Pfizer Independent Grants for Learning & Change
Request for Proposals (RFP)
Rheumatoid Arthritis
Mono- and Combination DMARD Therapy in RA Patients

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

<table>
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<tr>
<th>Date RFP Issued:</th>
<th>07/11/2013</th>
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<tr>
<td>Clinical Area:</td>
<td>Disease Modifying Anti-Rheumatic Drug (DMARD) Therapy in Rheumatoid Arthritis (RA) Patients.</td>
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**Specific Area of Interest for this RFP:**

It is our intent to support proposals for educational programs that focus on collating/synthesizing, critically appraising, and presenting evidence for mono- versus combination DMARD therapy for management of patients with RA.

Programs with the highest likelihood of improving rheumatologists’ understanding of the evidence for mono- versus combination therapy in managing RA will be given the highest priority. Therefore, programs should incorporate substantive contributions from one or more practicing rheumatologists in developing the proposed educational program.

One other aspect should be stressed. There is a need for more clarity on the clinical factors and the real world circumstances related to healthcare delivery that can potentially impact decisions about use of mono- versus combination therapy, including but not limited to, the duration of disease, prognostic factors, initial response to therapy, adherence to therapy, and potential toxicity of therapies. Existing attempts at synthesizing the scientific literature supporting monotherapy and combination therapy have focused primarily on compiling individual controlled clinical trials and meta-analyses of clinical trials studying the efficacy of DMARD agents. However, real world considerations merit attention in clinical decision making, including potential tradeoffs when combining agents: the potential to increase therapeutic response and the potential to increase non-adherence and side effects. There is a considerable amount of interest in receiving responses to the RFP for educational programs that address evidence broadly, looking not only at efficacy as established in clinical trials, but also effectiveness in practice settings and the range of factors that can impact effectiveness in real world settings, such as complexity and tolerability/potential toxicity of multi-drug treatment strategies.
| Disease Burden Overview: | RA, the most prevalent type of inflammatory arthritis, affects more than 1.5 million adults in the U.S.\(^1\) 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.\(^2\) 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 of clinical remission.\(^2\) Nevertheless, during this same period, the number of therapeutic options has increased substantially. Despite a rapidly growing literature of efficacy studies, relatively few have compared agents or treatment regimens head-to-head.\(^3\) Conversely, there have been several mixed-treatment comparison meta-analyses, many of which have included studies on monotherapy regimens and combination therapy regimens.\(^4\) A growing number of effectiveness studies have suggested rates of improvement on clinical measures in real world settings often fall well below the rates achieved in controlled clinical trials.\(^5\) At this time in the era of DMARD therapies for managing RA, clinicians and their patients can potentially benefit from a clearer understanding of the real world patient-level clinical factors and the healthcare delivery circumstances that support mono- versus combination DMARD therapy. |
| Recommendations and Target Metrics: | Related Guidelines and Recommendations |
| | • The ACR has issued treatment recommendations on use of disease modifying anti-rheumatic drugs and biologic agents in the treatment of RA.\(^6\) These recommendations address use of monotherapy and combination therapy, with evidence-based recommendations, citing results from controlled clinical trials. These recommendations also address a need to use disease activity metrics as part of treatment to a target. |
| | • An international task force has issued treat to target recommendations for the management of RA,\(^7\) also citing results from controlled clinical trials and addressing the need to use disease activity metrics as guidance for treatment. |
| **Gaps Between Actual and Target and Possible Reasons for Gaps:** | Although there are multiple individual controlled clinical trials and meta-analyses that have compared DMARD monotherapy to combination DMARD therapy, including non-biologic and biologic DMARDS, there is a need for a clearer understanding of the clinical and healthcare delivery circumstances in which to consider monotherapy vs combination therapy. Questions remain whether DMARD therapy should be initiated as monotherapy, with advancement to combination therapy only in patients who are non-responders or those with limited responses, versus whether DMARD therapy should be initiated as a combination of agents. Questions also remain whether agents should be reduced in dose and in some circumstances withdrawn in patients who have achieved a strong clinical response, potentially then moving from combination therapy to monotherapy. In addition to the clinical trial literature that provides a foundation of evidence for efficacy, there is background literature that raises questions about the possibility of reduced adherence to treatment when multiple agents are combined into complex therapeutic regimens. Additionally, there is literature that raises the question of increased potential for toxicity or limited tolerance to treatment when multiple drugs are used in combination. |
| **Barriers:** | One barrier to increasing the understanding clinicians have about use of monotherapy versus combination therapy is the focus of clinical literature and education efforts on controlled clinical trial efficacy results, without incorporating real world considerations, such as adherence and potential toxicity. A second barrier is the overall complexity of the literature, with the availability of at least 5 non-biologic DMARDS and 9 biologic DMARDS, and a myriad of published guidelines, recommendations, and meta-analyses. |
| **Current National Efforts to Reduce Gaps:** | There are numerous publications and educational efforts intended to increase awareness for treating RA to target, but they have not addressed real world issues potentially relevant to the question of monotherapy versus combination therapy, related to adherence and potential for toxicity. |
| **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:** | ☑ United States Only  
☐ 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 education of healthcare professionals 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:** | Individual grants requesting up to $500,000 will be considered. The total available budget related to this RFP is $1,000,000. 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. |
| **Key Dates:** | **RFP release date:** 07/11/2013  
**Letter of Intent due date:** 8/15/2013  
**Anticipated LOI Notification Date:** 10/2/2013  
**Full Proposal Deadline:** 11/1/2013  
*Only accepted LOIs will be invited to submit full proposals  
**Anticipated Full Proposal Notification Date:** 12/15/2013  
**Payment to follow execution of fully signed Letter of Agreement**  
**Period of Performance:** 1/2014 to 7/2016 |
| **How to Submit:** | Please go to the website at [www.pfizer.com/independentgrants](http://www.pfizer.com/independentgrants) and click on the button “Go to the Grant System”.  
If this is your first time visiting this site in 2013 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.  
Select the following Area of Interest: **Mono vs Combo DMARD Therapy**  
**Requirements for submission:**  
Complete all required sections of the online application and upload the completed LOI template. *(see Appendix)* |
Questions: 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 “Mono vs Combo DMARD Therapy 7-11-13”

Mechanism by Which Applicants will be Notified: All applicants will be notified via email by the dates noted above. Providers may be asked for additional clarification or to make a summary presentation during the review period.

References:

III. Terms and Conditions


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).
   a. Quantify the amount of change expected from this program in terms of your target audience.
   b. 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.