Pfizer Medical Education Group
Request for Proposals (RFP)
Rheumatoid Arthritis
Appropriate Immunizations in RA Patients

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 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, 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.pfizer.com/independentsupport) 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

Date RFP Issued:	12/20/2012
Clinical Area:	Immunization in Rheumatoid Arthritis (RA) Patients

Specific Area of Interest for this RFP:	It is our intent to support programs that focus on ensuring that patients with rheumatoid arthritis who are starting treatment with or are already being treated with disease-modifying anti-rheumatic drugs (DMARDs) are receiving appropriate vaccines for adults (determined by their age, gender, and specific clinical risk information such as having an immunocompromising condition like RA and going on immunomodulatory or immunosuppressant medications). <u>Category I</u> Grant support available for existing immunization initiatives. Eligible organizations may apply if they have a prior or ongoing project that addresses healthcare provider needs as it relates to increasing vaccination rates. Projects must have a proven track record of success with their educational methods and quality improvement approach. Documentation must be provided that the initiative has achieved success in the past and how additional funding can expand or improve the effort to specifically include patients with RA. Grant requests must not exceed $350,000. <u>Category II</u> Grant support available to individual hospitals or hospital networks for education and quality improvement programs that include implementation of and goals around the American College of Rheumatology recommendations on use of vaccines in RA patients who are starting or already taking nonbiologic or biologic DMARDs.[8] Grant requests must not exceed $100,000. <u>For all categories</u> Partnerships are encouraged when appropriate. During review the intended outcomes of the program are given careful consideration and, if appropriate based on the program goal, programs with the highest likelihood to directly impact patient care will be given the highest priority. One other aspect should be stressed. Existing studies have determined that educational efforts alone (targeted at healthcare providers and/or patients), while potentially useful/necessary, are not sufficient in and of themselves to produce substantial increases in vaccination rates.[5] There is high interest in receiving responses from programs that utilize system based changes (i.e. case management to identify RA patients and determine their vaccine status, generate steps to recommend and administer appropriate vaccines). Although educational efforts for providers and patients may be entirely appropriate components in responses to this RFP, programs that include an overt description of system changes will be given the highest priority.

Disease Burden Overview:	RA, the most prevalent type of inflammatory arthritis, affects more than 1.5 million adults in the U.S.[1] The association between RA and infections is well established, with the increased risk attributed to the pathobiology of the condition itself, the potential impact of comorbid conditions, and also the sequelae of using immunomodulatory or immunosuppressive disease-modifying therapies.[9] One possible means by which the risk of infection can be managed/reduced is appropriate use of vaccines. The Advisory Committee on Immunization Practices issues recommendations annually on appropriate immunization schedules for the general adult population, and also includes specific indications for adults with selected medical conditions.[2] The American College of Rheumatology also has included recommendations on use of vaccines in RA patients who are starting or already taking nonbiologic or biologic DMARDs.[8]

Recommendations and Target Metrics:	**Related Guidelines and Recommendations** • ACIP 2012 vaccination recommendations for adult immunocompromised patients include: influenza, pneumococcal, and in certain circumstances human papilloma virus (through age 21 for males, 26 for females), Hep B, Hep A, measles, mumps, rubella, meningococcal, and tetanus/diphtheria/pertussis booster; zoster vaccine recommended for those 60 or older and with selected chronic diseases but "contraindicated" in patients who are immunocompromised.[2] – Influenza vaccination rate for adults in 2010-11 was 40.5%.[3] – Pneumococcal vaccination rate among high risk adults 19-64 year olds in 2010 was 18.5%. Among those ≥ 65 the rate was 59.7%.[4] – Zoster vaccination rate among those ≥ 60 was 14.4%.[4] – Human papilloma virus vaccination rate among women 19-26 was 20.7%.[4] – Hepatitis B vaccination rates among 19-49 year old high risk persons was 42.0%.[4] • ACR 2012 Update to 2008 Recommendations included recommendation for the use of the following vaccines: pneumococcal, influenza (intramuscular), hepatitis B (all killed vaccines), human papilloma virus (recombinant vaccine), and herpes zoster (attenuated live vaccine).[8]

Gaps Between Actual and Target and Possible Reasons for Gaps:	• Despite ACIP and ACR recommendations on use of vaccines for adults in general and in immunocompromised patients, evidence suggests vaccination rates remain relatively low in rheumatology patients, including those with rheumatoid arthritis and other autoimmune conditions.
	  • Although studied infrequently, vaccination rates for influenza and pneumococcus remain relatively low in rheumatology patients (<70% and < 50%, respectively, in one health system, even after EMR prompts).[5]
	  • Although not well studied, herpes zoster vaccination rates in patients with autoimmune diseases such as RA remain low (< 5% in Medicare population).[6]
	  • New strategies (educational, system changes) are needed for improving vaccination rates in patients with rheumatoid arthritis, including those taking immunomodulatory therapies.[7]

Barriers:	A number of potential barriers have been identified that may limit achievement of higher vaccination rates, including lack of understanding of vaccine schedules/vaccination indications among RA patients, especially those taking immunomodulatory therapies, system communication and coordination issues (determination of which providers are responsible for ensuring appropriate vaccines are recommended/administered), patient understanding and acceptance of the role for vaccines in reducing infection risk.[5]
Current National Efforts to Reduce Gaps:	ACIP and ACR have issued recommendations on appropriate use of vaccines. The ACIP recommendations are for adults in general, and those with a range of medical conditions.[2] The ACR recommendations are specifically for patients with rheumatoid arthritis.[8] The ACR has also available *A Vaccination Primer for Rheumatologists* which address common questions and barriers to vaccination as it pertains to the practicing rheumatologist relating this to the ACIP recommendations.[10]
Target Audience:	Rheumatology healthcare professionals and colleagues involved in managing patients in conjunction with rheumatology healthcare professionals on a patient level and system level.
Geographic Scope:	☑ United States Only ☐ International(specify country/countries)_____

Applicant Eligibility Criteria:	Medical, dental, nursing, allied health, and/or pharmacy professional schools, healthcare institutions, professional associations and other 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.
Expected Approximate Monetary Range of Grant Applications:	Category I: Individual grants requesting up to $350,000 will be considered. Category II: Individual grants requesting up to $100,000 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 full proposal will depend upon the external review panel's evaluation of the proposal and costs involved and will be clearly stated in the grant approval notification.
Key Dates:	**RFP release date:** 12/20/2012 **Letter of Intent due date**: 2/7/2013 **Anticipated LOI Notification Date:** 3/15/2013 **Please note, full proposals can only be submitted following acceptance of an LOI** **Full Proposal Deadline:** To be communicated on acceptance of an LOI **Anticipated Full Proposal Notification Date:** 5/29/2013 **Anticipated award delivered following execution of fully signed LOA** **Period of Performance:** 7/2013 to 12/2015

How to Submit:	On or after January 2, 2013, please go to the website at www.pfizer.com/independentsupport and click on the button "Go to the Grant System". 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. Submit LOIs in the clinical area: LOI-Immunization in Rheumatoid Arthritis. **Requirements for submission:** Complete all required sections of the online application and upload the completed letter of intent template. (*see Appendix)*
Questions:	If you have questions regarding this RFP, please direct them in writing to the Education Director for this clinical area, Susan Connelly at (susan.connelly@pfizer.com), with the subject line "RFP Immunizations in RA 12-20-12"
Mechanism by Which Applicants will be Notified:	All applicants will be notified via email by the dates noted above. Providers may be asked for additional clarification or to make a summary presentation during the review period.

References:

1. 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.
2. MMWR 2012;61(04):1-7. Recommended Adult Immunization Schedule – United States, 2012.
3. MMWR 2011;60(22):737-743. Interim results: state-specific seasonal influenza vaccination coverage – US, August 2010-February 2011.
4. MMWR 2012;61 (04):66-72. Adult Vaccination Coverage – United States, 2010.
5. Ledwich L, Harrington TM, Ayoub WT, et al. Improved influenza and pneumococcal vaccination in rheumatology patients taking immunosuppressants using an electronic health record best practice alert. Arthritis Care Res 2009;61:1505-1510.
6. Zhang J, Delzell E, Xie F, et al. The use, safety, and effectiveness of herpes zoster vaccination in individuals with inflammatory and autoimmune diseases: a longitudinal observation study. Arthritis Res Ther 2011;13:R174.
7. Desai SP, Turchin A, Szent-Gyorgyi LE et al. Routinely measuring and reporting pneumococcal vaccination among immunosuppressed rheumatology outpatients: the first step in improving quality. Rheumatol 2011;50:366-372.

8. 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.
9. Listing J, Gerhold K, Zink A. The risk of infections associated with rheumatoid arthritis, with its comorbidity and treatment. Rheumatol 2012; Nov 28 (advance access e-publication).
10. Dao K, Cush JJ. A Vaccination Primer for Rheumatologists. *Drug Safety Quarterly*. 2012;4:1-2. Available at: http://www.rheumatology.org/publications/dsq/dsq_2012_01.pdf. Accessed December 10, 2012.

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.pfizer.com/independentsupport.

2. This RFP does not commit Pfizer to award a grant, or to pay any costs incurred in the preparation of a response to this request.

3. Pfizer reserves the right to accept or reject any or all applications received as a result of this request, or to cancel in part or in its entirety this RFP, if it is in the best interest of Pfizer to do so.

4. Pfizer reserves the right to announce the details of successful grant application(s) by whatever means insures transparency, such as on the Pfizer website, in presentations, and/or in other public media.

5. For compliance reasons and in fairness to all 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 education grants provided to medical, scientific and patient organizations in the United States. In the case of this

RFP, a list of all LOIs selected to move forward may be publicly disclosed. In addition, all approved full proposals, as well as all resulting materials (e.g., status updates, outcomes reports etc) may be posted on the Pfizer MEG 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. ***Any proposals not meeting these standards will not be considered.***

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 *overall* objectives you plan to meet with your intervention both in terms of learning and expected outcomes. Do not include learner objectives.

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 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 intervention. Please do not repeat this information within the LOI (you may reference the RFP if needed). Only include information that impacts your specific intervention, linking regional or local needs to those identified on the national basis if appropriate.

    2. Describe the primary audience(s) targeted for this intervention. Also indicate who you believe will directly benefit from the project outcomes..

E. Intervention Design and Methods
    1. Describe the planned intervention and the way it addresses the established need.
    2. Describe the overall population size as well as the size of your sample population.

F. Innovation
    1. Explain what measures you have taken to assure that this project idea is original and does not duplicate other programs or materials already developed.
    2. Describe how this initiative builds upon existing work, pilot projects, or ongoing programs, etc developed both by your institution or other institutions related to

this program

G. Design of Outcomes Evaluation
    1. Describe how you will determine if the practice gap identified in the needs assessment was addressed for the target group in terms of the metrics used for the needs assessment.
        - Identify the sources of data that 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 intervention (e.g., use of a control group, comparison with baseline data)
    b. Quantify the amount of change expected from this intervention in terms of your target audience
    c. Describe how you will determine if the target audience was fully engaged in the intervention.
    d. Describe how the project outcomes might be broadly disseminated.

H. Project Timeline

I. Requested Budget

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 and the leadership of the proposed intervention.

LOIs should be single spaced using Calibri 12-point font and 1-inch margins. There is a 3-page limit for the main section and 1 page limit for organizational detail. If extensive, references may be included on 1 additional page.

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****.*