Pfizer Independent Grants for Learning & Change
Request for Proposals (RFP)
Facilitation of the Diagnosis of 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 a 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 Request 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:	U.S. health care institutions, large and small; health care professional organizations and other organizations with a mission related to healthcare improvement; and government agency partners. More information on organizations eligible to apply directly for a grant can be found at: http://www.pfizer.com/files/IGLC_Organization_Eligiblilty.pdf. Collaborations within institutions (e.g., between departments and/or inter-professional), as well as between different institutions/organizations/associations, are encouraged. 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:	May 7, 2015
Clinical Area:	Rheumatology
Specific Area of Interest for this RFP:	It is our intent to support projects with an educational element that will facilitate the timely diagnosis and management of rheumatoid arthritis (RA) in patients with limitations on their access to healthcare be that due to geography or financial constraints. The ability of a project to be replicated at other institutions will be a key consideration when reviewing projects. Projects that can be disseminated and impact a wide range of demographic groups will be a priority. Institution-specific information that would inform health-systems in other practices and settings should be provided. Partnerships between smaller and larger institutions are highly encouraged. 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 the grant 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. When developing an educational element applicants can find more information on principals of learning and behavior change for health professionals here. *It is not our intent to support clinical research projects. Projects evaluating the efficacy of therapeutic or diagnostic agents will not be considered.*
Target Audience:	Rheumatology healthcare professionals and colleagues involved in managing adult patients 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.[1] Though the progression of RA can vary greatly from patient to patient[2,3], joint damage occurs most rapidly during the first several years.[2-6] There is strong evidence suggesting clinical outcomes are improved by use of therapy, including reduction in joint signs and symptoms, improvement in physical function, inhibition of progression of joint damage, and reduction in long-term disability.[7] Additional evidence on therapeutic strategies has evolved over the last two decades that supports diagnosis and treatment very early in the course of disease, and treatment to a defined target such as clinical remission or low disease activity.[7] The impact of RA can be seen both in the significantly reduced patient quality of life due to joint damage[8], and in the financial burden of the disease.[9,10] Activities of daily living (ADLs) such as shopping, cleaning, bathing, socializing, and maintaining employment become difficult to perform for patients with RA with half of patients being unable to perform at least one ADL.[8,11,12] It has been estimated that the societal cost of RA reaches $39.2 billion annually.[9,10]
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.[13-15] • Healthy People 2020 lists a goal is to prevent illness and disability related to arthritis and other rheumatic conditions, osteoporosis, and chronic back conditions.[16] There are 9 objectives related to arthritis. **Related Guidelines and Recommendations** • 2012 update of the 2008 ACR recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of RA.[17]

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.[16] It has been noted that the early diagnosis of RA (within 3 months of disease onset) along with the rapid inception of therapy can significantly improve patient outcomes and minimize long-term disabilities.[5,6,18-21] The initial diagnosis of RA typically occurs in the primary care setting with referral to a rheumatologist for confirmation and management.[22,23] 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.[24,25]
Barriers:	Patient access to rheumatology care in some rural and underserved US communities is limited.[24] The limited access to rheumatic disease expertise can limit the use of recommended therapy in the US.[17,26]
Current National Efforts to Reduce Gaps:	The American College of Rheumatology has recently developed a website that assists rheumatologists in practice improvement, local population management, and efficient, successful participation in national quality programs.[27] • Rheumatology Clinical Registry o http://www.rheumatology.org/Practice/Clinical/Rcr/Rheumatology_Clinical_Registry/
Expected Approximate Monetary Range of Grant Applications:	Individual projects requesting up to $350,000 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: 5/7/2015 LOI due date: 7/15/2015 Please note the deadline is midnight Eastern Time (New York, GMT -5). Review of LOIs by External Review Panel: August 2015 Anticipated LOI Notification Date: 8/31/2015 Full Proposal Deadline: * 10/12/2015 *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: Oct/Nov 2015 Anticipated Full Proposal Notification Date: 11/30/2015 Grants distributed following execution of fully signed Letter of Agreement Period of Performance: January 2016 to July 2018
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: Facilitation of Dx 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 B. Connelly at (susan.connelly@pfizer.com), with the subject line "Facilitation of Dx in RA 5-7-15."
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:

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4. Lindqvist E, Jonsson K, Saxne T, Eberhardt K. Course of radiographic damage over 10 years in a cohort with early rheumatoid arthritis. *Ann Rheum Dis* 2003;62(7):611-616.
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13. ACR. Quality of Care. Available at: http://www.rheumatology.org/practice/clinical/quality/index.asp. Accessed April 1, 2015.
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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 (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 the 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 discernible 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 Pfizer will not make any payments to any individuals; grant funding shall be paid directly to Provider (sponsor).

   Frequently Asked Questions related to IGLC's Sunshine Act Reporting Requirements are available on our website (http://www.pfizer.com/files/IGLC_SunshineFAQ_Oct2014.pdf).

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.

9. For all research projects the institution(s) must agree to assume all responsibilities as sponsor of the study as outlined in the proposal, which includes:
    - Obtaining institutional review board (IRB)/independent ethics committee (IEC) approval for studies involving human subjects or human tissue and obtaining a subsequent renewal of this approval as required by local regulations (e.g., yearly, biannually, etc.). In addition, obtaining any IRB/IEC approval for amendments to protocol as they pertain to the research.
    - Obtaining all required personal data privacy or informed consent documentation (as appropriate).
    - Obtaining all required regulatory approval(s) per local regulations.
    - Assuming all reporting obligations to local regulatory authorities.
    - A statement that the research will be conducted in compliance with relevant provisions of the International Conference on Harmonisation, Good Clinical Practice, or Good Pharmacoepidemiology Practice guidelines and all applicable local legal and regulatory Requirements

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.
        - 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. 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.
    2. 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.
            - The inclusion of these costs cannot cause the amount requested to exceed the budget limit set forth in the RFP.
        - 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****.*