Pfizer Independent Grants for Learning & Change
Request for Proposals (RFP)
Patient Care in Rheumatoid Arthritis

I. Background

The mission of Pfizer Independent Grants for Learning & Change (IGL&C) is to partner with the global healthcare community to improve patient outcomes in areas of mutual interest through support of 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.

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 (LOI) 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. 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.

When a RFP is issued, it is posted on the Pfizer IGL&C website (www.pfizer.com/independentgrants) in the *Requests for Proposals* section and is 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, as deemed appropriate.

II. Eligibility

Geographic Scope:	☑ United States Only ☐ International(specify country/countries)_____
Applicant Eligibility Criteria:	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. Collaborations within institutions (e.g., between departments and/or inter-professional), as well as between different institutions/organizations/associations, are encouraged. Key collaborators should include at a minimum both clinicians (specifically rheumatologists) and educators. Collaborations between resource-rich organizations and those in need of additional resources will be given high priority during review. Please note all partners must have a relevant role and the requesting organization must have a key role in the project.

III. Requirements

Date RFP Issued:	November 6, 2014
Clinical Area:	Rheumatoid Arthritis
Specific Area of Interest for this RFP:	It is our intent to support projects (e.g., process, outcomes, quality measures) to improve the management of patients with rheumatoid arthritis (RA). Projects previously funded have included a number of topics and issues relative to the care of patients with RA such as comorbid conditions (e.g., cardiovascular risk), fluctuations in disease activity (e.g., flares), and barriers to optimal care (e.g., medication adherence) as well as systematic interventions such as improving the input of patient generated information, using nurse coordinators in managing various aspects of disease management, and addressing barriers to optimal care. These and other concepts will be considered for grant funding. Projects that will impact care to adult patients with RA will be considered. *It is not our intent to support clinical research projects. Projects evaluating the efficacy of therapeutic agents will not be considered.* It has been noted there are limits to patient access to rheumatology care in rural and underserved U.S. communities due to an aging workforce, uncertain business climate and government regulation.[1,2] Projects targeting these issues and implemented in settings where rural, medically underserved populations reside will be given high priority. Projects with findings easily disseminated and implemented in facilities with limited resources will be a priority. Institution-specific information that would inform systems in other practices and settings should be provided. Partnerships between community hospitals and large academic institutions are a strategy to consider. Of particular interest are evidence-based projects that use a **well-considered** educational strategy to facilitate system-based changes resulting in a significant impact. A thorough evaluation designed to follow generally accepted educational and scientific principles is expected. During review the intended outcome of the project is given careful consideration, and if appropriate based on the project goal, projects with the maximum likelihood to directly impact patient care will be given high priority. Projects including an educational element can find more information on principals of learning and behavior change for health professionals here. Please note this RFP was purposely written to consider projects: 1) using a variety of project designs (e.g., mixed methods, quality improvement); and 2) investigating clinical topics important to improve the care of patients with RA that include an education component and an opportunity to make a system-based changes. Thus, a wide range of projects will be considered based on their potential to impact this population with special consideration given to projects that improve the care provided to those with limited access to care residing in rural areas.

Target Audience:	Rheumatology healthcare professionals and colleagues involved in managing adult patients in conjunction with rheumatology healthcare professionals on a patient level and system level.
Disease Burden Overview:	RA, the most prevalent type of inflammatory arthritis, affects more than 1.5 million adults in the U.S.[3] 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.[4] 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.[4] However, there is growing literature suggesting rheumatology healthcare 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.[5] 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).
Recommendations and Target Metrics:	**Target Metrics** • There are a number of RA quality indicators included in the CMS PQRS measures list, which are endorsed by the American College of Rheumatology.[6-8] • Healthy People 2020 lists a goal is to prevent illness and disability related to arthritis and other rheumatic conditions, osteoporosis, and chronic back conditions.[9] There are 9 objectives related to arthritis. **Related Guidelines and Recommendations** • 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.[10] • 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.[11]

Gaps Between Actual and Target, Possible Reasons for Gaps:	A review of data benchmarking metrics related to the Healthy People 2020 objectives for arthritis and progress between the years of 2008 and 2011 show that the targets have not been reached, nor, in many cases are the metrics trending toward improvement.[12] Although evidence supports treat-to-target (TTT) as an appropriate option for management of RA,[13,14] application of treat-to-target continues to present challenges in clinical practice.[15] One such challenge is that patients may not always readily see potential benefit or need for treating their disease to target.[15,16] Another challenge is the realization that successful execution of a treat-to-target approach requires frequent visits with rheumatology HCPs.[15] Nonadherence is common in chronic conditions and RA is no different. Adherence to RA drug therapy can range from 30-80%.[17,18] Understanding of patients' medication beliefs and attitudes towards different treatment options can play a critical role in efforts to improve adherence.[19] There is also growing recognition of the need to more effectively address the patient's perspective in setting goals and monitoring response to therapy,[11,16] 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 healthcare professionals and measures completed by patients, and the potential meaning of this discordance or disagreement.[16]

Barriers:	Patient access to rheumatology care in some rural and underserved US communities is limited.[1] The limited access to rheumatic disease expertise limits the use of DMARDs in the US which may ultimately reduce the dissemination of TTT.[15] There is a range of challenges for implementation of a treat-to-target (TTT) approach to managing RA.[15] From a provider perspective these challenges include continued clinical questions related to a sparse evidence base and a continued need for testing and refining of many concepts underpinning TTT in RA. Patient's fears of the risks of aggressive therapy may make them reluctant to engage in TTT. There may also be a misalignment of patient goals and objective target of low disease activity or remission.[15] Patient-provider communication becomes a barrier. 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.[11,16,20] 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 medications[1] but still found that 91% of non-adherent patients had concerns about adverse effects.[21] 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.[22]

Current National Efforts to Reduce Gaps:	The American College of Rheumatology spearheaded efforts to increase use of validated measures of disease activity and incorporation of some type of treat-to-target approach to care.[10] The International Task Force on treat-to-target provided additional guidance.[11]
	
	The American College of Rheumatology has recently developed a website that assist rheumatologists in practice improvement, local population management, and efficient, successful participation in national quality programs.[23]
	• Rheumatology Clinical Registry
	  ○ http://www.rheumatology.org/Practice/Clinical/Rcr/Rheumatology_Clinical_Registry/
	
	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.
	
	Many programs exist related to medication adherence. Below are a few examples
	• National Consumers League's Medication Adherence Campaign
	  ○ 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 *Adult Medication* focused on improving medication adherence in older adults.
	  ○ 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.
	  ○ http://info.cvscaremark.com/our-company/corporate-responsibility/customers/medication-adherence

Expected Approximate Monetary Range of Grant Applications:	Individual projects requesting up to $250,000 will be considered. The total available budget related to this RFP is $1,000,000. ○ The amount of the grant Pfizer will be prepared to fund for any project will depend upon the external review panel's evaluation of the proposal and costs involved, and will be stated clearly in the approval notification.

Key Dates:	RFP release date: 11/6/2014 LOI due date: 12/17/2014 Please note the deadline is midnight Eastern Time (New York, GMT -5). Review of LOIs by External Review Panel: January 2015 Anticipated LOI Notification Date: 2/6/15 Full Proposal Deadline*: 2/27/15 *Only accepted LOIs will be invited to submit full proposals Please note the deadline is midnight Eastern Time (New York, GMT -5). Review of Full Proposals by External Review Panel: March 2015 Anticipated Full Proposal Notification Date: 4/3/15 Grants distributed following execution of fully signed Letter of Agreement Period of Performance: May 2015 to Nov 2017
How to Submit:	Please go to the website at www.pfizer.com/independentgrants and click on the button "Go to the Grant System". Registered users should select the LOI link under Track 1 – Learning & Change. 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. Select the following Area of Interest: Patient Care in RA Requirements for submission: 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
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 "Patient Care in RA 11-6-2014."
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.

References:

1. The American College of Rheumatology, 2005 Workforce and Demographic Study
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3. 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.
4. O'Dell JR. Therapeutic Strategies for Rheumatoid Arthritis. NEJM 2004;350:2591-2602.
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7. ACR. Quality Metrics. Available at: http://www.rheumatology.org/Practice/Clinical/Quality/Quality_Measures/. Accessed May 20, 2014.
8. Centers for Medicare and Medicaid Services (CMS). 2014 Physician Quality Reporting System (PQRS) Measures List. Available at: http://www.apapracticecentral.org/update/2014/01-16/measures-list.pdf. Accessed May 28, 2014.
9. HealthyPeople.gov. 2020 Topics & Objectives. Arthritis, Osteoporosis, and Chronic Back Conditions. Available at: http://www.healthypeople.gov/2020/topicsobjectives2020/overview.aspx?topicid=3. Accessed August 8, 2014.
10. 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.
11. 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.
12. HealthyPeople.gov. 2020 Topics & Objectives. Arthritis, Osteoporosis, and Chronic Back Conditions: National Data. Available at: http://www.healthypeople.gov/2020/topicsobjectives2020/nationaldata.aspx?topicId=3. Accessed August 11, 2014
13. Vermeer M, Kuper HH, Hoekstra M, et al. Implementation of a treat-to-target strategy in very early rheumatoid arthritis. Results of the Dutch Rheumatoid Monitoring Remission Induction Cohort Study. Arthritis Rheum 2011;63:2865-2872.
14. Vermeer M, Kuper HH, Bernelot Moens HJ, et al. Sustained beneficial effects of a protocolized treat-to-target strategy in very early rheumatoid arthritis: Three-year results of the Dutch Rheumatoid Monitoring Remission Induction Cohort. Arthritis Care Res 2013;65:1219-1226.
15. Solomon DH, Bitton A, Katz JN, et al. Review: treat to target in rheumatoid arthritis: fact, fiction, or hypothesis? Arthritis Rheumatol. 2014 Apr;66(4):775-82
16. 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;65:1707-1712.
17. 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.
18. Barton JL. Patient Preferences and satisfaction in the treatment of rheumatoid arthritis with biologic therapy. Patient Preference Adherence 2009;3:335-344.
19. 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.
20. 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.
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23. Rheumatology Clinical Registry Website. American College of Rheumatology. Available at: http://www.rheumatology.org/Practice/Clinical/Rcr/Rheumatology_Clinical_Registry/. Accessed October 14, 2014.

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. Applicants should not contact other departments within Pfizer regarding this RFP. 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 ("Sunshine Act") under non-exempt conditions, Provider (sponsor) must provide names and other required information for the US-licensed physicians and US teaching hospitals ("Covered Recipients," as defined by Centers for Medicare and Medicaid Services) to whom the Provider (sponsor) furnished payments or other transfers of value stemming from the original independent grant awarded by Pfizer, if applicable. This includes compensation, reimbursement for expenses, and meals provided to faculty (planners, speakers, investigators, project leads, etc.) and "items of value" (items that possess a discernible value on the open market, such as textbooks) provided to faculty and participants, if such faculty and/or participants meet the definition of Covered Recipient. Such required information is to be submitted during the reconciliation process or earlier upon Pfizer's request in order to meet certain Sunshine Act reporting commitments. Be advised 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.*** *It is helpful to include a header on each page listing the requesting organization and project lead.*

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 you plan to meet with your project both in terms of learning and expected outcomes. Do not include individual activity objectives.
    2. Objectives should describe the population as well as the outcomes you expect to achieve as a result of conducting 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. Please 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. Anticipated Project Timeline

I. Requested Budget
    1. A total amount requested is the only information needed for the LOI stage. Full Budget is not required. This amount can be adjusted at the Full Proposal stage as applicable.
    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. Letters of support from partner organizations will be required at the Full Proposal stage only and should not be included with the LOI.

Please note that any project partners listed in this section should also be listed within the online system. Tax-IDs of partner organizations will be requested when entering this information. If a partnership is only proposed, please indicate the nature of the relationship in the Organizational Detail section of your LOI.

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).

All required sections should be combined in one document (MS Word or Adobe PDF). 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****.*