/loi">www.cybergrants.com/pfizer/loi</a> and sign in. First-time users should click “REGISTER NOW”.</li> <li>Select the following Competitive Grant Program Name: “Efforts for early detection of atrial fibrillation and prevent cardio embolic stroke”</li> <li>Requirements for submission: Complete all required sections of the online application and upload the completed LOI template (see Appendix).</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 through the wrong application type and/or submitted after the due date will not be reviewed by the committee.</p>
<b>Questions:</b>	If you have questions regarding this RFP, please direct them in writing to the Grant Officer, Akihiro Kamina ( <a href="mailto:meg.japan@pfizer.com">meg.japan@pfizer.com</a> ), with the subject line “Efforts for early detection of atrial fibrillation and prevent cardio embolic stroke.”
<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 or to make a summary presentation during the review period.</li> </ul>

## References:

- 1) Ohsawa, M et al. J Epidemiol. 2005; 15(5): 194-196.
- 2) Okumura, Ken, Electrocardiogram. 2011; 31: 292-296.
- 3) Overview of the basic survey on Japanese citizens’ life in Heisei 25th (Ministry of Health, Labor and Welfare)
- 4) Overview of the basic survey on Japanese citizens’ life in Heisei 26th (Ministry of Health, Labor and Welfare)
- 5) Five-Year Plans for overcoming stroke and cardiovascular disease (The Japan Stroke Society / The

Japanese Circulation Society)

- 6) Atrial Fibrillation Week(The Japan Stroke Association / Japanese Heart Rhythm Society)
- 7) Toyoda K, et al. *Circ J.* 2015;79(2):307-9.
- 8) Nakamura A, et al. *Cerebrovasc Dis.* 2016 ; 42(3-4) : 196-204.
- 9) Akao M, et al. *J Cardiol* 2013;6:260-266
- 10) Ritter MA, et al. *Stroke.* 2013 May;44(5):1449-52.
- 11) Gladstone DJ, et al: *N Engl J Med* 370: 2467–2477,2014
- 12) Lowres N, et al: *Thromb Haemost* 110: 213–222, 2013
- 13) The guideline for smooth implementation of specific health examinations and specific health guidance-the 3rd edition (Ministry of Health, Labor and Welfare)
- 14) Yoshiharu Taguchi, *Stroke*;37: 228–231, 2015
- 15) Kallmünzer B, et al: *Neurology* 83: 598–603, 2014
- 16) Gensini GF, et al: *G Ital Cardiol (Rome).* 2014 Jan;15(1):37-43.
- 17) The Guideline for Medication of Atrial Fibrillation(2013 revised edition)
- 18) The 2018 European Heart Rhythm Association Practical Guide on the use of non-vitamin K antagonist oral anticoagulants in patients with atrial fibrillation
- 19) Atarashi H, et al. *Circ J.* 2011;75(6):1328-33.
- 20) The guideline for Stroke treatment 2015(2017 enlarged edition)

#### **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:

<b>Goals and Objectives</b>	<ul style="list-style-type: none"> <li>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).</li> <li>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.</li> </ul>
<b>Assessment of Need for the Project</b>	<ul style="list-style-type: none"> <li>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.</li> </ul>
<b>Target Audience</b>	<ul style="list-style-type: none"> <li>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</li> </ul>
<b>Project Design and Methods</b>	<ul style="list-style-type: none"> <li>Describe the planned project and the way it addresses the established need.</li> <li>If your methods include educational activities, please describe succinctly the topic(s) and format of those activities</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 or materials already developed.</li> <li>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>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.</li> <li>Quantify the amount of change expected from this project in terms of your target audience.</li> <li>Describe how the project outcomes will be broadly disseminated.</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</li> </ul>
<b>Additional Information</b>	<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> </ul>
<b>Organization Detail</b>	<ul style="list-style-type: none"> <li>• 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.</li> </ul>
<b>Budget Detail</b>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• The budget amount requested must be in Japanese YEN (JPY).</li> <li>• While estimating your budget please keep the following items in mind:             <ul style="list-style-type: none"> <li>○ 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.</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 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</li> </ul>