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

Improve Outcomes and Optimize Healthcare Utilization for Patients with Chronic Pain in a Primary Care Setting by Employing Integrated and Coordinated Multimodal Therapies

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, you will be 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 sent via e-mail to 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.

Pfizer IGL&C issues RFPs related to addressing gaps in practice in order to identify and support initiatives designed to impact these gaps. RFPs generally identify a clinical challenge and encourage applicants to address this challenge using strategies that address the development, adoption and/or integration of evidence-based education and quality improvement projects to impact practice within specific settings.

Examples of approaches might include:

- Identification of strategies to encourage provision and use of effective health services
- Identification of strategies to promote the integration of evidence into policy and program decisions.
- Appropriate adaptation of education and quality improvement strategies according to population and setting
- Identification of approaches to scale-up effective quality improvement or education strategies

- Development of innovative approaches to improve healthcare delivery
- Setting up an impact evaluation for population based improvement strategies

Pfizer is particularly vested in supporting programs that develop and implement projects that are followed by rigorous assessment of the "efficacy" of quality improvement and education approaches examining outcomes that may include both short and long term improvements in physician behavior and patient care.

Intent and Objective:

The **intent** of this RFP is to encourage organizations with a focus in healthcare professional education and quality improvement to submit Letters of Intent (LOIs) related to the gaps described on the following pages. ***Successful applicants will be able to describe the specific quality gaps or problems in practice that exist for their own learners, or system, or community, and describe what they will do to close these gaps or problems.***

The **objective** of this RFP is to develop and implement an educational or quality improvement intervention that addresses current gaps in the treatment of chronic pain and leads to an improvement in patient outcome and/or optimization of health care utilization.

II. Requirements

Date RFP Issued:	08/27/13
Clinical Area:	Chronic Pain Care Outcomes

Specific Area of Interest for this RFP:	Design and implement a comprehensive interventional strategy with a diagnostic & treatment algorithm for the primary care setting, incorporating PCMH principles and approaches that promotes a multimodal and individualized approach to the treatment of adults with chronic pain. This algorithm should be applicable both to new patients and to those that are currently under treatment for their pain condition(s). Program should incorporate use of diagnostic tools to aid diagnosis of the underlying pain condition(s) and utilize current evidence-based treatment guidelines to guide appropriate treatment selection based on the underlying pain condition(s). Program should be designed to demonstrate how improvements in choosing and coordinating an appropriate mix of pharmacological and non-pharmacological treatments can facilitate treatment choice, enhance patient outcomes and increase patient satisfaction by reducing pain, improving function and/or optimizing healthcare utilization. The program should utilize systems within the patient electronic health record (EHR) to document patient history, to aid in patient assessment, guide and track PCP intervention, and monitor patient response. The "efficacy" of the educational intervention on PCP behavior and patient outcomes should be assessed by measuring changes in relevant clinical outcomes as outlined below. Successful proposals will include a detailed plan to generate quantitative evidence that the improvement in careful selection and implementation of treatment options is associated with improvement in pain relief and adherence to treatment, fewer repeat visits and more effective and appropriate use of pain medications and changes in direct and indirect healthcare costs. Proposals should show that this change in physician behavior and interventional educational strategy is associated with changes in both clinical and safety outcomes. The proposed approach should include a pre- and post-intervention assessment or a comparison to a control group receiving no education and tools and usual care. Programs must describe how the intervention, when implemented, will directly impact patient care and provide evidence of scalability (e.g., integration with an electronic medical record system) and sustainability (e.g., plan to extend beyond the proposed institution). **NOTE: This initiative is not associated with the ER/LA REMS program mandated by the FDA.**

Disease Burden Overview:	According to the 2011 IOM Report on Pain, as many as 100 million adults in the US report having a common chronic pain condition, exceeding the number affected by heart disease, cancer, and diabetes.1 When chronic pain is poorly managed, patients report a substantial burden of illness regardless of the type of pain condition.2, 3 Continuous, unrelieved pain can have negative effects on the immune, cardiovascular, gastrointestinal, and renal systems and can reduce patient mobility. It can lead to anxiety disorders including panic, generalized anxiety and post traumatic stress disorder.3, 4 , On-going and unrelieved pain can create a cycle of increased anxiety and depression which, in turn, can amplify the pain.5 Patients with greater pain severity report increased difficulties with functioning, sleep, and overall health status.6 Finally, inadequately managed pain can lead to unfavorable physical and psychological outcomes not only for individual patients, but also for their families.3The economic burden of pain to society is staggering. The 2011 IOM Report on Pain suggests that annual health economic impact of pain represents a $560 to $635 billion burden in the US (in 2010 dollars).[1] Management of chronic pain can be considered within the context of a chronic care model, where improved outcomes are achieved when patients are informed and engaged in their care, providers are proactive, care is patient-centric and collaborative, and community and other resources are appropriately accessed. As with other chronic conditions such as diabetes, hypertension and COPD, patient education and coordination of care are essential and need to be integrated with the diagnosis and continued throughout chronic pain management. Integration of non-pharmacologic treatment approaches early in the assessment and treatment plan helps to reinforce the importance of the patient's role in his or her own care.[7] Diagnosis of the underlying pain condition can be guided by the patients descriptions of the pain as well as by the use of diagnostic tools. Selection of the *initial* pharmacological treatment should be guided by the underlying pain pathology(s) and use of evidence-based guidelines that have been developed for specific chronic pain conditions such as osteoarthritis, low back pain, fibromyalgia and different neuropathic pain conditions. As chronic pain often involves multiple symptom domains in addition to pain the assessment and treatment plan should be individualized to reflect the individual patient's underlying chronic pain disorder, the particular mix of symptoms, the patient's priorities and preferences, cognitive / emotional and social support, and financial circumstances.

Gaps and Possible Reasons for Gaps:	Based on a national mail survey of primary care physicians, pain specialists, chiropractors, and acupuncturists primary care physicians treat the majority of chronic pain patients in the US.[11] In addition, primary care is typically where people first report pain to the health care system and in a national survey conducted in the late 1990s, 80% of people currently experiencing severe pain said they had never been referred to a specialized pain program or clinic (American Pain Society, 1999); thus the primary care practitioner's response may be crucial in providing timely relief and preventing acute or early chronic pain from progressing to a persistent or severe chronic state.[12] Thus, it is important that primary care physicians make every effort to address both the non-pharmacologic and pharmacologic aspects of pain management. However, there is a striking discrepancy between the high prevalence, cost, and complexity of pain and the sparse efforts to educate primary care physicians pain and pain management. Based on their own self-report, PCPs do not receive enough pain management education and training.[1, 13] In addition, a large number of U.S. medical schools do not teach pain or pain management, or devote fewer than 5 hours to the topic.[14] In addition to lack of education and training, a number of barriers to effective pain care involve the attitudes and training of the providers of care. First, health professionals may hold negative attitudes toward people reporting pain and may regard pain as not worth their serious attention. Second, the profession and culture of medicine generally focus on biological rather than psychosocial causes and effects of illnesses. Third, although pain is one of the most common reasons people seek treatment; clinicians may not ask about or thoroughly investigate pain. Fourth, while evidence-based protocols and guidelines exist to assist primary care practitioners in treating people with chronic pain these protocols are used only rarely to treat pain in primary care practice. Finally, while interdisciplinary, team approaches can facilitate high-quality pain care such team approaches are not consistently used in pain care.

Recommendations and Target Metrics:	The impact of the program on improving the diagnosis and management of chronic pain should be assessed including an increase in utilization of guideline-recommended treatment options and corresponding reduction in utilization of opioids as a first line treatment option. The impact of the program on patient outcome should be assessed including reduction in pain severity, and/or improvement in function. Finally, the program should assess the impact of the intervention on health care costs. Other suggested metrics include assessment of the impact of the educational intervention on the following: Clinical Outcome Measures: 1. Clinical outcome measures: • Objective measure of improvement in quality of life • Patient reported outcome of satisfaction • Increase use of EMR to track access of tools to aid diagnosis, guide treatment, monitor response, assess risk of misuse & abuse etc 2. Cost Measures: • Total pain related healthcare utilization and costs, including but not limited to inpatient, ER, outpatient, pharmacy, and physical therapy expenses • Total pain related indirect costs due to lost productivity, absenteeism, presenteeism, etc
Target Settings:	The focus of the program should be generating meaningful change in primary care providers (such as family medicine, internists, nurse practitioners, and physician assistants), patients, and healthcare systems.
Geographic Scope:	☑ United States Only ☐ International (specify country/countries)_____

Applicant Eligibility Criteria: **Selection Criteria:**	☑ United States Only ☐ International (specify country/countries)_____ Applicant organizations will be evaluated on the basis of • Knowledge of and experience with the area • Capability of carrying out the work • Collaboration if appropriate • Potential effect and expected outcomes of the project Dissemination strategies
Expected Approximate Monetary Range of Grant Applications:	Individual grants requesting up to $1,000,000 will be considered. Preference will be given to applications requesting $500,000 or less in order to permit support for more than one proposal. The total available budget related to this RFP is $2,000,000 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:** 08/27/2013 **Letter of Intent due date:** 09/19/2013 **Anticipated LOI Notification Date:** 10/22/2013 **Please note, full proposals can only be submitted following acceptance of an LOI** **Full Proposal Deadline:** To be communicated on acceptance of an LOI **Anticipated Full Proposal Notification Date:** 12/15/2013 **Anticipated award delivered following execution of fully signed LOA** **Period of Performance:**01/2014 to 01/2016

Date Grant Award Decisions Will Be Made:	December 2013

How to Submit:	Please go to the website at www.pfizer.com/independentsupport 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: Chronic Pain Care Outcomes **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, Robert Kristofco at (robert.kristofco@pfizer.com), with the subject line "RFP Chronic Pain Care Outcomes"

Date Grant Award Decisions Will Be Made:	December 2013
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.

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 and 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 and Change. Failure to comply will automatically disqualify providers.

IV. Transparency

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

V. References

1. Committee on Advancing Pain Research, C.a.E. and M. Institute of, *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*: The National Academies Press.
2. Cole BE. Pain Management: Classifying, understanding, and treating pain. Hosp Physician. 2002;38:23-30.
3. Winterowd C, Beck AT, Gruener, D. Cognitive Therapy for Chronic Pain Patients. New York: Springer Publishing Company; 2003.
4. Buenaver LF, Edwards RR, Haythornthwaite JA. Pain-related catastrophizing and perceived social responses: interrelationships in the context of chronic pain. Pain. 2007;127:234-42.
5. Wells N, Pasero C, McCaffery M. Improving the Quality of Care through Pain Assessment and Management. In: Hughes RG, ed. Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Rockville, MD: Agency for Healthcare Research and Quality (US); 2008.
6. Hoffman DL, Sadosky A, Dukes EM, Alvir J. How do changes in pain severity levels correspond to changes in health status and function in patients with painful diabetic peripheral neuropathy? Pain. 2010;149:194-201.
7. Argoff CE, Albrecht P, Irving G, Rice F. Multimodal analgesia for chronic pain: rationale and future directions. Pain Med. 2009;10(Suppl 2):S53-66.

8. Chou et al., Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain. J Pain. 2009;10:113-130.
9. VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain. 2012.
10. Butler SF, Cassidy TA, Chilcoat H, Black RA, Landau C, Budman SH, Coplan PM. Abuse Rates and Routes of Administration of Reformulated Extended-Release Oxycodone: Initial Findings From a Sentinel Surveillance Sample of Individuals Assessed for Substance Abuse Treatment. J Pain. 2012 (epub)
11. Breuer B, Cruciani R, Portenoy RK. Pain management by primary care physicians, pain physicians, chiropractors, and acupuncturists: a national survey. South Med J. 2010 Aug;103:738-47.
12. Dobkin PL, Boothroyd LJ. Organizing health services for patients with chronic pain: when there is a will there is a way. Pain Med. 2008; 9:881-9
13. Pizzo PA, Clark NM. Alleviating suffering 101 – pain relief in the United States. N Engl J Med. 2012;366:197-199.
14. Mezei N, Murinson B, Johns Hopkins Pain Curriculum Development Team. Pain education in north american medical schools. J Pain. 2011;12:1199-1208.

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 was 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)

2. Quantify the amount of change expected from this intervention in terms of your target audience
3. Describe how you will determine if the target audience was fully engaged in the Intervention.
4. 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.

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****.*