

**Pfizer Medical Education Group
Request for Proposals (RFP)
Cardiovascular Risk in Rheumatoid Arthritis:
Assessing the Impact of Screening**

I. Background

The mission of the Pfizer Medical Education Group 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 intent of this document is to encourage organizations with a focus in healthcare professional (HCP) 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 new RFP model is a two stage process: Stage 1 is the submission of the LOI. If, after review, your LOI is accepted, then you are 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 Medical Education Group website (www.Pfizermededgrants.com) as well as those of other relevant organizations and is sent via e-mail to internal lists of all registered organizations and users in our grants system.

II. Requirements

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| Date RFP Issued: | 7/25/2012 |
| Clinical Area: | Cardiovascular (CV) risk assessment in rheumatoid arthritis (RA) patients. |

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| Specific Area of Interest for this RFP: | <p>It is our intent to support programs that promote screening for cardiovascular risk factors in RA patients. The impact of this screening should be assessed, using existing measurement tools (e.g., patient history to determine age, gender, smoking history, 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 these measurements are used to generate an overall 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 program should focus on process of care outcomes: documentation of CV risk scores, active management of/improvement in modifiable risk factors:</p> <ul style="list-style-type: none">• smoking cessation,• dietary/nutrition planning and/or aerobic exercise and/or medication to lower blood sugar,• dietary/nutrition planning and/or aerobic exercise and/or medication to lower blood pressure, and• dietary/nutrition planning and/or medication to manage dyslipidemia. |
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| <p>Disease Burden Overview:</p> | <p>RA, the most prevalent type of inflammatory arthritis, affects more than 1.5 million adults in the U.S.⁵ RA is associated with premature mortality, and the leading cause of death in RA patients is CVD.⁶ 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.⁶ The risk of MI, congestive heart failure (CHF), and CV death among patients with RA has been observed to be 2-3 fold higher than in the general population.⁷ 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.⁷</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.^{8,9} Importantly though, established risk factors for CVD in the general population are also common among RA patients.^{10,11} Notably, the prevalence of modifiable risk factors is high, and these risk factors appear to go undetected frequently.¹⁰</p> |
| <p>Recommendations and Target Metrics:</p> | <p>Related Guidelines and Recommendations</p> <p>EULAR CV Risk Management Recommendations¹²</p> <ul style="list-style-type: none"> • Recommendations for cardiovascular risk management in patients with rheumatoid arthritis and other forms of inflammatory arthritis <p>ACCF/AHA CV Risk Guidelines¹³</p> <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> <p>Target metrics:</p> <ol style="list-style-type: none"> 1) 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). 2) Documentation of non-pharmacologic and pharmacologic management of modifiable cardiovascular risk factors |

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| Gaps Between Actual and Target and Possible Reasons for Gaps: | <p>Despite the evidence of a strong association between RA and CVD,¹⁴ evidence suggests that efforts to screen for and manage modifiable CVD risk factors in RA patients are lagging.¹⁰ Evidence-based recommendations for CV risk management in RA have been published by EULAR,¹² and calls are increasing for a greater focus on assessing and managing CV risk factors in RA in the practice setting.¹⁰⁻¹²</p> |
| Barriers: | <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.¹⁰⁻¹² 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.^{10,15} 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> |
| Current National Efforts to Reduce Gaps: | <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.¹² 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.¹¹ 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 on CV risk assessment and management in RA patients,¹⁰⁻¹² studies on how to improve CV risk factor assessment and management in RA patients are clearly warranted.</p> |
| Target Audience: | <p>Rheumatology health care professionals</p> |
| Geographic Scope: | <p><input checked="" type="checkbox"/> United States Only <input type="checkbox"/> International(specify country/countries)_____</p> |
| Applicant Eligibility Criteria: | <p>Medical, dental, nursing, allied health, and/or pharmacy professional schools, healthcare institutions, professional associations and other not-for-profit entities with a mission related to healthcare improvement may apply. Collaborations between schools within institutions, as well as between different institutions/organizations/associations, are encouraged. Inter-professional collaborations that promote teamwork among institutions/organizations/associations are also encouraged.</p> |

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| <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 \$1,500,000.</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> |
| <p>Key Dates:</p> | <p>RFP release date: 7/25/2012</p> <p>Questions regarding the RFP are due: 8/2/2012</p> <p>Responses to common questions will be posted on the PFE MEG RFP Web site: 8/8/2012</p> <p>Letter of Intent due date: 8/28/2012. <i>(Please note you must be registered in the system to submit an LOI. Please attempt to complete this process at least one week prior to submission in order to avoid delays as all registrations must be approved before access to the system is granted).</i></p> <p>Anticipated LOI Notification Date: 10/8/2012</p> <p>Please note, full proposals can only be submitted following acceptance of an LOI</p> <p>Full Proposal Deadline: To be communicated on acceptance of an LOI.</p> <p>Anticipated Full Proposal Notification Date: 12/14/2012</p> <p>Anticipated award delivered following execution of fully signed LOA.</p> <p>Period of Performance: 1/2013 to 7/2015</p> |
| <p>Mechanism by Which Applicants will be Notified:</p> | <p>All applicants will be notified via email by the dates noted above.</p> <p>Providers may be asked for additional clarification or to make a summary presentation during the review period.</p> |

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| <p>How to Submit:</p> | <p>Submit LOIs online via the Pfizer Medical Education Group website www.pfizermededgrants.com Submit LOIs in the clinical area: LOI-RFP Rheumatoid Arthritis. In the Program Name Field, please include the reference “RFP CV Risk in RA 7-25-12”</p> <p>Requirements for submission: If not already registered, register in the system to submit an LOI. Please attempt to complete this process at least one week prior to submission in order to avoid delays as all registrations must be approved before access to the system is granted.</p> <p>Complete all applicable sections of the online application and upload the completed LOI guidance template (<i>See Appendix</i>).</p> <p>Note that only certain sections/questions of the application are applicable to the Letter of Intent submission (<i>see details in LOI guidance below</i>).</p> |
| <p>Questions:</p> | <p>If you have questions, please submit them in writing so that, if appropriate, Questions and Answers can be posted on the website. Send questions to MedEdGrants@Pfizer.com with the subject line “RFP CV Risk in RA 7-25-12” Responses to common questions will be posted on the PFE MEG RFP Web site.</p> <p>Other communications may also be directed to the Education Director for this clinical area, Susan Connelly, via email Susan.Connelly@pfizer.com.</p> <p>You may also contact the Medical Education Group through e-mail (mededgrants@pfizer.com) or voicemail (1-866-MEG 4647).</p> |

References

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3. D’Agostino RB Sr, Vasani RS, Pencina MJ et al. General cardiovascular risk profile for use in primary care: the Framingham Heart Study. *Circulation* 2008;117:743-753.
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11. 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.
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14. Kaplan MJ. Cardiovascular disease in rheumatoid arthritis. *Curr Opin Rheumatol* 2006;18:289-297.
15. Redelmeier DA, Tan SH, Booth GL. Treatment of unrelated disorders in patients with chronic medical diseases. *N Engl J Med* 1998;338:1516-1520.

III. Terms and Conditions

1. Complete TERMS AND CONDITIONS for Certified and/or Independent Professional Healthcare Educational Activities are available upon submission of a grant application on the Medical Education Group website www.Pfizermededgrants.com.
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.
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 providers, all communications about the RFP must come exclusively to the Medical Education Group. Failure to comply will automatically disqualify providers.

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 requestor for the applicant 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 its medical education grants and support for medical and patient organizations in the United States. In the case of this RFP, a list of all LOIs selected to move forward will be publicly disclosed. In addition, all approved full proposals, as well as all resulting materials (e.g., status updates, outcomes reports etc) will be posted on the website.

Appendix : Letter of Intent Submission Guidance

LOIs should be single spaced using Calibri 12-point font and 1-inch margins. *Note that the main section of the LOI has a 3-page limit and the Organizational detail has a 1-page limit.*

LOIs will include the following sections

Main Section (not to exceed 3 pages):

A. Title

B. Goal

1. Briefly state the overall goal of the intervention

C. Objectives

1. List the objectives you plan to meet with your intervention both in terms of learning and expected outcomes

D. Assessment of Need for the Intervention

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 describes the problem). Describe the source and method used to collect the data. Describe how the data was analyzed to determine that a gap existed.
2. Describe the primary audience(s) who will directly utilize or benefit from the project outcomes and how the project outcomes might be broadly disseminated to the primary audience. Describe how you will determine if the target audience was fully engaged in the intervention.

E. Intervention Design and Methods

1. Describe the way the intervention planned addresses the established need and produces the desired results. Please provide a rational showing the desired results are feasible using the intervention being proposed

F. 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.
2. Identify the sources of data that you anticipate using to make the determination.
3. Describe how you expect to collect and analyze the data.
4. Identify the method used to control for other factors outside this intervention (e.g., use of a control group)

G. Preexisting Work

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. Describe

how this initiative builds upon existing work, pilot projects, or ongoing programs, etc

H. Project Timeline

I. Requested Amount

J. Additional Information

1. If there is any additional information you feel Pfizer should be aware of concerning the importance of this project, please note 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.

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.

*Please note the 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.***

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Common Questions and Answers

Program Scope

- ❖ *Clinical Research:* In reading through the RFP, process of care is emphasized, suggesting that Pfizer is seeking only projects related to quality research. I am wondering whether other types of clinical research studies not involving a process intervention would be considered.
 - The scope of Pfizer Medical Education Group funding does not include research evaluating the efficacy of any therapeutic interventions. Researchers seeking funding for studies of this nature can submit requests to our Investigator Initiated Research (IIR) group. There may be a perceived overlap and we are happy to provide feedback on specific scenarios.
- ❖ *PI-CME:* Regarding the RFP noted above, is a national performance improvement initiative acceptable for this submission?
 - It is possible for a national PI initiative to meet the scope of this RFP.

Although not received for this RFP, common questions submitted in response to past RFPs are included below.

Geographic Distribution

The RFP itself does not limit the size and requests of a broad range will be considered. Questions were modified to be applicable to this RFP.

- ❖ Would a state-specific program be acceptable or not? What about a regional program? National program? Local program?
 - The geographic scope of this RFP is only limited to the United States. Programs with national, regional, state, or local focus will all be considered. The impact on patient care will be a deciding factor.
- ❖ Is it more desirable to reach a limited number of learners with significant gaps; or, to reach a larger number of learners but have an overall smaller impact?
 - An interesting question, this is something that should be evaluated based on the needs of the specific population as well as the resources of the applicant. It is our hope that applicants will approach this in the way that best utilizes their resources to make the greatest impact on improving patient care.

Educational Partners

We received one question, in multiple formats, related to educational partners.

- ❖ In reference to the Applicant Eligibility Criteria, can you clarify if it is acceptable for corporations (for-profit organizations) to be involved as partners as long as a not-for-profit organization directly submits the grant?
 - Pfizer's policy regarding the elimination of all direct funding for CME/CE programs by commercial providers remains in effect. MECCs are not eligible to register and should continue to partner with other organizations on collaborative projects.

Budget

- ❖ What will the grant cover? Will it cover the salary, computer expenses, or travel?
 - Institutional overhead and indirect costs can 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.

Ongoing Programs

- ❖ Could we include ongoing interventions that have been implemented? Or does it have to be a future intervention?
 - Pfizer cannot retroactively fund programs that have already been implemented. Pfizer does encourage the use of pre-existing material in future programming if it appropriately addresses the identified need. Programs that build on previous or ongoing interventions will also be considered.

Timelines

- ❖ Is the 7/2015 end date for the funding timeline or educational timeline (e.g., can program evaluation/final reporting extend beyond that date)?
 - The final reporting can extend beyond 7/2015

Format and Layout

- ❖ The instructions state a 3-page limit to the main section of the LOI. Does this include references?
 - If extensive, references can be included on a separate page.
- ❖ Can an appendix be included within the LOI?
 - No. Aside from references the main section of the LOI should not exceed 3 pages and the organizational detail should not exceed 1 page. *A submission exceeding this limit WILL BE REJECTED and RETURNED UNREVIEWED.*