

**Pfizer Independent Grants for Learning & Change
Request for Proposals (RFP)
*Cardiovascular Risk in 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 healthcare professionals, patients, and Pfizer, through support of independent professional education activities. The term “independent” means 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 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 (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 project 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. Eligibility

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 (both large and small), professional associations and other not-for-profit entities with a mission related to healthcare improvement may apply.</p> <p>Collaborations within institutions, as well as between different institutions/organizations/associations, are encouraged; all partners should have a relevant role. Inter-professional collaborations that promote teamwork among institutions/organizations/associations are also encouraged. Please note the requesting organization should have a key role in the project.</p>

III. Requirements

Date RFP Issued:	2/14/2014
Clinical Area:	Cardiovascular (CV) risk assessment in rheumatoid arthritis (RA) patients.

Specific Area of Interest for this RFP:	<p>It is our intent to support projects that promote screening for and modification of modifiable cardiovascular risk factors in RA patients. The impact of screening and risk factor modification should be assessed, using existing measurement tools (e.g., patient history to determine age, gender, smoking history, exercise habits/physical activity level, presence of diabetes diagnosis/use of medications to control blood sugar, presence of hypertension diagnosis/use of medications to control blood pressure; patient examination to determine systolic blood pressure; lab testing to determine serum total cholesterol [TC], high density lipoprotein fraction of cholesterol [HDL], confirmatory fasting blood sugar, and high sensitivity C-reactive protein [hs-CRP]).¹⁻⁴</p> <p>Typically the above measurements are combined to generate an overall estimate for risk of coronary artery death or myocardial infarction (MI), or overall risk of broader categories of cardiovascular disease (CVD) events, including myocardial infarction (MI), stroke, transient ischemic attack (TIA), claudication, and heart failure, using tools such as the Framingham risk score¹, the Framingham/Adult Treatment Panel III (ATP III) risk score², the Framingham general cardiovascular risk score³, or the Reynolds risk score⁴.</p> <p>Successful proposals will include a plan for generating evidence of change in clinical outcomes. Given the long lead time needed to demonstrate changes in CVD endpoints, changes in clinical outcomes for this project should focus on process of care outcomes: documentation of initial/baseline CV risk scores, active management of/improvement in modifiable risk factors, and follow-up CV risk scores, using the same measures. The focus of screening and risk factor modification should be on modifiable risk factors (smoking; hypertension; overweight/obesity; insulin resistance/diabetes; dyslipidemia; physical inactivity) established for the general population, and generally accepted objectives:</p> <ul style="list-style-type: none">• Smoking cessation,• dietary/nutrition counseling and/or exercise and/or medication to lower blood pressure,• dietary/nutrition counseling and/or exercise and/or medication to lower blood sugar, and• dietary/nutrition counseling and/or medication to manage dyslipidemia.• Counseling to increase physical activity
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	<p>Increasingly, it has been recognized that efforts to modify cardiovascular risk factors are more successful when the interventions are tailored to the specific needs of individual patients. Adapting interventions on a patient level is further enhanced by recognizing that different behavioral change strategies may be helpful for patients of diverse and often underserved racial/ethnic groups.⁵ Applications that articulate a means to tailor projects to the patient level and adapt strategies to meet the needs of diverse and underserved groups are of particular interest.</p> <p>Multi-disciplinary collaborations are encouraged when appropriate, but all partners should have a relevant role. It is expected that projects will be evidence-based (education and/or quality improvement) and the proposed research/evaluation will follow generally accepted scientific principles. 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 the highest priority.</p> <p>There is a considerable amount of interest in receiving projects that utilize system-based changes. Although educational efforts for providers and patients may be entirely appropriate components in responses to this RFP, projects that include an overt description of system changes will be given the highest priority.</p>
Target Audience:	Rheumatology health care professionals
Disease Burden Overview:	<p>RA, the most prevalent type of inflammatory arthritis, affects more than 1.5 million adults in the U.S.⁶ RA is associated with premature mortality, and the leading cause of death in RA patients is CVD.⁷ The CV event risk over a 10-year period has been reported to be 50-60% higher in RA patients than in age- and sex-matched peers.⁷ The risk of MI, congestive heart failure (CHF), and CV-related death among patients with RA has been observed to be 2-3 fold higher than in the general population.⁸ Expressed in different terms, it appears that the CV event risk in RA patients is similar to the risk in patients without RA who are 5-10 years older.⁸</p> <p>The root of some of the association between RA and cardiovascular disease may lie in commonalities of the underlying pathogenesis of each condition, particularly increases in pro-inflammatory cytokines.^{9,10} Importantly though, established risk factors for CVD in the general population are also common among RA patients.^{11,12} Notably, the prevalence of modifiable risk factors is high, and these risk factors often go undetected, or if detected, frequently are not addressed.^{11,13}</p>

<p>Recommendations and Target Metrics:</p>	<p>Related Guidelines and Recommendations</p> <ul style="list-style-type: none"> • EULAR CV Risk Management Recommendations¹⁴ <ul style="list-style-type: none"> ○ Recommendations for cardiovascular risk management in patients with rheumatoid arthritis and other forms of inflammatory arthritis • ACCF/AHA CV Risk Guidelines¹⁵ <ul style="list-style-type: none"> ○ Guideline for assessment of CV risk in asymptomatic adults. <p>Modifiable CV risk factors: smoking, diabetes, hypertension, dyslipidemia</p> <ul style="list-style-type: none"> • Target metrics: <ul style="list-style-type: none"> ○ Documentation of smoking status, fasting blood sugar (and presence or absence of diabetes diagnosis), blood pressure (and presence or absence of hypertension diagnosis), and lipid measures (presence or absence of low levels of HDL and high levels of non-HDL cholesterol, high TC/HDL ratio). ○ Documentation of non-pharmacologic and pharmacologic management of modifiable cardiovascular risk factors
<p>Gaps Between Actual and Target, Possible Reasons for Gaps:</p>	<p>Despite the evidence of a strong association between RA and CVD,¹⁶ evidence suggests that efforts to screen for and manage modifiable CVD risk factors in RA patients are lagging.¹¹ Evidence-based recommendations for CV risk management in RA have been published by EULAR,¹⁴ and calls are increasing for a greater focus on assessing and managing CV risk factors in RA in the practice setting.^{11-12,14}</p>

<p>Barriers:</p>	<p>Numerous barriers appear to have limited progress on assessment and management of modifiable CV risk factors in RA patients, including lack of awareness of the relatively high prevalence of those risk factors, and gaps in communication between those responsible for assessing and managing co-morbid conditions in patients.^{11-12,14} Specifically, it may not always be clear who is responsible for screening and management of risk factors or overt comorbid conditions in patients with a clinically significant chronic disease such as RA that is typically managed by a specialist, the rheumatologist.^{11,17} Is it the primary care provider? The rheumatologist? Another specialist, such as a cardiologist, in the case of CVD? What role does/can the patient play in overcoming these potential barriers?</p> <p>Another recognized potential barrier is the difficulty encountered when health care providers attempt to induce behavior change using the same strategies across all types of patients, despite evidence that patients from diverse, often underserved groups may respond differently to different types of strategies.⁵</p>
<p>Current National Efforts to Reduce Gaps:</p>	<p>EULAR’s issuance of recommendations for CV risk management in RA patients is an important first step, in highlighting the need for assessment and management of modifiable CV risk factors.¹⁴ Questions remain about how best to modify or adapt more general risk indices to improve their specificity for determination of risk of CVD in RA, given that risk in RA likely reflects the combination of both inflammation and established CV risk factors.¹² However, based on what is now known about the clinical value of identifying and managing modifiable CV risk factors and the relative lack of attention to CV risk assessment and management in RA patients,^{11-12,14} studies on how to improve CV risk factor assessment and management in RA patients are clearly warranted.</p>
<p>Expected Approximate Monetary Range of Grant Applications:</p>	<p>Individual grants requesting up to \$500,000 will be considered. The total available budget related to this RFP is \$1,250,000.</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: 2/14/2014</p> <p>Letter of Intent due date: 3/26/2014</p> <p>Review of LOIs by External Review Panel: 4/4/2014 to 5/2/2014</p> <p>Anticipated LOI Notification Date: 5/5/2014</p> <p>Full Proposal Deadline: * 5/30/2014 *Only accepted LOIs will be invited to submit full proposals</p> <p>Review of Full Proposals by External Review Panel: 6/13/2014 to 7/30/2014</p> <p>Anticipated Full Proposal Notification Date: 7/31/2014</p> <p>Anticipated award delivered following execution of fully signed Letter of Agreement</p> <p>Period of Performance: Aug 2014 to Jan 2017</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 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.</p> <p>Select the following Area of Interest: CV Risk in RA 2014</p> <p>Requirements for submission: Complete all required sections of the online application and upload the completed LOI template (see Appendix).</p> <p>If you encounter any technical difficulties with the website, please click the "need support?" link at the bottom of the page</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 "CV Risk in RA 2-14-14."</p>
Mechanism by which Applicants will be Notified:	<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. Wilson PW, D'Agostino RB, Levy D et al Prediction of coronary heart disease using risk factor categories. Circulation 1998;97:1837-1847.

2. National Cholesterol Education Program [NCEP] Expert Panel on Detection, Evaluation, and Treatment of High Cholesterol in Adults (Adult Treatment Panel III. *Circulation* 2002;106:3143-3421.
3. D'Agostino RB Sr, Vasan RS, Pencina MJ et al. General cardiovascular risk profile for use in primary care: the Framingham Heart Study. *Circulation* 2008;117:743-753.
4. Ridker PM, Paynter NP, Rifai N, et al. C-reactive protein and parental history improve global cardiovascular risk prediction: the Reynolds Risk Score for men. *Circulation* 2008;118:2243-2251.
5. Stuart-Shor EM, Berra KA, Kamau MW, Kumanyika SK. Behavioral Strategies for Cardiovascular Risk Reduction in Diverse and Underserved Racial/Ethnic Groups. *Circulation*. 2012;125:171-184.
6. 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.
7. Bartels CM, Kind AJH, Everett C, et al. Low frequency of primary lipid screening among Medicare patients with rheumatoid arthritis. *Arthritis & Rheumatism* 2011;63:1221-1230.
8. Kremers HM, Crowson CS, Therneau TM, et al. High ten-year risk of cardiovascular disease in newly diagnosed rheumatoid arthritis patients. *Arthritis & Rheumatism* 2008;58:2268-2274.
9. Libby P, Ridker PM, Hansson GK. Inflammation in atherosclerosis: from pathophysiology to practice. *J Am Coll Cardiol* 2009;54:2129-2138.
10. McInnes IB, Schett G. The pathogenesis of rheumatoid arthritis. *New Engl J Med* 2011;365:2205-2219.
11. Chung CP, Giles JT, Petri M et al. Prevalence of traditional modifiable cardiovascular risk factors in patients with rheumatoid arthritis: comparison with control subjects from the multi-ethnic study of atherosclerosis. *Semin Arthritis Rheum* 2012;41: 535-544.
12. Crowson CS, Gabriel SE. Towards improving cardiovascular risk management in patients with rheumatoid arthritis: the need for accurate risk assessment. *Ann Rheum Dis* 2011;70:719-721.
13. van den Oever IAM, van Sijl AM, Nurmohamed MT. Management of cardiovascular risk in patients with rheumatoid arthritis: evidence and expert opinion. *Ther Adv Musculoskel Dis*. 2013;5(4):166–181.
14. Peters MJL, Symmons DPM, McCarey D et al. EULAR evidence-based recommendations for cardiovascular risk management in patients with rheumatoid arthritis and other forms of inflammatory arthritis. *Ann Rheum Dis* 2010;69:325-331.
15. Greenland P, Alpert JS, Beller GA, et al, American College of Cardiology Foundation, American Heart Association. 2010 ACCF/AHA guideline for assessment of cardiovascular risk in asymptomatic adults: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol* 2010;56:e50-103.
16. Kaplan MJ. Cardiovascular disease in rheumatoid arthritis. *Curr Opin Rheumatol* 2006;18:289-297.
17. Redelmeier DA, Tan SH, Booth GL. Treatment of unrelated disorders in patients with chronic medical diseases. *N Engl J Med* 1998;338:1516-1520.

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 Independent Grants for Learning & Change. 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 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).
6. To comply with the National Physician Payment Transparency Program (“Sunshine Act”), 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. 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 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 will be used for food and/or beverage for learners and/or participants in any capacity. Provider (sponsor) will be required to certify during final grant reconciliation that the funds were not used for food and/or beverage for learners and/or participants.

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.***

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. Describe how this goal aligns with the focus of the RFP, the goals of the applicant organizations and the proposed project.
- 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 encompass key aspects of project design and population but should also clearly describe the outcomes you expect to achieve as a result of conducting the project.
- D. Assessment of Need for the Project
 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 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.
 - If your methods include educational activities, please describe succinctly the content 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, etc., 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, 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. Project Timeline

I. Requested Budget

1. A total amount requested is the only information needed at this time.
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.

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).

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**.*