Pfizer Independent Grants for Learning & Change
Request for Proposals (RFP)

Medication-Overuse Headache (MOH)

I. Background

The mission of Pfizer Independent Grants for Learning & Change (IGL&C) is to accelerate the adoption of evidence-based innovations that align the mutual interests of the healthcare professional, patients, and Pfizer, through support of independent professional education activities. The term "independent" means the initiatives funded by Pfizer are the full responsibility of the recipient organization. Pfizer has no influence over any aspect of the initiatives, and only asks for reports about the results and impact of the initiatives in order to share them publicly.

The intent of this document is to encourage organizations with a focus in healthcare professional education and/or quality improvement to submit letters of intent (LOIs) in response to a Request for Proposal (RFP) that is related to education in a specific disease state, therapeutic area, or broader area of educational need. The RFP model is a two stage process: Stage 1 is the submission of the LOI. If, after review, your LOI is accepted, then you are invited to submit your full program proposal. Stage 2 is the submission of the Full Grant Proposal.

When a RFP is issued, it is posted on the Pfizer IGL&C website (www.pfizer.com/independentgrants) and is sent via e-mail to internal lists of all registered organizations and users in our grants system. Some RFPs may also be posted on the websites of other relevant organizations as deemed appropriate.

II. Requirements

Date RFP Issued:	09/09/13
Clinical Area:	Medication-Overuse Headache (MOH)
Specific Area of Interest for this RFP:	It is our intent to support programs focused on the design and implementation of a comprehensive learning and change strategy that encourages **the appropriate prevention, diagnosis and management of medication-overuse headache (MOH) in the primary care setting.** It is expected that interventions will be evidence-based (education and/or quality improvement) and that any proposed research/evaluation will follow generally accepted scientific principles. **Category I — Non-US-based Organizations** Grant support available for initiatives to be implemented in one or more of the following countries: France, Italy, Netherlands, Switzerland, Denmark, Finland, United Kingdom, Spain and/or Australia. Eligible organizations must be non-US-based. Eligibility requirements are posted on the Pfizer Independent Grants for Learning & Change website.

	Category II — US-based Organizations Grant support available for existing initiatives to be implemented in France, Italy, Netherlands, Switzerland, Denmark, Finland, United Kingdom, Spain, Australia and/or the United States. Eligible organizations must be US-based and may apply if they have a prior or ongoing project that addresses healthcare provider needs as it relates to prevention, diagnosis and/or management of medication-overuse headache (MOH). Projects must have a proven track record of success with their educational methods and quality improvement approach. Documentation must be provided that shows the initiative has achieved success in the past and highlights how additional funding can support efforts to implement the project in a new geography. During review the intended outcome of the program is given careful consideration. Programs with the highest likelihood to directly impact patient care in one or more of the previously cited countries (France, Italy, Netherlands, Switzerland, Denmark, Finland, United Kingdom, Spain and/or Australia) will be given the highest priority.

Disease Burden Overview:	Medication-overuse headache is oppressive, persistent and often at its worst on awakening in the morning. [1] A typical history begins with episodic headache – migraine or tension type headache. The condition is treated with an analgesic or other medication for each attack. Over time, headache episodes become more frequent, as does medication intake. In the end stage, which not all patients reach, headache persists all day, fluctuating with medication use repeated every few hours. This evolution occurs over a few weeks or much, much longer. It is both preventable and remediable. [2]
	
	• MOH is a common headache disorder and a serious public health problem all over the world. [3]
	  ○ MOH is the most common secondary headaches. [1]
	  ○ The most common underlying headache disorder in medication overuse headache is migraine.[4]
	  ○ Medication-overuse headache as the cause of specialist consultation rises from 1 % in low-income countries to over 10 % in upper middle- and high-income countries. Drugs and medications are the top risk factor in upper middle and high-income countries, which is consistent with the higher consultation rates in these countries for medication-overuse headache. [2]
	
	• Epidemiological studies all over the world have revealed that about 1–2% of the general population suffer from chronic daily headache associated with the overuse of headache medication [3]
	  ○ It may affect up to 5% of some populations, women more than men. [1]
	  ○ A typical patient is a 30-60 year-old female, with a history of more than a decade of migraine or tension-type headache.[5]
	
	• Among patients presenting with a daily headache in headache centers in Europe, medication overuse headache is suspected in up to 30% of those patients. [6]
	
	• The burden of headache is reported to be higher in patients with medication overuse headache resulting in decreased quality of life. [4]
	  ○ Headache disorders are amongst the top ten causes of disability in Europe [4]
	  ○ High cause of disability and financial costs to society through lost productivity [2]
	
	• Medication overuse is a behavior dependent upon unrestricted access to medication. Better-resourced countries are more likely to provide this, and in these countries more medication overuse headache is seen. [2]

Recommendations and Target Metrics:	The management of headache disorders (including medication-overuse headache) belongs in primary care. This is where the great majority of patients with headache are and should be managed. [2, 7] **Prevention through education** [7] The best strategy is to prevent the overuse of acute medications, especially in migraine patients. This can be accomplished by effective physician–patient communication and patient education about the risks and proper use of medications, and the use of preventive therapies early in the natural history of patients at risk of MOH [8] Education of people with headache about how to treat their headaches effectively and efficiently is of considerable public-health importance. This is particularly relevant to the avoidance of medication overuse and risk of medication-overuse headache. The implications are educational: better public awareness is required. [2] In better-resourced countries especially, one focus of education should be the avoidance of medication overuse and the consequence of medication-overuse headache, itself a high cause of disability. [2] **Internationally accepted guidelines for the diagnosis of MOH:** • http://www.ihs-headache.org/frame_non_members.asp **Recommendations for the complete management of Medication Overuse Headache (MOH)** [7, 9, 10] 1. Achieve withdrawal from the overused medication 2. Following withdrawal, recovery from MOH 3. Review and reassess the underlying primary headache disorder (migraine or tension-type headache) 4. Prevent relapse

Gaps Between Actual and Target and Possible Reasons for Gaps:	The program should aim to address the following gaps: **Diagnosis of Headache** ○ A minority of people with headache disorders worldwide are professionally diagnosed. The diagnosis rate for medication-overuse headache is only 10%. [2] ○ Globally, only 56% of the specialists use the International Headache Society diagnostic criteria to support a headache diagnosis. In a primary care setting, the percentage is unknown but is suspected to be considerably less. [2] **Management of Headache** Worldwide, about 50 % of people with headache are estimated to be primarily self-treating, without contact with health professionals [2] ○ This proportion is unlikely to change even with better health care; consequently, education of people with headache about how to treat their headaches effectively and efficiently is of considerable public-health importance. This is particularly relevant to the avoidance of medication overuse and risk of medication-overuse headache[2] ○ MOH is usually present for a long time before it is recognized and treated [5] ○ Globally, headache management guidelines are used routinely only 55 % of the time [2]
Barriers:	• Lack of professional education/training for medical providers [2] • Low priority given to headache disorders and under-recognition of their impact [2] • Lack of headache-specific health-care resources [2] • Lack of public awareness [2] • Patients may be reluctant to reveal their entire drug consumption [11]

Current Efforts to Reduce Gaps	• A series of patient information leaflets developed by *Lifting The Burden* are currently available in Danish, Dutch, English, French, German, Italian, Portuguese and Spanish. They provide basic explanations of migraine, tension-type headache, cluster headache and medication-overuse headache and their treatments. http://www.l-t-b.org/assets/13/B2813DE1-CB7E-6298-D5DEB5FC0734EF28_document/What_is_Chronic_Daily_Headache.pdf • Eurolight is a European project currently underway to highlight the impact of headache. The proposed project will be the first independent data collection on headache at European level focusing on a holistic, patient-driven and scientifically validated approach. http://www.eurolight-online.eu/ • Similar efforts are observed in Australia to reduce the incidence and impact of the headache disorder through the provision of community awareness and research. http://headacheaustralia.org.au/headache-register-why-register; http://headacheaustralia.org.au/news/81-medication-overuse-headache
Target Audience	Primary Care
Geographic Scope:	☐ United States Only ☑ International (specify country/countries)_Due to resource constraints we are targeting this first RFP towards organizations that will focus on closing MOH practice gaps in the following countries: France, Italy, Netherlands, Switzerland, Denmark, Finland, United Kingdom, Spain, Australia or United States. **Programs that can potentially be applicable in different primary care settings (global applicability) will be given the highest priority.**
Applicant Eligibility Criteria:	Medical, nursing, allied health, and/or pharmacy professional schools, healthcare institutions, for-profit health systems, professional associations and other not-for-profit entities may apply. Collaborations between organizations are encouraged. Inter-professional collaborations that promote teamwork among institutions/organizations/associations are also encouraged.
Expected Approximate Monetary Range of Grant Applications:	Individual grants requesting up to $500,000 will be considered. The total available budget related to this RFP is $1,500,000. The amount of the grant Pfizer will be prepared to fund for any full proposal will depend upon Pfizer's evaluation of the proposal and costs involved and will be clearly stated in the grant approval notification.

Key Dates:	**RFP release date:** 09/9/13 **Letter of Intent due date**: 10/4/13 **Anticipated LOI Notification Date:** 10/20/13 **Please note, full proposals can only be submitted following acceptance of an LOI** **Full Proposal Deadline:** 11/18/13 **Anticipated Full Proposal Notification Date:** 12/15/13 **Anticipated grant delivered following execution of fully signed LOA** **Period of Performance:** 1/2014 to 12/2015
How to Submit:	Please go to the website at www.pfizer.com/independentgrants and click on the button "Go to the Grant System". You will be prompted to take the *Eligibility Quiz* to determine the type of support you are seeking. Please ensure you identify yourself as a first-time user. Submit LOIs in the clinical area: **Medication-Overuse Headache** **Requirements for submission:** Complete all required sections of the online application and upload the completed letter of intent template. (*see Appendix)*
Questions:	If you have questions regarding this RFP, please direct them in writing to the Grant Officer for this clinical area, Amanda Stein at (IGLC@pfizer.com), with the subject line "RFP MOH"
Mechanism by Which Applicants will be Notified:	All applicants will be notified via email by the dates noted above. Providers may be asked for additional clarification or to make a summary presentation during the review period.

References:

1. World Health Organization: Headache Disorders Fact Sheet. http://www.who.int/mediacentre/factsheets/fs277/en/index.html . Accessed August 5, 2013.
2. World Health Organization (2011) Atlas of headache disorders and resources in the world 2011. World Health Organization, Geneva.

3. Katsarava, Zaza a; Obermann, Mark b . Medication-overuse headache: Current Opinion in Neurology. 26(3):276-281, June 2013.
4. Stovner, L., Hagen, K., Jensen, R., Katsarava, Z., Lipton, R., Scher, A., Steiner, T. and Zwart, J.-A. (2007), The global burden of headache: a documentation of headache prevalence and disability worldwide. Cephalalgia, 27: 193–210. doi: 10.1111/j.1468-2982.2007.01288.x
5. Williams D. Medication overuse headache. Aust Prescr 2005;28:143-5
6. Evers S, Marziniak M. Clinical features, pathophysiology, and treatment of medication-overuse headache. Lancet Neurol 2010;9:391–401.
7. Lifting the Burden: European principles of management of common headache disorders in primary care, Journal of Headache Pain 2007 8:S3
8. Dodick, D. and Silberstein, S. (2008), How clinicians can detect, prevent and treat medication overuse headache. Cephalalgia, 28: 1207–1217. doi: 10.1111/j.1468-2982.2008.01737.x
9. Evers S, Jensen R, European Federation of Neurological Societies. Treatment of medication overuse headache--guideline of the EFNS headache panel. Eur J Neurol. 2011 Sep;18(9):1115-21.
10. Dodick, D. and Freitag, F. (2006), Evidence-Based Understanding of Medication-Overuse Headache: Clinical Implications. Headache: The Journal of Head and Face Pain, 46: S202–S211. doi: 10.1111/j.1526-4610.2006.00604.x
11. Hans-Christoph Diener, Volker Limmroth, Medication-overuse headache: a worldwide problem, The Lancet Neurology, Volume 3, Issue 8, August 2004, Pages 475-483, ISSN 1474-4422, http://dx.doi.org/10.1016/S1474-4422(04)00824-5.

III. Terms and Conditions

1. Complete TERMS AND CONDITIONS for Certified and/or Independent Professional Healthcare Educational Activities are available upon submission of a grant application on the Independent Grants for Learning & Change website www.pfizer.com/independentgrants.

2. This RFP does not commit Pfizer to award a grant, or to pay any costs incurred in the preparation of a response to this request.

3. Pfizer reserves the right to accept or reject any or all applications received as a result of this request, or to cancel in part or in its entirety this RFP, if it is in the best interest of Pfizer to do so.

4. Pfizer reserves the right to announce the details of successful grant application(s) by whatever means insures transparency, such as on the Pfizer website, in presentations, and/or in other public media.

5. For compliance reasons and in fairness to all providers, all communications about the RFP must come exclusively to the Independent Grants for Learning & Change group. Failure to comply will automatically disqualify providers.

6. Pfizer reserves the right to share the title of your proposed project, and the name, address, telephone number and e-mail address of the requestor for the applicant organization, to organizations that may be interested in contacting you for further information (e.g., possible collaborations).

IV. Transparency

Consistent with our commitment to openness and transparency, Pfizer reports education grants provided to medical, scientific and patient organizations in the United States. In the case of this RFP, a list of all LOIs selected to move forward may be publicly disclosed. In addition, all approved full proposals, as well as all resulting materials (e.g., status updates, outcomes reports etc) may be posted on the Pfizer IGLC website.

Appendix: Letter of Intent Submission Guidance

LOIs should be single spaced using Calibri 12-point font and 1-inch margins. Note that the main section of the LOI has a 3-page limit. ***Any proposals not meeting these standards will not be considered.***

LOIs will include the following sections

Main Section (not to exceed 3 pages):

A. Title

B. Goal
    1. Briefly state the overall goal of the intervention

C. Objectives
    1. List the *overall* objectives you plan to meet with your intervention both in terms of learning and expected outcomes. Do not include learner objectives.

D. Assessment of Need for the Intervention
    1. Please include quantitative baseline data summary, initial metrics (e.g., quality measures), or 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. The RFP includes a national assessment of the need for the intervention. Please do not repeat this information within the LOI (you may reference the RFP if needed). Only include information that impacts your specific intervention, linking regional or local needs to those identified on the national basis if appropriate.

    2. Describe the primary audience(s) targeted for this intervention. Also indicate who you believe will directly benefit from the project outcomes..

E. Intervention Design and Methods
    1. Describe the planned intervention and the way it addresses the established need.
    2. Describe the overall population size as well as the size of your sample population.

F. Innovation
    1. Explain what measures you have taken to assure that this project idea is original and does not duplicate other programs or materials already developed.
    2. Describe how this initiative builds upon existing work, pilot projects, or ongoing programs, etc developed both by your institution or other institutions related to this program

G. Design of Outcomes Evaluation
    1. Describe how you will determine if the practice gap identified in the needs assessment were addressed for the target group in terms of the metrics used for the needs assessment.
        - Identify the sources of data that you anticipate using to make the determination.

- Describe how you expect to collect and analyze the data.
- Explain the method used to control for other factors outside this intervention (e.g., use of a control group, comparison with baseline data)

b. Quantify the amount of change expected from this intervention in terms of your target audience
c. Describe how you will determine if the target audience was fully engaged in the intervention.
d. Describe how the project outcomes might be broadly disseminated.

H. Project Timeline

I. Requested Budget

J. Additional Information
    1. If there is any additional information you feel Pfizer should be aware of concerning the importance of this project, please note it in within the page limitations

Organizational Detail (not to exceed 1 page)

Describe the attributes of the institutions/organizations/associations that will support and facilitate the execution of the project and the leadership of the proposed intervention.

LOIs should be single spaced using Calibri 12-point font and 1-inch margins. There is a 3-page limit for the main section and 1 page limit for organizational detail. If extensive, references may be included on 1 additional page. **Final submissions should not exceed 5 pages in total** (3 pages for the main section, 1 page for organizational detail, and 1 page for references).

Please note the formatting and page limit for the LOI. The LOI is inclusive of additional information of any kind. A submission exceeding the page limit ***WILL BE REJECTED*** *and* ***RETURNED UNREVIEWED****.*