

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

Patient-Reported Outcome Measures in Management of Rheumatoid Arthritis

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 is 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.

II. Requirements

Date RFP Issued:	07/11/2013
Clinical Area:	Use of Patient-Reported Outcome Measures in Management of Rheumatoid Arthritis (RA)

Specific Area of Interest for this RFP:

It is our intent to support programs that demonstrate utilization of patient reported outcome measures in the management of patients with rheumatoid arthritis (RA) who are starting treatment with or are already being treated with disease-modifying anti-rheumatic drugs (DMARDs). Specifically, the intent is to support programs in which RA patients are being treated to an RA disease activity target, and within these programs patient-reported outcomes (for example, assessment of pain, fatigue, function) are being incorporated into assessing patients and monitoring their response to an overall treatment plan.

The target for DMARD therapy should be measured using a validated disease activity measure such as the Simplified Disease Activity Index (SDAI) or the Clinical Disease Activity Index (CDAI).¹ Patient-reported outcomes should be measured using validated standardized measures at different points of time in a continuum of caring for patients, so that it is evident in the patient's medical record that the information from these measures is being utilized in the assessment of patients and to monitor their response to an overall treatment plan. In other words, initial assessment and monitoring of response to treatment should not focus solely on the disease activity measure that constitutes the "target" in treating to target, but should also include assessment with patient reported outcome measures and then monitoring response to management of symptoms or problems identified through use of those measures, regardless of whether these symptoms or problems are thought to be related to synovitis and thereby potentially responsive to DMARD treatment. Proposals are encouraged that stratify results by disease activity/success in treating to an RA disease activity measure target (i.e., those that are successfully treated to a target of clinical remission or low disease activity versus those that are not), thus permitting exploration of the relationship between success in treating to target and success in managing symptoms or problems identified with patient-reported outcome measures.

Please note the intent of this RFP is not to support programs to develop or validate new disease activity measures or to develop or validate new patient-reported outcome measures. The use of one or more validated RA disease activity measure in treating patients to a target, and use of one or more validated questionnaires/tools to assess patient-reported outcomes would be appropriate and within the scope of this RFP.

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.

Disease Burden Overview:	<p>RA, the most prevalent type of inflammatory arthritis, affects more than 1.5 million adults in the U.S.² There is strong evidence suggesting clinical outcomes are improved by use of DMARD therapy, including reduction in joint signs and symptoms, improvement in physical function, inhibition of progression of joint damage, and reduction in long-term disability.³ Additional evidence on therapeutic strategies has evolved over the last two decades that supports diagnosis and treatment with DMARDs very early in the course of disease, and treatment to a defined target such as clinical remission or low disease activity.³ However, there is growing literature suggesting rheumatology health care providers and their patients may not always agree on what the goals or objectives are for treating the patients' RA, and how to best assess disease activity initially and monitor response to treatment. Additionally, there is evidence that providers and patients often differ in their ratings of disease activity or severity.⁴ In many instances patients may be basing their assessment of disease activity and their ratings of symptoms and functional impairment on factors beyond RA itself (such as concomitant conditions, including fibromyalgia). Patient management may be enhanced by an approach that addresses not only treating to an RA disease activity target but also addresses treatment of symptoms or problems that might be identified and characterized using patient-reported outcome measures.⁵ Possible outcomes might include improved patient satisfaction with treatment and greater adherence to therapy.</p>
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<p>Recommendations and Target Metrics:</p>	<p>Related Guidelines and Recommendations</p> <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 RA.⁶ • The ACR issued recommendations on use of RA disease activity measures in management of RA, noting there are several measures that are valid and feasible to perform in clinical settings, and indicating incorporation of these measures into clinical practice can facilitate adherence to the ACR's guidelines for the treatment of RA and aid in treating RA to a targeted goal. The ACR also added that routine use of these measures enables clinicians to demonstrate they are providing a high quality of care by incorporating quality measures into their management of patients.⁷ • An International Task Force has published recommendations on treating RA to a targeted goal, and indicated the treatment of RA be based on a shared decision between patient and rheumatologist.⁸
<p>Gaps Between Actual and Target and Possible Reasons for Gaps:</p>	<p>There is growing recognition of the need to treat RA to target. There is also growing recognition of the need to more effectively address the patient's perspective in setting goals and monitoring response to therapy,^{8,9} but implementation into clinical practice has lagged. Possible reasons for slowness in incorporating measurement of patient-reported outcomes into assessment and monitoring response to therapy include concern about the validity of patient-reported outcomes, and feasibility of using the measures in clinical practice. Additionally, there are concerns about discordance, or disagreement between measures completed by health care professionals and measures completed by patients, and the potential meaning of this discordance or disagreement.⁹</p>

Barriers:	There are two general types of barriers to the use of patient-reported outcomes in clinical practice as part of the process of setting goals or objectives for treatment and monitoring response to treatment. The first is concern about the availability of validated measures, and the second is concern about the feasibility of using such measures in clinical practice. However, there are valid patient-reported outcome measures that can be used to assess pain, fatigue, and function, and the feasibility of incorporating these measures into clinical practice has also been established. ⁷⁻⁹
Current National Efforts to Reduce Gaps:	Although guidelines and recommendations have indicated a need to incorporate the perspective of patients into clinical practice for assessing patients and monitoring their response to treatment, there has been little documentation of national efforts to accomplish this process.
Target Audience:	Rheumatology healthcare professionals and colleagues involved in managing patients in conjunction with rheumatology healthcare professionals on a patient level and system level.
Geographic Scope:	<input checked="" type="checkbox"/> United States Only <input type="checkbox"/> International(specify country/countries)_____
Applicant Eligibility Criteria:	Medical, dental, nursing, allied health, and/or pharmacy professional schools, healthcare institutions, professional associations and other 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.
Expected Approximate Monetary Range of Grant Applications:	<p>Individual grants requesting up to \$350,000 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 is 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: 07/11/2013</p> <p>Letter of Intent due date: 8/15/2013</p> <p>Anticipated LOI Notification Date: 10/2/2013</p> <p>Full Proposal Deadline*: 11/1/2013 *Only accepted LOIs will be invited to submit full proposals</p> <p>Anticipated Full Proposal Notification Date: 12/15/2013</p> <p>Payment to follow execution of fully signed Letter of Agreement</p> <p>Period of Performance: 1/2014 to 7/2016</p>
How to Submit:	<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 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>Select the following Area of Interest: Use of PROS in RA</p> <p>Requirements for submission: Complete all required sections of the online application and upload the completed LOI template. (<i>see Appendix</i>)</p>
Questions:	<p>If you have questions regarding this RFP, please direct them in writing to the Grant Officer, Susan Connelly at (susan.connelly@pfizer.com), with the subject line "Use of PROS in RA 7-11-13"</p>
Mechanism by Which Applicants will be Notified:	<p>All applicants will be notified via email by the dates noted above.</p> <p>Providers may be asked for additional clarification or to make a summary presentation during the review period.</p>

References:

1. Aletaha D, Smolen JS. The Simplified Disease Activity Index (SDAI) and the Clinical Disease Activity Index (CDAI): A review of their usefulness and validity in rheumatoid arthritis. Clin Exp Rheumatol 2005;23(Suppl. 39):S100-S108

2. Sacks JJ, Luo Y, and 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.
3. O’Dell JR. Therapeutic Strategies for Rheumatoid Arthritis. *NEJM* 2004;350:2591-2602.
4. Khan NA, Spencer HJ, Abda E, et al. Determinants of discordance in patients’ and physicians’ rating of rheumatoid disease activity. *Arthritis Care Res* 2012;64:206-214.
5. Dougados M, Nataf H, Steinberg G, et al. Relative importance of doctor-reported outcomes vs patient-reported outcomes in DMARD intensification for rheumatoid arthritis: the DUO study. *Rheumatology (Oxford)*. 2013;52:391-9.
6. 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* 2012;64:625–639.
7. Anderson J, Caplan L, Yazdany J, et al. Rheumatoid Arthritis Disease Activity Measures: American College of Rheumatology Recommendations for Use in Clinical Practice. *Arthritis Care & Res* 2012;64:640-647.
8. Smolen JS, Aletaha D, Bijlsma JW et al. Treating rheumatoid arthritis to target: recommendations of an international task force. *Ann Rheum Dis* 2010;69: 631-637.
9. Curtis JR, Shan Y, Harrold L et al. Patient Perspectives on Achieving T2T Goals: A Critical Examination of Patient Reported Outcomes. *Arthritis Care & Res* 2013; DOI 10.1002/acr.22048 (accepted article).

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 applicants, all communications about the RFP must come exclusively to Pfizer Independent Grants for Learning & Change. Failure to comply will automatically disqualify applicants.
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 applicant for the requesting 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 IGL&C website.

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 program
- C. Objectives
 1. List the *overall* objectives you plan to meet with your program both in terms of learning and expected outcomes. Do not include learner objectives.
- D. Assessment of Need for the Program
 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 program. Please do not repeat this information within the LOI (you may reference the RFP, if necessary). Only include information that impacts your specific program, linking regional or local needs to those identified on the national basis, if appropriate.

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

E. Program Design and Methods

1. Describe the planned program 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 either 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 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 program (e.g., use of a control group, comparison with baseline data).
- b. Quantify the amount of change expected from this program in terms of your target audience.
- c. Describe how you will determine if the target audience was fully engaged in the program.
- 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 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 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 later invited 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 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 program.

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—you are encouraged to include all required sections in one document. 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.***