

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

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

I. Background

Pfizer Independent Grants for Learning & Change's (IGL&C) mission: improve patient outcomes by partnering with the global healthcare community and supporting measurable learning and change strategies. "Independent" means that the projects funded by Pfizer are the full responsibility of the recipient organization. Pfizer has no influence over any aspect of the projects and only asks for reports about the results and the impact of the projects in order to share them publicly.

To fulfill its mission, Pfizer IGL&C issues RFPs addressing practice and/or knowledge gaps. RFPs generally identify a clinical challenge and encourage applicants to address that challenge by creating programs that foster quality improvement and adoption or integration of evidence-based education. For instance, programs may

- identify strategies to encourage provision and use of effective health services;
- identify strategies to promote the integration of evidence into policy and program decisions;
- adapt education and quality-improvement strategies to a particular population or setting;
- identify how to enhance existing quality-improvement or education strategies;
- develop innovative approaches to improve healthcare delivery;
- develop tools for extracting clinically significant information;
- develop and assess ability of technologies and other non-pharmacological resources to support patient empowerment and patient-generated data;
- develop and assess strategies that change patient-provider interactions that improve patient outcomes and lower healthcare costs; or
- create impact evaluation for population-based improvement strategies.

Through this RFP, we encourage organizations with a focus in healthcare professional education and/or quality improvement to submit a letter of intent (LOI) addressing education in the specific disease state, therapeutic area, or broader area of educational need that the RFP concerns. The RFP model is a two-stage process. Stage 1 is the submission of the LOI. After review of the LOI, you may be invited to submit your Full Grant Proposal. Stage 2 is the submission of the Full Grant Proposal.

RFPs are posted on the Pfizer IGL&C website (www.pfizer.com/independentgrants) and are sent via e-mail to all registered users in our grants system. Some RFPs may also be posted on the websites of other relevant organizations.

Pfizer especially supports programs that develop and implement projects followed by rigorous assessment of the project’s conclusion or outcome. Successful applicants will specifically describe the quality gaps or practice problems for their own learners, system, or community, and will describe what they will do to close these gaps or problems.

II. Eligibility

Geographic Scope:	<input checked="" type="checkbox"/> United States Only <input type="checkbox"/> International(specify country/countries)_____
Applicant Eligibility Criteria:	<p>The following may apply: medical, dental, nursing, allied health, and/or pharmacy professional schools; healthcare institutions (both large and small); professional associations; and other not-for-profit entities with a mission related to healthcare improvement.</p> <p>Collaborations within institutions (e.g., between departments and/or inter-professional), as well as between different institutions/organizations/associations, are encouraged. All partners must have a relevant role and the requesting organization must have a key role in the project.</p> <p>Applicant organizations will be evaluated according to</p> <ul style="list-style-type: none"> • knowledge of and experience with the area, • capability of carrying out the proposed work, • collaboration, • potential effect and expected outcomes of the project, and • dissemination strategies.

III. Requirements

Date RFP Issued:	June 17, 2014
Clinical Area:	Chronic Pain Care Outcomes

<p>Specific Area of Interest for this RFP:</p>	<p>Applicants should select at least one evidence-based or innovative chronic-pain-intervention to implement in their institution when they receive a grant award.</p> <p>The intervention(s) should aim to (a) impact behavior of patients, providers, or both; and (b) improve choice and coordination of appropriate treatments, which may be pharmacological and non-pharmacological.</p> <p>Applicants must</p> <ul style="list-style-type: none"> • develop a complete implementation plan, • describe how the intervention will impact the process of care, • provide a budget for the proposed project, and • explain how the applicant will determine whether the chronic-pain intervention is effectively adopted within the target institution. <p>Proposals should demonstrate how the intervention (1) will improve choice and coordination of appropriate treatments, which may be pharmacological and non-pharmacological treatments; (2) enhance patient outcomes; and (3) increase patient satisfaction by reducing pain and by improving function and/or optimization of healthcare utilization.</p> <p>The methodology employed in the proposed project should apply to new patients and to those that are currently under treatment for their pain condition(s).</p> <p>For instance, projects may involve</p> <ul style="list-style-type: none"> • developing and assessing evidence-based chronic-pain algorithms; • developing and exploring supplemental impacts of patient-portal resources in primary care settings; • developing and assessing supplemental impacts of non-pharmacological patient-resources that would improve patient care; or • Development and assessment of supplemental impacts of motivational interviewing in patient care <p>Proposed programs should use tools to aid diagnosis of underlying pain condition(s) and current, evidence-based</p>
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	<p>treatment guidelines to guide appropriate treatment selection based on the underlying pain condition(s).</p> <p>The programs should use patient electronic health records (EHR) to document patient history, capture pain data, aid in patient pain assessment, provide clinical decision support, track PCP intervention, and monitor patient response. The “efficacy” of the educational intervention on PCP behavior should be assessed by measuring changes in triple-aim outcomes: higher-quality care, lower costs of care, and higher-quality patient experience of care.</p> <p>Successful proposals will include a detailed plan to generate quantitative evidence showing that improved selection and implementation of treatments is associated with improvements in pain relief, adherence to treatment, reduced visits, effective and appropriate use of pain medications, healthcare costs. Proposals should show that physician behavior changes 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.</p> <p>Programs must describe how the intervention will directly impact patient care and provide evidence of how the project can be replicated and sustained over time.</p> <p>NOTE: This initiative is not associated with the ER/LA REMS program mandated by the FDA.</p>
<p>Target Audience:</p>	<p>Primary-care providers (e.g., family medicine, internists, nurse practitioners, and physician assistants), patients, and healthcare systems.</p>
<p>Disease Burden Overview:</p>	<p>According to the 2011 IOM Report on Pain, as many as 100 million adults in the US report having common, chronic pain; that is more than the number of people affected by heart disease, cancer, and diabetes.¹ Regardless of the type of pain condition, patients report a substantial illness burden when chronic pain is poorly managed.^{2, 3} Continuous, unrelieved pain can negatively affect 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} Ongoing and unrelieved pain can create a cycle of increased anxiety and depression which, in turn,</p>

	<p>can amplify the pain.⁵ Patients with greater pain severity report increased difficulties with functioning and sleep and overall poorer health.⁶ Inadequately managed pain can lead to unfavorable physical and psychological outcomes for individual patients and their families.³</p> <p>Pain’s economic burden on society is great. Health economists from Johns Hopkins University writing in <i>The Journal of Pain</i> reported the annual cost of chronic pain is as high as \$635 billion a year, which is more than the yearly costs for cancer, heart disease and diabetes⁷.</p>
<p>Recommendations and Target Metrics:</p>	<p>The program should result in improvements in the diagnosis and management of chronic pain.</p> <p>The program’s impact on patient outcome should be assessed according to</p> <ul style="list-style-type: none"> • Increase in the utilization of guideline-recommended treatment options • Reduction in the inappropriate utilization of opioids as a first line treatment option. • reduction in pain severity, • improvement in patient function, and • impact of the intervention on health care costs. <p>Other suggested metrics include:</p> <ul style="list-style-type: none"> • Clinical outcome measures, such as <ul style="list-style-type: none"> ○ objective measures of improvement in quality of life; ○ patient reported satisfaction with outcomes and ○ use of EMR to track access of tools to aid diagnosis, guide treatment, monitor response, assess risk of misuse & abuse. • Cost Measures, such as total costs for pain-related-healthcare and pain-related consequences.
<p>Gaps Between Actual and Target, Possible Reasons for Gaps:</p>	<p>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.⁸ The primary-care practitioner’s response may be crucial to providing timely relief and preventing acute or early chronic pain from progressing to a persistent or severe chronic state.⁹ However, there are sparse efforts to educate primary-care physicians on pain and pain management. Based on their own self-report, primary-care physicians believe they do not receive enough pain management education and training.^{1, 10} In</p>

	<p>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.⁷</p>
<p>Barriers:</p>	<p>Regulatory, legal, financial, and other barriers limit the availability of pain care and contribute to the disparities found among some groups.¹</p> <p>According to Kirsh and others, “The souring of the regulatory and legal climates surrounding pain management creates fear, and fear widens the gulf between doctor and patient”¹² and detracts from empathetic patient care.^{11, 12}</p> <p>Another system-related barrier is the lack of adequate reimbursement by third party payers resulting in lower attention to and interest in pain management.^{12, 13}</p> <p>“There are also patient-centered barriers that, to a significant degree, mirror the clinician-related problems of ignorance and fear concerning the use of opioids in pain management.”¹²</p> <p>According to the results of the Mayday Fund Survey, patients worry about becoming too dependent on medication and that medication will be less effective if used too often.¹⁴</p> <p>In 2011, The Health Management Academy (The Academy) conducted a survey of chronic pain management in 50 Large Integrated Health Systems and found that the top 5 most significant barriers preventing progress in chronic pain management were:</p> <ul style="list-style-type: none"> • Lack of chronic pain training for physicians, nurses, and Advanced Practice Nurses (APNs), • Physician engagement/adoption of protocols, • Lack of performance measures and benchmarks specifically for chronic pain, • Payers’ reimbursement policy for chronic pain treatments, and • Translating research into practice to develop standards of care.¹⁵
<p>Current National Efforts to Reduce Gaps:</p>	<p>Many state medical board policies, and the model policy of the Federation of State Medical Licensing Boards, admonish physicians that effective pain management is an essential feature</p>

	<p>of quality patient care. Failure to provide such care, or to refer a patient to a clinician who can provide it, can constitute the basis for disciplinary action and/or malpractice liability.</p> <p>Organizations such as the American Academy of Pain Medicine and the American Pain Society promulgated clinical practice guidelines to assist clinicians in fulfilling their responsibilities to all patients with pain.</p> <p>In 2011, the Institute of Medicine released a report entitled <i>“Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research.”</i>¹ In it, a committee offered a blueprint transforming pain prevention, care, education, and research. Recommendations included developing a comprehensive strategy for reducing barriers in care, supporting collaboration between pain specialists and primary care clinicians, and designating a lead institute at the NIH that is responsible for moving pain research forward.</p>
<p>Expected Approximate Monetary Range of Grant Applications:</p>	<p>Individual projects requesting up to \$350,0000 will be considered. The total available budget related to this RFP is \$2,000,000.</p> <p>The grant amount that Pfizer will be prepared to fund depends upon the external review panel’s evaluation of the proposal(s) and costs involved and will be stated clearly in the approval notification.</p>

<p>Key Dates:</p>	<p>RFP release date: June 17, 2014</p> <p>LOI due date: July 17, 2014</p> <p>Review of LOIs by external review panel: July 17 to August 14, 2014</p> <p>Anticipated LOI notification date: August 18, 2014</p> <p>Full proposal deadline: * September 30, 2014 *Only accepted LOIs will be invited to submit full proposals</p> <p>Review of full proposals by external review panel: October 1st to November 18, 2014</p> <p>Anticipated full proposal notification date: November 20, 2014</p> <p>Grants distributed following execution of fully signed Letter of Agreement</p> <p>Period of Performance: December 2014 to June 2017</p>
<p>How to Submit:</p>	<p>Please go to the website at www.pfizer.com/independentgrants and click on the button “Go to the Grant System”.</p> <p>If this is your first time visiting this site 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.</p> <p>Select the following Area of Interest: <i>“Improving Chronic Pain Outcomes.”</i></p> <p>Requirements for submission:</p> <p>Complete all required sections of the online application and upload the completed LOI template (see Appendix). If you encounter any technical difficulties with the website, please click the “Need Support?” link at the bottom of the page.</p>
<p>Questions:</p>	<p>If you have questions regarding this RFP, please direct them in writing to the grant officer, Robert E. Kristofco, at (Robert.kristofco@pfizer.com), with the subject line <i>“Improving Chronic Pain Outcomes”</i>.</p>

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 or to make a summary presentation during the review period.
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References:

1. Committee on Advancing Pain Research, Care, and Education. Institute of Medicine, *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.
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8. 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.
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11. Passik SD, Kirsh KL. Fear and loathing in the pain clinic. *Pain Med*. 2006; 7(4):363–4.
12. Kirsh KL, Passik SD, Rich BA. Failure to treat pain. In: Deer TR, Leong MS, Buvanendran A, et al, eds. *Comprehensive Treatment of Chronic Pain by Medical, Interventional, and Integrative Approaches. The American Academy of Pain Medicine Textbook on Patient Management*. New York, NY: Springer; 2013.
13. Hoffman DE. Pain management and palliative care in the era of managed care: issues for health insurers. *J Law Med Ethics*. 1998; 26:267–89.
14. Bostrom M. Summary of the mayday fund survey: public attitudes about pain and analgesics. *J Pain Symptom Manage*. 1997; 13:166–8.

15. *Profiling Best Practices: Chronic Pain Management in the Leading Health Systems*. The Health Management Academy Benchmarking Series. A White Paper. Reporting on a survey of chronic pain management in Large Integrated Health Systems. Conducted by The Health Management Academy with financial support from Pfizer.

IV. Terms and Conditions

1. This RFP does not commit Pfizer or its partners to award a grant or a grant of any particular size if one is awarded, nor to pay any costs incurred in the preparation of a response to this request.
2. Pfizer reserves the right to accept or reject any or all applications received as a result of this request, or to cancel this RFP in part or in its entirety, if it determines it is in the best interest of Pfizer to do so.
3. For compliance reasons and in fairness to all applicants, all communications about the RFP must come exclusively to Pfizer IGL&C. Failure to comply will disqualify applicants.
4. Consistent with its commitment to openness and transparency, Pfizer reports education grants provided to medical, scientific, and patient organizations in the United States. 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. 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 IGL&C website and/or any other Pfizer document or site.
5. Pfizer reserves the right to share with organizations that may be interested in contacting you for further information (e.g., possible collaborations) the title of your proposed project and the name, address, telephone number, and e-mail address of the applicant from the requesting organization.
6. To comply with 42 U.S.C. § 1320a-7h and 42 C.F.R. §§ 403.900-.914 (the Sunshine Act), Provider (sponsor) must provide to Pfizer specific information for the U.S.-licensed physicians and U.S. teaching hospitals (“Covered Recipients,” as defined by applicable law) to whom Provider (sponsor) furnished payments or other transfers of value from the original independent grant awarded by Pfizer. Those payments or transfers-of-value include compensation, reimbursement for expenses, and meals provided to faculty (planners, speakers, investigators, project leads, etc.) and “items of value” (items that possess a value on the open market, such as textbooks) provided to faculty and participants, if those faculty and/or participants meet the definition of Covered Recipient. Provider (sponsor) must submit the required information during the reconciliation process or earlier, upon Pfizer’s request, so Pfizer can meet Sunshine Act

reporting commitments. Be advised that Pfizer will not make any payments to any individuals; grant funding shall be paid directly to Provider (sponsor).

7. No portion of a Pfizer independent grant may be used for food and/or beverages for learners and/or participants in any capacity. Provider (sponsor) will be required to certify during the reconciliation process and/or the periodic collection of Sunshine reporting that funds were not used for food and/or beverages for learners and/or participants.
8. In the performance of all activities related to an independent grant, the Provider (sponsor) and all participants must comply with all applicable Global Trade Control Laws. "Global Trade Control Laws" include, but are not limited to, U.S. Export Administration Regulations; the International Traffic in Arms Regulations; EU export controls on dual-use goods and technology; Financial Sanctions Laws and Restrictive Measures imposed within the framework of the CFSP - Treaty on European Union; and the economic sanctions rules and regulations administered by the U.S. Treasury Department's Office of Foreign Assets Control.

Appendix: Letter of Intent Submission Guidance

LOIs should be single-spaced using Calibri 12-point font and 1-inch margins. Note there is a 3-page limit in the main section of the LOI. ***LOIs not meeting these standards will not be reviewed.***

LOIs should include the following sections

Main Section (not to exceed 3 pages):

A. Title

B. Goal

1. 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).

C. Objectives

1. List the *overall* objectives, in terms of learning and expected outcomes, you plan to meet with your project. Do not include individual activity objectives.
 - Objectives should describe the population and the outcomes you expect to achieve due to the project.

D. Assessment of Need for the Project

1. 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. **The RFP includes a national assessment of the need for the project. Please do not repeat this information within the LOI (you may reference the RFP, if necessary). Only include information that impacts your specific project, linking regional or local needs to those identified on the national basis, if appropriate.**
2. 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

E. Project Design and Methods

1. 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.

F. Innovation

1. Explain what measures you have taken to assure that this project idea is original and does not duplicate other projects or materials already developed.
2. 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.

G. Design of Outcomes Evaluation

1. 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.
 - Identify the sources of data 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 project (e.g., use of a control group or comparison with baseline data).
2. Quantify the amount of change expected from this project in terms of your target audience.
3. Describe how you will determine if the target audience was fully engaged in the project.
4. Describe how the project outcomes might be broadly disseminated.

H. Project Timeline

I. Requested Budget

1. A total amount requested is the only information needed at this time.
2. The budget amount requested must be in U.S. dollars (USD).
3. While estimating your budget please keep the following items in mind:
 - Institutional overhead and indirect costs may be included within the grant request. Examples include human resources department costs, payroll processing and accounting costs, janitorial services, utilities, property taxes, property and liability insurance, and building maintenance as well as additional project expenses such as costs for publication, IRB / IEC review fees, software license fees, and travel. Please note: Pfizer does not provide funding for capital equipment.
 - It should be noted that grants awarded through IGLC cannot be used to purchase therapeutic agents (prescription or non-prescription).
 - Pfizer maintains a company-wide, maximum allowed overhead rate of 28% for independent studies and projects.

J. Additional Information

1. If there is any additional information you feel Pfizer should be aware of concerning the importance of this project, please summarize 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 project. Articulate the specific role of each partner in the proposed project.

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 a 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).

Make every effort to submit as **few** documents as possible—you are encouraged to include all required sections in one document. There is no need to submit the organization detail or references in a document separate from the main section of the LOI.

*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**.*