

The Japanese Headache Society and Pfizer Independent Medical Education Request for Proposals

Efforts to Improve Quality of Migraine Medical Care

Competitive Grant Program - using Expert Review Panel

Overview

This is a request for proposal (RFP) covering a competitive bidding on grant projects to be sponsored by the Japanese Headache Society and Pfizer in the area of migraine.

We are supporting educational projects in the area of migraine, aimed specifically in navigating behavioral changes to facilitate early diagnosis and appropriate treatment to improve the quality of healthcare surrounding migraine.

Geographic Scope/Location of Project

Japan

Project Types and Area of Interest

This RFP targets migraine and covers grants for projects aimed at improving the quality of medical care, specifically by:

- Changing behaviors of patients who require treatment but have not sought medical consultation;
- Facilitating cooperation between expert doctors and non-expert doctors;
- Promoting early diagnosis and appropriate treatment (by disseminating specialized knowledge);
- Assisting children and adolescents with migraine to understand the disease; and
- Educating school physicians, industrial physicians, public health nurses, and pharmacists to improve their comprehensive knowledge and disease awareness.

Key Milestones

- Application submission deadline: July 9, 2024
- Anticipated decision notification date: October 31, 2024
- Anticipated project start date: December 1, 2024

Funding Range and Project Length

- Individual projects requesting up to 1,200,000 JPY will be considered.
- Project execution period: December 1, 2024 November 30, 2025





I. Eligibility

Geographic Scope/Location of Project:

Japan

Applicant Eligibility Criteria

- The following may apply: medical, dental, nursing, allied health, and/or pharmacy professional schools; healthcare institutions (both large and small); professional organizations/medical societies; medical education companies; and other entities with a mission related to healthcare professional education and/or healthcare improvement.
- Only organizations are eligible to receive grants, not individuals or medical practice groups (i.e., an
 independent group of physicians not affiliated with a hospital, academic institution, or professional
 society).
- If the project involves multiple departments within an institution and/or between different institutions / organizations / associations, all institutions must have a relevant role and the requesting organization must have a key role in the project.
- The applicant must be the project/program lead or an authorized designee of such individual (e.g., project/program lead's grant coordinator).
- The project/program lead must be an employee or contractor of the requesting organization.
- Requesting organization must be legally able to receive award funding directly from Pfizer International LLC. We strongly recommend that applicants confirm this with their organization or institution prior to submitting an application. Grants awarded to organizations that are subsequently found to be unable to accept funding directly from Pfizer International LLC may be subject to rescission.

II. Requirements

Date RFP Issued:

May 8, 2024

Clinical Area

Migraine

Specific Area of Interest for this RFP:

This RFP covers grants to support educational programs intended to improve medical and scientific knowledges among healthcare and related professionals and to navigate their behavioral changes toward optimized diagnosis and treatment so that migraine patients can timely access clinical healthcare and necessary information related to migraine.

Currently, in the area of migraine, the following issues have been raised:

Quite a few patients rely on OTC analgesics for self-treatment without seeking medical consultation 1) 2). These patients are vulnerable to a risk of chronic migraine and medication-overuse headache (MOH) due to prolonging and inadequate self-treatment with a lack of appropriate medical intervention in line with the degree of severity.

Treatment surrounding migraine which causes a great deal of interference to daily activities has been going through big changes recently; both in Japan and overseas, there is an increasing awareness on the significance of prophylactic therapy for migraine. For early diagnosis and proper treatment of



migraine, it is desirable that the latest knowledge is shared among doctors who are non-specialists of headache and likely involved in the initial phase of treatment, and that they strengthen ties with specialists.

Early diagnosis of migraine in children and adolescents is difficult due to their clinical signs which can be different from adults, and in addition, patients' family members, school professionals, and industrial physicians tend to lack understanding and knowledge about migraine; suggesting that patients may be losing opportunities for early therapeutic intervention via referral to relevant clinics.

With such background, this RFP targets the following "Target Audience" and covers grants for projects aimed at improving the quality of medical care in the area of migraine, specifically by:

- Changing behaviors of patients who require treatment but have not sought medical consultation;
- Facilitating cooperation between expert doctors and non-expert doctors;
- Promoting early diagnosis and appropriate treatment (by disseminating specialized knowledge);
- Assisting children and adolescents with migraine to understand the disease; and
- Educating school physicians, industrial physicians, public health nurses, and pharmacists to improve their comprehensive knowledge and disease awareness.

It is not our intent to support clinical research projects. Projects evaluating the efficacy of therapeutic or diagnostic agents will not be considered. This RFP also does not cover projects that may generate COI such as those involving preparation of clinical practice guidelines, consensus, etc.

Target Audience

 Healthcare and related professionals involved in migraine treatment (school nurses, teachers, public health nurses, etc.)

Note: This RFP does not cover educational programs for which audience is "patients only."

Expected Approximate Monetary Range of Grant Applications:

- Individual projects requesting up to 1,200,000 JPY will be considered.
- Award amounts include direct costs, institutional overhead costs (capped at 28% per Pfizer policy), and indirect costs.
- The amount of the grant Pfizer will be prepared to fund for any project will depend upon the expert review panel's evaluation of the proposal and costs involved and will be stated clearly in the grant agreement.

Key Dates:

- RFP Release Date: May 8, 2024
- LOI Due Date: July 9, 2024
 - Please note the deadline is 23:59 Eastern Standard Time (e.g., New York, GMT -5).
- Review of LOIs by ERP: July 2024
- Anticipated LOI Notification Date: July 2024
- Full Proposal Due Date: August 2024
 - Only accepted LOIs will be invited to submit full proposals.
 - Please note the deadline is 23:59 Eastern Standard Time (e.g., New York, GMT -5).
- Review of Full Proposals by ERP: September 2024
- Anticipated Full Proposal Notification Date: October 2024
- Project execution period: December 1, 2024 November 30, 2025



How to Submit:

Note: Please read this section carefully since applications submitted not following these instructions will not be accepted and will be cancelled.

- Please go to http://www.cybergrants.com/pfizer/loi and sign in. First-time users should click "Create your password".
- Click the "Start a New LOI" button.
- In the application:
 - For the question "What type of request are you submitting?" select Response to a Request for Proposal (RFP)
 - For the question "Are you replying to a Request for Proposal (RFP) as part of the Competitive Grant Program?" select Yes
- Select the following Competitive Grant Program Name: 2024 IM Japan JHS Efforts to Improve Quality of Migraine Medical Care IME
 - Select the following Primary Area of Interest: Pain Migraine LOI
- Requirements for submission:
 - Complete all required sections of the online application and upload your project proposal (see Appendix) in the Specific RFP Submission field.
- 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 after the due date will not be reviewed.

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 to Improve Quality of Migraine Medical Care."

Grant Agreements:

- If your grant is approved, your institution will be required to enter into a written grant agreement with Pfizer International LLC. Please click here to view the core terms of the agreement.
- Under Pfizer's competitive grant program, modifications to grant agreements will not be reviewed
 unless a genuine conflict exists as between applicable law and the terms of the relevant grant
 agreement. Applicant is encouraged to share the core terms with counsel for approval prior to
 submitting an application.
- Except where prohibited by applicable law and, in any case, subject to review by Pfizer Legal, payment of grant funding may only be paid to the grantee organization.
- This RFP is supported by Pfizer Inc. and, if approved, payment will be sent from the United States.

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 during the review period.



References

- Takeshima T, et al. Prevalence, burden, and clinical management of migraine in China, Japan, and South Korea: a comprehensive review of the literature. J Headache Pain. 2019;20:111.
- 2) Hirata K, et al. Comprehensive population-based survey of migraine in Japan: results of the observational Survey of the Epidemiology, tReatment, and Care Of MigrainE (OVERCOME [Japan]) study. Curr Med Res Opin. 2021;37:1945-55.

About The Japanese Headache Society and Pfizer Global Medical Grants

The Japanese Headache Society has entered into a partnership agreement with Pfizer to implement innovative education and transformation strategies.

The Japanese Headache Society is a group of physicians, dentists, and healthcare professionals who are interested in headache, aiming to improve headache care in Japan and contribute to the promotion of the health and welfare of people. We are working to disseminate information and knowledge concerning headache and related medical care, promote scientific researches on headache disorders, and develop preventive and therapeutic treatment for headache, which many people suffer from.

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

For all independent medical education 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 of the independent education program.



Appendix

Specific RFP Submission 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.
- List the objectives you plan to meet with your project, in terms of learning and expected outcomes.

Needs Assessment for the Project

• Include a description of your organization's needs assessment for this proposed project which may include a quantitative baseline data summary, initial metrics, 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.

Target Audience

Describe the primary audience(s) targeted for this project. 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, the educational approach, and the way the planned methods address the established need.

Innovation

• Explain what measures you have taken to assure that this project 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.

Evaluation and Outcomes

• In terms of the metrics used for the needs assessment, describe how your organization will determine if the gap was addressed for the target group. Identify the sources of data your organization anticipates using to make the determination. Describe how your organization is expected to collect and analyze the data. Explain the method used to control for other factors outside this project (e.g., use of a control group or comparison with baseline data). Quantify the amount of change expected from this project in terms the target audience. Describe how your organization will determine if the target audience was fully engaged in the project.

Dissemination Plan

Describe how the project may have extended benefit beyond the grant. Will the teaching materials be
made available to others to use? Will there be tools or resources that are made publicly available
beyond the initial project. Describe how the project outcomes might 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.

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:
 - General organizational running costs such as legal fees, insurance, heating, and lighting etc. should
 be included in an Institutional Overhead (if required). These costs are not specific to a grant request
 and therefore, should not appear as line items in budgets. However, costs that are specific to the
 study (e.g., some countries require insurance to be taken out on a per-study basis for clinical
 research) would be acceptable to be included as line items.
 - The inclusion of overhead costs cannot cause the amount requested to exceed the budget limit set forth in the RFP.
 - Pfizer does not provide funding for capital purchases (infrastructure expenses such as equipment, purchases of software or software licenses, technology or bricks and mortar). Equipment hire/leasing is acceptable and may be included in project budget.
 - It should be noted that grants awarded through GMG cannot be used to purchase Pfizer therapeutic agents (prescription or non-prescription).
 - Pfizer maintains a company-wide, maximum allowed overhead rate of 28% for independent studies and projects. Please <u>click here</u> for details.

