

Pfizer Medical Education Group
Request for Proposals (RFP)
Rheumatoid Arthritis
Adherence to Medications for RA

I. Background

The Pfizer Medical Education Group (MEG) is the unit within Pfizer that provides independent grants to facilitate patient care improvements by supporting initiatives aimed at exploring approaches to closing gaps in clinical practice. The term “independent” means the initiatives that our grants support 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.

A gap in clinical practice is considered to be the difference between what is currently happening and what should be happening to meet the highest optimal standard of care. Gaps may relate to:

- the ability or competencies of the healthcare professionals themselves,
- the capabilities of the systems in which they work to promote or allow proper management and
- other factors related to the external environment or patient population.

Pfizer MEG posts 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 deal with the development, adoption and/or integration of evidence-based health interventions 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 interventions according to population and setting
- Identification of approaches to scale-up effective interventions
- Development of innovative approaches to improve healthcare delivery
- Setting up an impact evaluation for a population based intervention

Pfizer is particularly vested in supporting programs that develop and implement interventions that are followed by rigorous assessment of the “efficacy” of the intervention; examining outcomes that may include both short and long term improvements in physician behavior and patient care.

The intent of this RFP is to encourage organizations with a focus in healthcare professional learning & change strategies 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 solve these problems.***

This RFP model employs 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 Medical Education Group website (www.pfizer.com/independentsupport) as well as those of other relevant organizations and is sent via e-mail to internal lists of all registered organizations and users in our grants system.

II. Requirements

Date RFP Issued:	3/14/2013
Clinical Area:	Adherence to Medications for RA
Specific Area of Interest for this RFP:	<p>It is our intent to support programs that focus on improving adherence to medications for rheumatoid arthritis, particularly oral disease-modifying anti-rheumatic drugs (DMARDs). The shift in recent years to injectable or infusible medications has focused attention on managing adherence for that mode of administration. However, oral agents have been and continue to be important options and adherence to oral agents presents specific challenges that differ from those associated with injectables or infusibles. This RFP cites the definition of adherence as “taking > 80% of medications as prescribed”.¹</p> <p><u>Category I</u> Grant support available for existing medication adherence initiatives. Eligible organizations may apply if they have a prior or ongoing project that addresses healthcare provider needs as it relates to increasing medication adherence in patients. Projects must have a proven track record of success with their educational methods and quality improvement approach. Documentation must be provided that the initiative has achieved success in the past and how additional funding can significantly expand or improve the effort to specifically include patients with RA. Grant requests must not exceed \$500,000.</p> <p><u>Category II</u> Grant support available to individual hospitals or hospital networks that include outpatient rheumatology or multi-specialty practices. The anticipated focus will be on documenting, optimizing, and sustaining medication adherence in RA patient populations starting or already taking prescription nonbiologic and biologic DMARDs. Grant requests must not exceed \$200,000.</p>

	<p><u>For all categories</u></p> <p>Please note the intent of this RFP is not to support programs determining how to measure adherence or identify why it occurs. The use of one or more of either an electronic means or a validated questionnaire/tool to assess adherence would be within the scope of this RFP.</p> <p>Partnerships are encouraged when appropriate. During review the intended outcomes of the program are given careful consideration and, if appropriate based on the program goal, programs with the highest likelihood to directly impact patient care will be given the highest priority.</p> <p>One other aspect should be stressed. There is high interest in receiving responses from programs that utilize system based changes. Although educational efforts for providers and patients may be entirely appropriate components in responses to this RFP, programs that include an overt description of system changes will be given the highest priority.</p>
<p>Disease Burden Overview:</p>	<p>Treatment with pharmacotherapeutic agents is most likely to be beneficial when patients follow prescribed regimens closely.² The potential for nonadherence may rise as complexity of treatment regimens increases.³ Patient beliefs and attitudes about medications can play an important role in adherence.⁴</p> <p>RA, the most prevalent type of inflammatory arthritis, affects more than 1.5 million adults in the US.⁵ Adherence to drug therapy in chronic disease is only approximately 50% overall, and in RA ranges from 30-80%.^{2,6} Nonadherence in RA can lead to loss of potential benefit, worsening signs and symptoms, loss of function, joint damage, and disability, but also increased direct /indirect costs.^{2,7}</p>

<p>Recommendations and Target Metrics:</p>	<p>Related Guidelines and Recommendations</p> <ul style="list-style-type: none"> • The 2012 update of ACR’s recommendations for the use of DMARDs and biologic agents in the treatment of RA.⁸ <ul style="list-style-type: none"> ○ 2012 update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis.⁸ • The WHO defines medication adherence as the extent to which a patient’s behavior corresponds with agreed recommendations from a HCP.⁹ <ul style="list-style-type: none"> ○ World Health Organization. Adherence to long-term therapies: evidence for action. (2003). www.who.int/chp/knowledge/publications/adherence_full_report.pdf⁹
<p>Gaps Between Actual and Target and Possible Reasons for Gaps:</p>	<p>Nonadherence is common in chronic conditions and RA is no different. Adherence to RA drug therapy can range from 30-80%.^{2,6} Understanding of patients’ medication beliefs and attitudes towards different treatment options can play a critical role in efforts to improve adherence.⁴</p> <p>The potential for nonadherence may rise as complexity of treatment regimens increases.^{3,7} The potential for differences in adherence for injectable/infusible medications versus adherence for oral medications is largely unknown. In a study of attitudes towards osteoporosis treatment options, patients expressed a preference for infusions over oral medications.¹⁰ In the context of current approaches to managing RA, additional studies are needed that examine the impact of different strategies for improving adherence to oral DMARD medications when used alone or in combination with injectable/infusible DMARD medications.</p>

<p>Barriers:</p>	<p>Barriers to patient medication adherence can be divided into two main categories, intentional non-adherence due to perceived risks vs. benefits (decision to take less than recommended or no medication) and unintentional non-adherence due to practical barriers (e.g., forgetfulness, regimen complexity, physical problems such as dexterity, or economic issues).²</p> <p>While unintentional non-adherence can be considered a universal issue, intentional non-adherence varies depending on the disease state. Studies specific to RA have found positive beliefs related to the necessity of RA medications¹ but still found that 91% of non-adherent patients had concerns about adverse effects.¹¹</p> <p>In addition to many patient factors that impact adherence, one should also consider health-system factors and provider factors. Health-system factors can include formularies, prior-authorization requirements and benefit caps, fragmentation of care, and access to care. Provider factors can include patient-provider trust and satisfaction, time spent discussing medications, and other communication issues.¹²</p>
<p>Current National Efforts to Reduce Gaps:</p>	<p>Many programs exist related to medication adherence. Below are a few examples</p> <ul style="list-style-type: none"> ● National Consumers League’s Medication Adherence Campaign <ul style="list-style-type: none"> ○ http://www.nclnet.org/health/106-prescription-drugs/234-ncls-medication-adherence-campaign ● American Society on Aging and American Society of Consultant Pharmacists Foundation’s website <i>Adult Meducation</i> focused on improving medication adherence in older adults. <ul style="list-style-type: none"> ○ http://www.adultmeducation.com/ ● Various websites and programs through national managed care organizations and pharmacy chains such as CVS/Caremark’s Advancing Medication Adherence website. <ul style="list-style-type: none"> ○ http://info.cvscaremark.com/our-company/corporate-responsibility/customers/medication-adherence
<p>Target Audience:</p>	<p>Rheumatology healthcare professionals and colleagues involved in managing patients in conjunction with rheumatology healthcare professionals on a patient level and system level.</p>

Geographic Scope:	<input checked="" type="checkbox"/> United States Only <input type="checkbox"/> International(specify country/countries)_____
Applicant Eligibility Criteria:	<p>Medical, dental, nursing, allied health, and/or pharmacy professional schools, healthcare institutions, professional associations and other not-for-profit entities with a mission related to healthcare improvement may apply. Collaborations between schools within institutions, as well as between different institutions/organizations/associations, are encouraged. Inter-professional collaborations that promote teamwork among institutions/organizations/associations are also encouraged.</p>
Expected Approximate Monetary Range of Grant Applications:	<p><u>Category I:</u> Individual grants requesting up to \$500,000 will be considered.</p> <p><u>Category II:</u> Individual grants requesting up to \$200,000 will be considered.</p> <p>The total available budget related to this RFP is \$1,000,000.</p> <p>The amount of the grant Pfizer will be prepared to fund for any full proposal will depend upon the external review panel’s evaluation of the proposal and costs involved and will be clearly stated in the grant approval notification.</p>
Key Dates:	<p>RFP release date: 3/14/2013</p> <p>Letter of Intent due date: 4/19/2013</p> <p>Anticipated LOI Notification Date: 6/14/2013</p> <p>Please note, full proposals can only be submitted following acceptance of an LOI</p> <p>Full Proposal Deadline: 7/15/2013</p> <p>Anticipated Full Proposal Notification Date: 8/30/2013</p> <p>Anticipated award delivered following execution of fully signed LOA</p> <p>Period of Performance: 10/2013 to 7/2016</p>

<p>How to Submit:</p>	<p>Please go to the website at www.pfizer.com/independentsupport and click on the button “Go to the Grant System”.</p> <p>If this is your first time visiting this site in 2013 you will be prompted to take the <i>Eligibility Quiz</i> to determine the type of support you are seeking. Please ensure you identify yourself as a first-time user.</p> <p>Submit LOIs in the clinical area: LOI-Adherence in Rheumatoid Arthritis.</p> <p>Requirements for submission: Complete all required sections of the online application and upload the completed letter of intent template (<i>see Appendix</i>).</p>
<p>Questions:</p>	<p>If you have questions regarding this RFP, please direct them in writing to the Education Director for this clinical area, Susan Connelly at (susan.connelly@pfizer.com), with the subject line “RFP Adherence in RA 3-14-13”</p>
<p>Mechanism by Which Applicants will be Notified:</p>	<p>All applicants will be notified via email by the dates noted above.</p> <p>Applicants may be asked for additional clarification or to make a summary presentation during the review period.</p>

References:

1. Pasma A, van't Spijker A, M.W. Hazes, et al. Factors associated with adherence to pharmaceutical treatment for rheumatoid arthritis. *Sem Arthritis Rheum*. 2013; In Press. Available at: <http://www.sciencedirect.com/science/article/pii/S0049017212002831>. Accessed March 11, 2013.
2. van den Bemt BJ, Zwikker HE, van den Ende CH. Medication adherence in patients with rheumatoid arthritis: a critical appraisal of the existing literature. *Expert Rev Clin Immunol* 2012;8:337-351.
3. Claxton AJ, Cramer J, Pierce C. A systematic review of the associations between dose regimens and medication compliance. *Clin Ther* 2001;23:1296-1310.
4. Barton JL. Patient Preferences and satisfaction in the treatment of rheumatoid arthritis with biologic therapy. *Patient Preference Adherence* 2009;3:335-344.
5. Sacks JJ, Luo Y, Helmick CG. Prevalence of specific types of arthritis and other rheumatic conditions in the ambulatory health care system in the United States, 2001-2005. *Arthritis Care Res* 2010;62:460-464.
6. van den Bemt BJ, van den Hoogen FH, Benraad B, et al. Adherence rates and associations with nonadherence in patients with rheumatoid arthritis using disease modifying antirheumatic drugs. *J Rheumatol* 2009;36:2164-2170.
7. Salt E, Frazier SK. Adherence to disease-modifying antirheumatic drugs in patients with rheumatoid arthritis: a narrative review of the literature. *Orthop Nurs* 2010;29:260-275.
8. Singh JA, Furst DE, Bharat A, et al. 2012 update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. *Arthritis Care Res (Hoboken)* 2012 May;64(5):625-39.
9. World Health Organization. Adherence to long-term therapies: evidence for action. (2003). www.who.int/chp/knowledge/publications/adherence_full_report.pdf
10. Fraenkel L, Gulanski B, Wittink D. Patient treatment preferences for osteoporosis. *Arthritis Rheum* 2006;55:729-735.
11. Neame R, Hammond A. Beliefs about medications: a questionnaire survey of people with rheumatoid arthritis. *Rheumatology (Oxford)*44(6),762–767 (2005).

12. Gellad WF, Grenard J, McGlynn EA. A Review of Barriers to Medication Adherence: A Framework for Driving Policy Options. Santa Monica, CA: RAND Corporation, 2009. Available at: http://www.rand.org/pubs/technical_reports/TR765. Accessed March 7, 2013.

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 Medical Education Group website www.pfizer.com/independentsupport.
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 Medical Education 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 MEG 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 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)
- 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

1. A total amount requested is the only information requested at this time
2. While estimating your budget please keep the following items in mind:
 - Institutional overhead and indirect costs can 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 initiative 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.
 - Pfizer maintains a company-wide, maximum allowed overhead rate of 28% for independent studies and initiatives. If your institution has a preexisting and published indirect overhead rate that exceeds this amount, you will be asked to provide the appropriate documentation if you are requested to submit a full proposal. Exceptions may be reviewed on an initiative by initiative basis, but we cannot guarantee approval.

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).

Make every effort to submit as few documents as possible (preferably 1). There is no need to submit the organization detail or references in a separate document 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.***