

The Japanese Headache Society / Pfizer Quality Improvement 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 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 promoting behavioral change among healthcare professionals and improving the quality of medical care, specifically by:

- Building a mechanism to change 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 4, 2025

Extended Due Date: July 13, 2025

- Anticipated decision notification date: October 30, 2025
- Anticipated project start date: December 1, 2025

Funding Range and Project Length

Individual projects requesting up to 1,200,000 JPY will be considered.

 Anticipated Project Start and End Dates: December 1, 2025 to November 30, 2027 (up to 2 years)



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; government agencies; and other entities with a mission related to 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).
- 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.
- The applicant must be the Project Lead/Principal Investigator (PI) or an authorized designee of such individual (e.g., Project Lead/PI's grant/research coordinator).
- The Project Lead/PI 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.
- For projects offering continuing education credit, the requesting organization must be accredited.

II. Requirements

Date RFP Issued

April 16, 2025

Clinical Area

Migraine (including pediatric migraine)

Specific Area of Interest for this RFP:

It is our intent to support projects that focus on improving 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 is difficult in children and adolescent migraine patients because they may
 present with a different clinical symptom than adult patients. Furthermore, the lack of
 understanding and knowledge of migraine among family members surrounding the patient,
 school-related personnel, and occupational physicians in the workplace suggests that
 opportunities for early treatment intervention may be lost due to lost opportunity to seek medical
 care.

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:

- Building a mechanism to change 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.
- This RFP also;
 - 1. Not making good use of medical and scientific knowledge in practice
 - 2. Medical and scientific knowledge is being applied to practice, but without results or outcome To improve the above situation, the program supports projects that promote behavioral change among healthcare professionals.

The project will not be about knowledge improvement itself, but will include building systems and mechanisms to translate knowledge into practice or to link practice to results.

Therefore, please note that educational programs that are solely for the purpose of knowledge acquisition are not eligible for grants.

It is not our intent to support clinical research projects. Projects evaluating the efficacy of therapeutic or diagnostic agents will not be considered.

Target Audience

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

Disease Burden Overview

- Migraine is one of the most common diseases, and the prevalence of migraine in Japan is estimated to be 8.4%³⁾. Most of the affected patients are women in their 30s and 40s, and this age group is also involved in employment and child rearing. Thus, the social impact of the disease is significant³⁾.
- On the other hand, as an epidemiological reality of migraine in children and adolescents in Japan, a survey conducted by an educational institution reported the prevalence of 3.5% in elementary school students⁴, 4.8⁵ to 5.0%⁴ in junior high school students, and 9.8% in high school students⁶, suggesting that the number of affected patients is not small as well as the incidence of migraine in this age group¹.



Despite the fact that migraine is ranked as the second most disruptive disease in daily life in a WHO survey reported in 2019, it has been pointed out that many migraine patients do not seek medical care^{3) 7) 8)}.

Recommendations and Target Metrics

 Clinical Practice Guideline for Headache 2021 (Supervision: the Japanese Society of Neurology, the Japanese Headache Society, the Japanese Society of Neurological Therapeutics)

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: April 16, 2025
- LOI Due Date: July 4, 2025 Extended Due Date: July 13, 2025
 - Please note the deadline is 23:59 Eastern Standard Time (e.g., New York, GMT -5).
- Anticipated LOI Notification Date: August 2025
- Full Proposal Due Date: September 2025
 - 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).
- Anticipated Full Proposal Notification Date: October 30, 2025
- Grants will be distributed following a fully executed agreement and submission of Final Protocol, documentation of IRB/IEC approval, regulatory approval (if applicable), exemption or waiver.

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 www.cybergrants.com/pfizer/loi /
- Click the "Start a New LOI" button.
- In the application:
 - For the question "Project Type" select Quality Improvement
- Select the following Competitive Grant Program Name: 2025 IM JP JHS Efforts to Improve Quality of Migraine Medical Care QI
 - 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 Full Proposal 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. Please click <u>here</u> 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 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 Japanese Headache Society 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.
- Institutions (organizations) will be required to present the summary/the results of the project at the Annual Meeting of the Japanese Headache Society.
- If your project was selected for the "The Japanese Headache Society/Pfizer Publicly Invited Medical Education Project Grants" for FY2024 and has still been in progress at the time of application, you are not eligible to apply for this RFP. However, if your project was selected in FY2024 and has been completed at the time of application, you may apply to this RFP.

References

- 1) 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
- 3) Sakai F, et al: Prevalence of migraine in Japan: a nationwide survey. Cephalagia. 1997;17:15-22.
- 4) Goto M, et al: Characteristics of headaches in Japanese elementary and junior high school students: A school-based questionnaire survey. Brain Dev. 2017;39:791-8.
- 5) Ando N, et al: Prevalence and features of migraine in Japanese junior high school students aged 12-15 yr, Brain Dev. 2007;29:482-5.
- 6) Suzuki S, et al: The prevalence and character of primary headache in Japanese high school students. Rinsho Shinkeigaku. 2005;45:717-23.
- 7) Global, regional, and national burden of migraine and tension-type headache, 1990-2016: a systematic analysis for the Global Burden of Disease Study 2016. Lancet Neurol. 2018;17:954-76.



8) Sakai F and Igarashi H. A study to investigate the prevalence of headache disorders and migraine among people registered in a health insurance association in Japan. J Headache Pain. 2022;23:70.

About The Japanese Headache Society

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.

About Pfizer Global Medical Grants & Partnerships

Pfizer Global Medical Grants & Partnerships (GMGP) 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 GMGP 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 expert 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.



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. 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.

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 GMGP 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.

