

Pfizer Quality Improvement Request for Proposals

Improving care in headache medicine and the management of migraine

Competitive Grant Program – using Expert Review Panel

Overview

This competitive program seeks projects that will address quality gaps in headache medicine, support tools and interventions that can lead to measurable improvements in healthcare services for migraine patients.

Geographic Scope/Location of Project

Israel

Project Types and Area of Interest

Projects to identify and address the needs, barriers and gaps in migraine management are eligible for support, including but not limited to:

- Needs assessment to better understand and identify knowledge gaps and opportunities for action.
- Enhancement of diagnosis and management of migraine patients with a special interest in under-represented populations.
- Delivery of headache care in the primary care settings.

Key Milestones

- Application submission deadline: September 8, 2024
- Anticipated decision notification date: October 8, 2024
- Anticipated project start date: December 20, 2024

Funding Range and Project Length

Individual projects requesting up to \$47,000 USD will be considered. Anticipated Project Start and End Dates: from December 20, 2024 for a maximum duration of 12 Months.



I. Eligibility

Geographic Scope/Location of Project:

Israel

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.

II. Requirements

Date RFP Issued

August 8, 2024

Clinical Area

Migraine

Specific Area of Interest for this RFP:

It is our intent to support Quality Improvement initiatives that focus on:

- Needs assessment to better understand and identify knowledge gaps and opportunities for action.
- Enhancement of diagnosis and management of migraine patients with a special interest in underrepresented populations.
- Delivery of headache care in the primary care settings.

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 professionals focused on diagnosis and management of headache and migraine (e.g., neurologist, family medicine doctors, primary health care providers, clinical pharmacists and specialty nurses)

Disease Burden Overview

- Despite Migraine widespread prevalence, available treatment options and comprehensive diagnostic criteria, clinical care remains suboptimal — misdiagnosis and under-treatment of migraine are substantial public health challenges ⁽¹⁾.
- The overall prevalence of migraine in Israel is between 5% (according to our recent data collection study) to 7.25 % (according to previous local studies), varies in different country districts and among different socioeconomic status groups ⁽²⁾. While the estimated global prevalence of migraine is around 14.0% ⁽³⁾, this gap implies a critical mis/under diagnosis of migraine in Israel.

Recommendations and Target Metrics

• According to the European Headache Federation Guidelines, headache disorders are amongst the top ten causes of disability in Europe. Three of these (migraine, tension-type headache and medication-overuse headache) are important in primary care because they are common and responsible for almost all headache related burden. Their management belongs largely in primary care and an important goal is to help primary-care physicians correctly diagnose these few disorders, manage them well when they can, recognize warnings of serious headache disorders and refer for specialist care whenever necessary (4).

Gaps Between Actual and Target, Possible Reasons for Gaps

• Knowledge gaps in the primary care setting and low disease awareness by the general public are main challenges in our local healthcare environment.

Barriers

- Understanding the barriers to achieving the best possible care for patients with migraine is key to improving the migraine burden for patients. These barriers, occur at the patient, physician, and healthcare system level (5)
- Good medical care for migraine patients requires that individuals seek care from a health care professional (HCP) knowledgeable in the management of migraine, receive an accurate diagnosis, and receive an individualized treatment plan with evidence-based and guideline-appropriate acute pharmacologic treatment, and preventive pharmacologic treatment, if indicated, as well as lifestyle education and other evidence-based, guideline-recommended therapies as appropriate (5)

Expected Approximate Monetary Range of Grant Applications:

- Individual projects requesting up to \$ 47,000 will be considered. The estimated total available budget related to this RFP is \$ 94,000
- 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: August 8, 2024
- Full Proposal Due Date: September 8, 2024
 - 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 8, 2024
- 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/QI and sign in. First-time users should click "Create your password". [Note: there are individual portals for each grant application type. Please be sure to use the URL above.]
- Click the "Start a New Quality Improvement Application" button.
- In the application:
 - For the question "Competitive Grant?" select Yes
 - Select the following Competitive Grant Program Name: 2024 IM Israel Migraine Management
 QI
- Select the following Primary Area of Interest: Pain-Migraine-QI
- 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, Rehab Elsaie (rehab.z.elsaie@pfizer.com), with the subject line "Improving care in headache medicine and the management of migraine, August 2024"

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.



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

- 1. Eigenbrodt, A.K., Ashina, H., Khan, S. et al. Diagnosis and management of migraine in ten steps. Nat Rev Neurol 17, 501–514 (2021). https://doi.org/10.1038/s41582-021-00509-5
- 2. Peles I, Asla M, Abayev M, Gordon M, Novack V, Ribalov R, Lengil T, Maor R, Elizur M, Ifergane G. Migraine epidemiology and comorbidities in Southern Israel: a clinical database study in a universal health coverage setting. J Headache Pain. 2022 Dec 14;23(1):160. doi: 10.1186/s10194-022-01513-w. PMID: 36517741; PMCID: PMC9749247.
- 3. Stovner, L.J., Hagen, K., Linde, M. et al. The global prevalence of headache: an update, with analysis of the influences of methodological factors on prevalence estimates. J Headache Pain 23, 34 (2022). https://doi.org/10.1186/s10194-022-01402-2
- 4. J Headache Pain (2007) 8:S1 DOI 10.1007/s10194-007-0366-y
- 5. Buse, Dawn C., et al. "Barriers to care in episodic and chronic migraine: Results from the Chronic Migraine Epidemiology and Outcomes Study." *Headache: The Journal of Head and Face Pain* 61.4 (2021): 628-641.

About Pfizer Global Medical Grants

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 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

Applications will be accepted via the online portal listed in the How to Submit section. Project Proposals/ Protocols should be single-spaced using Calibri 12-point font and 1-inch margins. Note there is a 15-page limit exclusive of references. When uploading your Full Proposal please ensure it addresses the following sections:

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

- The budget amount requested must be in U.S. dollars (USD).
- 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.

