Pfizer Announces

-Quality improvement activities to prevent fatal pulmonary thromboembolism-

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

Geographic Scope:	Japan
Applicant Eligibility Criteria	• Applications are invited from organizations such as 1. Medical, nursing, allied health, and/or pharmacy professional schools 2.Health care institutions, medical organizations , associations , or government agencies 3. Other entities with a mission related to healthcare improvement. • 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 28, 2019
Clinical Area	Pulmonary Thromboembolism
Specific Area of Interest for this RFP:	It is our interest to support projects that focus on the prevention of fatal pulmonary thromboembolism (PTE) by improving the quality of diagnosis and treatment. Proposals of activities aimed at improving the quality of diagnosis and treatment of PTE would be eligible for the support. Examples of proposals are as follows, ○ Projects to improve the disease awareness among Healthcare Providers (HCPs) including non-specialists and/or nurses ○ Projects to promote information sharing about Venous Thromboembolism (VTE) risk of each patient within a hospital. ○ Projects facilitating patients proactively practicing prophylactic actions for VTE and inform the staff as soon as such symptoms appear as are suspected of acute PTE or Deep Vein Thrombosis (DVT). ○ Projects leading to an early detection and early diagnosis of PTE. ○ Projects to establish a system of medical-to-medical collaboration within the facility or in the local area in order to promote early diagnosis and early treatment of PTE. The following points should be considered when preparing the proposals.

	○ The projects should use innovative, not conventional nor already tried, approaches to achieve the goal ○ The 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. ○ The projects are preferable if they are not a single-shot and could have continuous positive impacts on clinical practice in Japan over the future. ○ The projects should have a SMART (specific, measurable, attainable, relevant, and time-bound) goal. The following projects can be out of scope. ○ Duplicated requests of support to a single project ○ Research: the main purpose of the projects is acquisition of data or validation of the scientific hypothesis ○ Request for support to the general annual activities which are on-going or to be conducted routinely ○ The projects including activities outside Japan. *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. More information can be found at Quality Improvement Grants
Target Audience:	Healthcare providers who care for patients at risk for VTE or those who have interest in activities to improve the quality of diagnosis and/or treatment of VTE.
Disease Burden Overview:	Acute PTE is one of fatal diseases, which suddenly develop sometimes without symptoms. Although its incidence rate had been considered to be lower in Japan compared to the Western counties, recent reports have suggested that the incidence rate has been increased due to changes in lifestyle habits and an increase in elder populations. The first Japanese guidelines for VTE were issued in 2004 and other related guidelines have been also published by academic societies, which have been revised every 3-5 years. Additionally, countermeasures are also taken to encourage medical institutions to carry out a variety of activates such as setting up preventive management incentives in the medical payment system. Due to these continuous efforts, the incidence of PTE has been decreased, and mortality during perioperative period was also decreased. However, Japan Medical Safety Research Organization still receives many reports about acute PE-related deaths and it has finally issued the recommendations to prevent the deaths from PTE.

	It is difficult to diagnose PTE from its initial symptoms. Additionally, the disease is characterized by rapid progression, from occurrence to death. As a result, prevention and early treatment are difficult, leading to unexpected death without being diagnosed or appropriately treated. The following points are very important to prevent deaths from PTE. 1. Having enough knowledge about characteristics of PTE. 2. Educating patients at risk of PTE to understand about the disease and take spontaneous prophylactic actions. 3. Appropriately detecting DVT in acute phase, which is the major cause of PTE. 4. Early detection and early diagnosis of PTE. 5. Optimized initial treatment in the acute phase. 6. Establishment of in-hospital collaboration system. However, there are still significant gaps in depth of awareness to VTE between HCPs and patients, among area or among medical institutes, which could be a barrier to save the patients from PTE-related deaths and should be filled as soon as possible.
Recommendations and Target Metrics:	Related Guidelines and Recommendations ○ Guidelines for the Diagnosis, Treatment and Prevention of Pulmonary Thromboembolism and Deep Vein Thrombosis (JCS 2017)［by Japanese Circulation Society］ ○ Japanese Guideline for Prevention of Venous Thromboembolism.［By Editorial Committee on Japanese Guideline for Prevention of Venous Thromboembolism］ ○ Guideline for Prevention of Symptomatic Venous Thromboembolism (JOA 2017)［by The Japanese Orthopedic Association, Guideline Editorial Committee of the JOA］ ○ Antithrombotic Therapy for VTE Disease: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. Chest Volume 141, Issue 2, Supplement, February 2012, Pages e419S-e496S ○ 2014 ESC Guidelines on the diagnosis and management of acute pulmonary embolism. European Heart Journal, Volume 35, Issue 45, 1 December 2014, Pages 3145–3151

Gaps Between Actual and Target, Possible Reasons for Gaps:	Japan Medical Safety Research Organization have collected the detailed data regarding acute PTE-related deaths and identified the current issues and gaps based on the analysis of the data. The organization has recommended medical institutions to take the following actions in order to prevent deaths from acute PTE. • It is important to grasp the possible risks of developing acute pulmonary thromboembolism (acute PTE) in hospitalized patients and it should always be aware that acute PTE occurs suddenly and affects the patient's life, whereas it shows very poor specific initial symptoms, which makes early diagnosis difficult. • HCPs and patients should share the risk. Patients should be instructed to proactively practice prophylactic actions, and to inform the staff as soon as such symptoms appear as are suspected of VTE. • Many of the embolic sources of acute PTE are thrombi in the lower extremity veins and the pelvic veins. When clinical symptoms are suspected of DVT, an echographic examination of the lower extremity veins should be performed to confirm the presence or absence of thrombus. • If symptoms of dyspnea, chest pain, tachycardia, tachypnea and/or blood pressure decrease with unknown obvious etiology are complained or observed, HCPs should be reminded of a possibility of acute PTE and consider to carry out a contrast-enhanced CT scan or other exams for early diagnosis. • In situations where acute PTE is strongly suspected, or when the diagnosis is confirmed as acute PTE, an immediate anticoagulation therapy, that is, a single intravenous administration of heparin, should be discussed. • Regarding risk assessment, prevention, diagnosis and treatment of acute PTE, an in-hospital organization (like response team or nominated staff) where related problems can be consulted should be structured as part of a medical safety program. A cooperative system with other institutions should be established where out-hospital consultations and transfers are available as required. However, irrespective of the recommendations, awareness to VTE is not always high enough both in HCPs and in patients, and patient information including risk levels of VTE has not been fully shared among HCPs in a hospital mainly due to poor establishment of in-hospital cooperative system. This could be one of the critical reasons why there is still significant number of patients with PTE whose disease was overlooked and unfortunately died without being accurately diagnosed.
Barriers:	• Low awareness to VTE both in HCPs and in patients. • Patient information including risk of VTE is not always shared among HCPs due to poor or a lack of in-hospital between-hospital cooperation

	systems.
Current National Efforts to Reduce Gaps:	The first Japanese guidelines for VTE were published in 2004 and other similar guidelines have been also issued by related academic societies, which have been revised every 3-5 years. Japan Medical Safety Research Organization has issued the recommendations based on its own analysis of PTE-related death cases, which strongly recommended every medical institution to take preventive actions for PTE-related deaths. However, there are no comprehensive nation-wide actions aiming to reduce the number of deaths from acute PTE.
Expected Approximate Monetary Range of Grant Applications:	Individual projects requesting up to 5,000,000 Yen (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:	Expected Approximate Monetary Range of Grant Applications: • RFP release date: February 28, 2019 • LOI due date: June 20, 2019 lease note the deadline is midnight Eastern Time (New York, GMT -5). • Review of LOIs by External Review Panel: August, 2019 • Anticipated LOI Notification Date: August, 2019 • Full Proposal Deadline: September, 2019* *Only accepted LOIs will be invited to submit full proposals lease note the deadline is midnight Eastern Time (New York, GMT -5). • Review of Full Proposals by External Review Panel: October, 2019 • Anticipated Full Proposal Notification Date: October, 2019 • Grants distributed following execution of fully signed Letter of Agreement • Period of Performance: January, 2020
How to Submit:	• Please go to www.cybergrants.com/pfizer/loi and sign in. First-time users should click "Create your password". • Select the following Competitive Grant Program Name: "Quality improvement activities to prevent fatal pulmonary thromboembolism" • 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 "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) Analysis of death cases related to acute pulmonary thromboembolism - Japan Medical Safety Research Organization (4.Recommedations and explanations for preventing recurrence：10-19）

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:
	  ○ 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