Pfizer Independent Grants for Learning & Change
Request for Proposals (RFP)
Accelerating Improvements in Medication Optimization

1. Background

Pfizer Independent Grants for Learning & Change (IGLC) and the Institute for Healthcare Improvement (IHI) are collaborating to offer a new grant opportunity focused on medication optimization, a concept developed by IHI that is focused on four key areas for medication management: 1) optimal medication selection (including shared decisions that incorporate patient preferences and circumstances); 2) coordinated prescribing among providers; 3) clear timeframes for medication duration and follow-up; and 4) improved adherence.

Medication optimization recognizes that, in addition to the package of possible therapeutic recommendations, it is critical to take into consideration aspects of an individual’s life that impact medication adherence and management. The goal of this Request for Proposals (RFP) is to support the development of processes and practices that optimize medication prescribing for and treatment of patients with rheumatoid arthritis (RA).

The mission of IGLC is to partner with the global health care 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 grant recipient organization. Pfizer has no influence over any aspect of the funded projects and asks only for reports about the results and the impact of the projects in order to share them publicly.

The IHI is a leading innovator in health and health care improvement worldwide. For more than 25 years, IHI has partnered with visionaries, leaders, and frontline practitioners around the globe to spark bold, inventive ways to improve the health of individuals and populations. IHI is recognized as an innovator, convener, trustworthy partner, and driver of credible results based on scientific quality improvement methods. To advance its mission, IHI’s work is focused in five key areas: Improvement Capability; Person- and Family-Centered Care; Patient Safety; Quality, Cost, and Value; and Triple Aim for Populations. A strategic goal of IHI is to reduce disparities in health and health care, promoting equity in the US and globally. Learn more at ihi.org.

IGLC and IHI encourage organizations with an interest in improving management of RA, including medication optimization, to submit a letter of intent (LOI) in response to this RFP, which has two-stages. RFP Stage 1 is the submission of the LOI. After review of the LOI, you may be invited to submit a Full Grant Proposal. RFP Stage 2 is the submission of the Full Grant Proposal.

When a RFP is issued, it is posted on the Pfizer IGLC website (www.pfizer.com/independentgrants) in the Request for Proposals section and is sent via e-mail to all registered users in the Pfizer grants system. Some RFPs may also be posted on the websites of other relevant organizations, as deemed appropriate.
## II. Eligibility

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<th>Geographic Scope:</th>
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<td>☑ United States Only</td>
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<td>☐ International (specify country/countries)________________</td>
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**Applicant Eligibility Criteria:**

The following may apply: medical, nursing, allied health, and/or health care systems, pharmacy, professional schools, health care institutions, professional associations, and others with a mission related to health care improvement. Collaborations across providers, institutions, organizations, and associations are encouraged. Interprofessional collaborations that promote teamwork among institutions, communities, and state-based organizations and associations are also encouraged.


For programs offering credit, the requesting organization must be the accredited provider.

## III. Requirements

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<th>Date RFP Issued:</th>
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**Clinical Area:**

Medication optimization for adult rheumatoid arthritis patient populations

**Target Audience:**

Healthcare providers caring for adult patients with rheumatoid arthritis and the patients themselves

**Specific Area of Interest for this RFP:**

This RFP is focused on designing and evaluating innovative programs that optimize medication regimens for adult rheumatoid arthritis patients in any clinical setting in the United States. The intent is to support the development and adoption of approaches that lead to medication optimization resulting in treatment that has high therapeutic benefit, lower risk of harm, lower anxiety and emotional stress for patients, conforms to principles of patient- and family-centered care and shared decision making, and potentially lower overall costs of care.

Medication optimization can involve at least four key components:

1. Optimal medication selection
2. Coordinated prescribing among providers
3. Clear timeframes for medication duration and follow-up
4. Improved adherence.
It is expected that research projects will focus in on **one or more** of the above listed components and will follow generally accepted scientific principles. Applicants may utilize other helpful frameworks so long as their theory and research base is outlined in their proposal.

Projects that include the following factors will be given high priority:

- Utilization of scientific improvement principles and methods
  - Organizations may use a variety of improvement principles and or methods (e.g., Lean, Lean SixSigma, Model for Improvement.)

- Reducing disparities in the care of patients
  - IGLC and IHI place a high priority on reducing disparities in the care of patients with chronic conditions such as RA. To be considered, all proposals must indicate how the applicant will identify and address equity in the population it serves.

- Maximum likelihood to directly impact patient care
  - Projects with maximum likelihood to directly impact patient care will be given high priority. Projects should include an educational element to the research intervention. Find more information on principals of learning and behavior change for health professionals at: [www.pfizer.com/files/HealthProfessionalsLearningandBehaviorChange_AFewPrinciples.pdf](http://www.pfizer.com/files/HealthProfessionalsLearningandBehaviorChange_AFewPrinciples.pdf).

Grantees will conduct their own proposed medication optimization project. In addition, the grantee will participate in an IHI Collaborative Learning Network that will deepen their understanding of improvement science and enable innovative ideas and promising practices to be shared across all the grantees, to accelerate learning and spread of effective solutions. Regardless of the terminology for such learning networks (e.g., COINs, collaboratives, communities of practice), all have the common goals of rapidly identifying and testing innovative ideas and disseminating the specifications of these innovations so they can be tested, adapted, and adopted in diverse organizations. Using this model, a group of grantee organizations will work toward making improvements in a similar area — optimization of medications and management for patients with rheumatoid arthritis.
It is recognized that applicant organizations may already have access to scientific improvement expertise and resources, but applicants will have the option of accessing IHI’s improvement science resources to build their internal capability, including:

1. The IHI Open School – An interprofessional educational community that offers online courses developed by world-renowned faculty, which include case studies, podcasts, videos, and featured articles. The IHI Open School offers more than 25 courses in the following areas: Improvement Capability; Patient Safety; Leadership; Quality, Cost and Value; Person- and Family-Centered Care; and Triple Aim for Populations.

2. IHI Improvement Coach Professional Development Program – One member of each chosen grantee will participate in this program. The aim of the Improvement Coach program is to develop health care improvement acumen so that each participant can coach improvement teams and facilitate improvement strategies in their organization. (Travel costs for one person to attend this program are included in the granting opportunity.)

We anticipate that the convergence of a group of high-quality research projects, rigorous training in improvement science methods, and a facilitated Collaborative Learning Network will accelerate innovation, leading to improved medication optimization and adherence to therapeutic regimens for RA — knowledge and practices that can be shared rapidly among all grantees, leading to improved clinical outcomes, reduced cost, and reduction in avoidable hospital admissions.

It is not our intent to support clinical research projects that seek to evaluate new therapeutic or diagnostic modalities. Projects evaluating the efficacy of therapeutic or diagnostic agents will not be considered.

Information on how to submit requests for support of clinical research projects can be found at www.Pfizer.com/iir.
Disease Burden Overview:

According to the CDC, an estimated 1.5 million Americans suffer from rheumatoid arthritis, a chronic inflammatory condition that impacts many systems, joint, eye, lung, blood vessels and heart with women diagnosed more and at a growing rate. Treatment for RA generally involves medications in the following categories: disease-modifying anti-rheumatic drugs (DMARDs), biologic response modifiers (a type of DMARD), JAK inhibitors, glucocorticoids, nonsteroidal anti-inflammatory medications (NSAIDs), and analgesics (painkillers). It often takes months for patients and prescribers to identify a medication regimen that can successfully treat their RA. Once identified, a regimen may need frequent modification over time to preserve its clinical effectiveness in an individual patient.

A number of factors affect a patient’s adherence to the regimen. A study in the *Journal of American Geriatrics Society* found that “a busy lifestyle and middle age were more determinant of who was at risk of non-adherence.” A study by the British Society for Rheumatology Biologics Register (BSRBR) for RA found patients treated with certain medications to be most influenced by illness and treatment beliefs. The BSRBR study concluded that “wider recognition of the importance of psychological factors, particularly medication beliefs, in driving medication adherence could have a substantial clinical and health economic benefit,” for patients with rheumatoid arthritis. Without health professional and family support, however, up to one quarter of RA patients practiced only low to moderate adherence to the prescription medication.

The risk for patient harm rises with an increasing number of medications, greater numbers of comorbidities, and increasing number of involved prescribers. Patients living with RA suffer from other chronic conditions at a very high rate and multiple chronic conditions may impact treatment decisions and effectiveness of treatment for patients. ADEs are common in patients with chronic conditions with multiple pharmaceutical classes such as RA and osteoarthritis. Medications for these other chronic conditions often interact with RA medications, leading to scenarios that may result in exposure to risk of iatrogenic harm or complication, or diminished therapeutic benefit. In addition, the burden of multiple chronic diseases adds emotional stress and anxiety and may complicate individual efforts to adhere to complex drug regimens.

Even without complications from additional medications, adherence rates for RA patients can vary wildly. A literature review spanning 10 years of published rates of adherence with nonbiologic DMARDs reported 1-year rates of adherence ranging from 30% to 81%. Similarly, 2 systematic reviews of adherence and persistence to biologic DMARDs for RA reported 1-year adherence rates ranging from 32% to 91% and 32% to 81%. Additionally, rates of adherence decrease with an increasing number of medications.
Recommendations and Target Metrics:

RFP applicants should consider a measurement strategy that contains the following outcomes:

- Optimal medication selection
- Improved adherence
- Adverse drug events
- Coordinated prescribing among providers
- Clear timeframes for medication duration and follow-up

Gaps Between Actual and Target, Possible Reasons for Gaps:

Research on medication adherence and optimization has identified evidence-based factors that correlate with a high level of risk of non-adherence among patients. These factors can be thought of in two categories: those imposed by the health care system and those imposed by the patient’s context and personal circumstances.

**Health Care System Factors:**

- Patients on five or more medications\textsuperscript{12,13,14,15}
- Multiple providers writing prescriptions\textsuperscript{16,17,18}
- Prescribed high-risk medications (hormones, anti-depressants, anti-coagulants, opioids)\textsuperscript{19,20}
- The strength of the patient/provider relationship\textsuperscript{21,22,23}
- Patients with three or more comorbid conditions\textsuperscript{24,25,26}

**Patient Context and Personal Factors:**

- Presence of memory/cognitive impairment\textsuperscript{27,28}
- Financial stress\textsuperscript{29,30}
- Behavioral health/mental health needs\textsuperscript{31,32,33}
- Ability to engage in decision making; level of understanding of health\textsuperscript{34,35,36}
- Level of social/family support\textsuperscript{37,38,39,40,41}

To achieve medication optimization the provider and the patient need a shared understanding of the level of risk, possible mitigation factors, and a strategy for executing an effective therapeutic plan.

Expected Approximate Monetary Range of Grant Applications:

Individual projects requesting up to $300,000 will be considered. The total available budget related to this RFP is $1,000,000.

The amount of the grant Pfizer is prepared to fund for any project will depend on the external review panel’s evaluation of the proposal and estimated costs involved, and will be stated clearly in the approval notification.
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<th><strong>Key Dates:</strong></th>
<th>RFP release date: June 2, 2016</th>
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<tr>
<td></td>
<td>All questions due: June 15, 2016</td>
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<td>Letter of Intent (LOI) due: August 1, 2016</td>
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<td>Please note the deadline is midnight Eastern Time (New York, GMT -5 hours).</td>
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<td>Review of LOIs by External Review Panel: TBD</td>
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<td>Applicants notified/Full Grant Submission Invitations: September 1, 2016</td>
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<td>Full Grant Proposals Due (to be communicated on acceptance of LOI): October 3, 2016</td>
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<td>Review of Full Grant Proposals by External Review Panel: TBD</td>
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<td>Notification of Decisions: November 10-20, 2016</td>
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<td>Funded Projects Start: January 1, 2017</td>
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<td>Grants will be distributed following execution of fully signed Letter of Agreement.</td>
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<td>Period of Performance: January 2017 to January 2019</td>
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<th><strong>How to Submit an RFP:</strong></th>
<th>LOIs are submitted through the IGLC Grant Management System (GMS).</th>
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<td></td>
<td>Please go to the website <a href="http://www.cybergrants.com/pfizer/loi">www.cybergrants.com/pfizer/loi</a> to submit.</td>
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<td>If you are a first-time user, please click “REGISTER NOW”.</td>
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<td>Select the following Area of Interest: <em>Accelerating Improvements in Medication Optimization</em>.</td>
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<td>Requirements for submission: Complete all required sections of the online application and upload the completed LOI template (see Appendix).</td>
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<td>If you encounter any technical difficulties with the website, please click the “Need Support?” link at the bottom of the page.</td>
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| **Questions:** | If you have questions regarding this RFP, please direct them in writing to the Grant Officers, Susan Connelly ([Susan.Connelly@pfizer.com](mailto:Susan.Connelly@pfizer.com)) or Jennifer Lenoci-Edwrads ([jlenoci-edwards@ihi.org](mailto:jlenoci-edwards@ihi.org)) with the subject line “*Accelerating Improvements in Medication Optimization, June 2, 2016.*” |
**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.

**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 IGLC. 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 IGLC 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/IGLCsunshineFAQ_updatedJan2016.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 Dissemination and Implementation 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.

LOIs should include the following sections.

Main Section (not to exceed 3 pages):

A. Title

B. Goal and Objectives
   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).
   2. List the overall objectives you plan to meet with your project both in terms of learning and expected outcomes. Objectives should describe the target population as well as the outcomes you expect to achieve as a result of conducting the project.

C. 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. If a full analysis has not yet been conducted, please include a description of your plan to obtain this information.

D. Target Audience
   1. 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 and rationale for the sample size.

E. Project Design and Methods
   1. Please describe the overall primary outcome measure and any additional measures that will be part of the measurement and evaluation scheme for the project.
      - Proposed Project Design: Quality improvement projects should be described in terms of generally accepted principles of improvement science. We recognize a variety of rigorous approaches to scientific improvement, and organizations may use different terminology to describe the science (e.g., improvement science, implementation science, health care delivery science) and methods (e.g., Lean, Lean SixSigma, Model for Improvement).
      - The projects should include a component of education using generally accepted principals of adult learning. More information on principals of learning and behavior change for health professionals can be found at: [www.pfizer.com/files/HealthProfessionalsLearningandBehaviorChange_AFewPrinciples.pdf](http://www.pfizer.com/files/HealthProfessionalsLearningandBehaviorChange_AFewPrinciples.pdf).
   2. Describe the planned intervention that will be tested in the research project and the way it addresses the established need.
3. If your methods include educational activities, please describe succinctly the topic(s) and format of those activities.
4. Describe the experimental design of the project — how many patients will be part of the intervention, will there be a control group, how will participant selection be done.

F. Innovation
1. Explain how 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. Evaluation and Outcomes
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. Describe how you expect to collect and analyze the data.
2. Quantify the amount of change expected from this project in terms of your target audience.
3. Describe how the project outcomes will 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 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 Grant 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.**

4. Park et al. (1999)


Field et al (2004), “Risk factors for adverse drug events among nursing home residents,” Archives of Internal Medicine


Piette et al (2005), “The Role of Patient-Physician Trust in Moderating Medication Nonadherence Due to Cost Pressures,” JAMA Internal Medicine


Field et al. (2004)


Gertler et al (2014)


Barat et al (2001)