

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

**I. 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](http://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](http://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

<b>Geographic Scope:</b>	<input checked="" type="checkbox"/> United States Only <input type="checkbox"/> International (specify country/countries)_____
<b>Applicant Eligibility Criteria:</b>	<p>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.</p> <p>More information on organizations eligible to apply directly for a grant can be found at: <a href="http://www.pfizer.com/files/IGLC_OrganizationEligibility_effJuly2015.pdf">http://www.pfizer.com/files/IGLC_OrganizationEligibility_effJuly2015.pdf</a>.</p> <p>For programs offering credit, the requesting organization must be the accredited provider.</p>

## III. Requirements

<b>Date RFP Issued:</b>	Oct 7, 2016
<b>Clinical Area:</b>	Medication optimization for adult rheumatoid arthritis patient populations
<b>Target Audience:</b>	Healthcare providers caring for adult patients with rheumatoid arthritis and the patients themselves
<b>Specific Area of Interest for this RFP:</b>	<p>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.</p> <p>Medication optimization can involve at least four key components:</p> <ol style="list-style-type: none"><li>1. Optimal medication selection</li><li>2. Coordinated prescribing among providers</li><li>3. Clear timeframes for medication duration and follow-up</li><li>4. Improved adherence.</li></ol>

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](http://www.Pfizer.com/iir).

<b>Disease Burden Overview:</b>	<p>According to the CDC, an estimated 1.5 million Americans suffer from rheumatoid arthritis<sup>1</sup>, 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.</p> <p>A number of factors affect a patient’s adherence to the regimen. A study in the <i>Journal of American Geriatrics Society</i> found that “a busy lifestyle and middle age were more determinant of who was at risk of non-adherence.”<sup>2</sup> 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.<sup>3</sup> 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.<sup>4</sup></p> <p>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<sup>5</sup> and multiple chronic conditions may impact treatment decisions and effectiveness of treatment for patients.<sup>6</sup> ADEs are common in patients with chronic conditions with multiple pharmaceutical classes such as RA and osteoarthritis<sup>7</sup>. 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.</p> <p>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%<sup>8</sup> . Similarly, 2 systematic reviews of adherence and persistence to biologic DMARDs for RA reported 1-year adherence rates ranging from 32% to 91%<sup>9</sup> and 32% to 81%<sup>10</sup>. Additionally, rates of adherence decrease with an increasing number of medications.<sup>11</sup></p>
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<p><b>Recommendations and Target Metrics:</b></p>	<p>RFP applicants should consider a measurement strategy that contains the following outcomes:</p> <ul style="list-style-type: none"> <li>• Optimal medication selection</li> <li>• Improved adherence</li> <li>• Adverse drug events</li> <li>• Coordinated prescribing among providers</li> <li>• Clear timeframes for medication duration and follow-up</li> </ul>
<p><b>Gaps Between Actual and Target, Possible Reasons for Gaps:</b></p>	<p>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.</p> <p><b>Health Care System Factors:</b></p> <ul style="list-style-type: none"> <li>• Patients on five or more medications<sup>12,13,14,15</sup></li> <li>• Multiple providers writing prescriptions<sup>16,17,18</sup></li> <li>• Prescribed high-risk medications (hormones, anti-depressants, anti-coagulants, opioids)<sup>19,20</sup></li> <li>• The strength of the patient/provider relationship<sup>21,22,23</sup></li> <li>• Patients with three or more comorbid conditions<sup>24,25,26</sup></li> </ul> <p><b>Patient Context and Personal Factors:</b></p> <ul style="list-style-type: none"> <li>• Presence of memory/cognitive impairment<sup>27,28</sup></li> <li>• Financial stress<sup>29,30</sup></li> <li>• Behavioral health/mental health needs<sup>31,32,33</sup></li> <li>• Ability to engage in decision making; level of understanding of health<sup>34,35,36</sup></li> <li>• Level of social/family support<sup>37,38,39,40,41</sup></li> </ul> <p>To achieve <i>medication optimization</i> 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.</p>
<p><b>Expected Approximate Monetary Range of Grant Applications:</b></p>	<p>Individual projects requesting up to \$200,000 will be considered. The total available budget related to this RFP is \$1,000,000.</p> <p>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.</p>

<p><b>Key Dates:</b></p>	<p>RFP release date: October 7, 2016</p> <p>All questions due:</p> <p>Note there will be no LOI stage for this RFP</p> <p>Full Grant Proposals Due: Nov 4, 2016</p> <p>Review of Full Grant Proposals by External Review Panel: TBD</p> <p>Notification of Decisions: Dec 15, 2016</p> <p>Funded Projects Start: January 1, 2017</p> <p>Grants will be distributed following execution of fully signed Letter of Agreement.</p> <p>Period of Performance: January 2017 to January 2019</p>						
<p><b>How to Submit an RFP:</b></p>	<p>Proposals are submitted through the IGLC Grant Management System (GMS).</p> <p>Please go to the website <a href="http://www.cybergrants.com/pfizer/loi">www.cybergrants.com/pfizer/loi</a> to submit.</p> <p>If you are a first-time user, please click "REGISTER NOW".</p> <p>Select the following Area of Interest: <b><i>Accelerating Improvements in Medication Optimization</i></b>.</p> <p>Requirements for submission: Be advised the grant system is designed for a two-stage submission process: 1) Letter of Intent and 2) Full Proposal. However, for this RFP, we are not using a Letter of Intent. Instead, there will only be one stage, during which the Full Proposal and budget will be submitted. Complete all required sections of the online application. In the "Required Uploads" section, please follow the table below.</p> <table border="1" data-bbox="467 1440 1227 1549"> <tr> <td>For Field Name:</td> <td>Please upload:</td> </tr> <tr> <td>Letter of Intent</td> <td>Full Proposal</td> </tr> <tr> <td>LOI Additional Required Uploads</td> <td>Budget</td> </tr> </table> <p>Once you have submitted your request, it will be converted to a full proposal and sent back to you to complete additional sections concerning Sunshine Act reporting and payee information. You will have two business days to complete the additional sections.</p> <p>If you encounter any technical difficulties with the website, please click the "Need Support?" link at the bottom of the page.</p>	For Field Name:	Please upload:	Letter of Intent	Full Proposal	LOI Additional Required Uploads	Budget
For Field Name:	Please upload:						
Letter of Intent	Full Proposal						
LOI Additional Required Uploads	Budget						

<b>Questions:</b>	If you have questions regarding this RFP, please direct them in writing to the Grant Officers, Susan Connelly ( <a href="mailto:Susan.Connelly@pfizer.com">Susan.Connelly@pfizer.com</a> ) or Jennifer Lenoci-Edwards ( <a href="mailto:jlenoci-edwards@ihi.org">jlenoci-edwards@ihi.org</a> ) with the subject line <b><i>“Accelerating Improvements in Medication Optimization, Oct 7, 2016.”</i></b>
<b>Mechanism by which Applicants will be Notified:</b>	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 ensure compliance with applicable local law, Pfizer may publicly disclose the support it provides. Pfizer may disclose in any lawful manner the terms of the letter of agreement, the support or funding that Pfizer is providing under the letter of agreement, and any other related information, to the extent necessary for Pfizer to meet its obligations under those laws, regulations and industry codes that require Pfizer to report payments or other transfers of value to certain healthcare professionals and teaching hospitals (collectively, the “Transparency Laws”). Transparency Laws include, without limitation, section 6002 of the U.S. Affordable Care Act and the EFPIA Code on Disclosure of Transfers of Value. Disclosures may include identifying information for organizations and U.S. physicians, such as name, business address, specialty,



National Provider Identifier (NPI), and licensure numbers. Grantee will agree to (and will cause other agents, employees and contractors to) reasonably cooperate with Pfizer in Pfizer's collection and disclosure of information to fulfill its Transparency Law obligations. Grantee will provide Pfizer with complete and accurate information about payments or other transfers of value reportable under Transparency Laws.

Frequently Asked Questions related to IGLC's Sunshine Act Reporting Requirements are available on our website ([http://www.pfizer.com/files/IGLCsunshineFAQ\\_updatedJan2016.pdf](http://www.pfizer.com/files/IGLCsunshineFAQ_updatedJan2016.pdf)).

7. No portion of an independent grant may be used for food and/or beverages for learners and/or participants in any capacity. Grantee 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 Grantee 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 A: Full Proposal Submission Guidance**

**Background: Specific Area of Interest:** 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.

High priority is given to projects that are structured to use quality improvement approaches to:

- Directly impact patient care and
- Reducing disparities in the care of patients

The intent of this RFP is to use rigorous quality improvement to address medication optimization for patients with rheumatoid arthritis. For this proposal to be funded in a timely fashion (January 1, 2017), it is important that the proposal be written using a quality improvement design. Please see the attached ***Criteria for Distinguishing Rigorous QI from Research*** in Appendix C for design assistance.

Proposals must be single-spaced, using Calibri 12-point font and 1-inch margins. Note that the main section (section C, below) of the proposal has a 15-page limit and the organization detail (section E, below) has a 3-page limit. **Please limit the number of attachments uploaded in the system.** There is no reason to submit the organization detail (section E) as a separate document from the main section (section C) of the proposal. **All proposals must follow the outline detailed below.**

Proposal requirements will include the following sections:

**A. Cover Page** (do not exceed 1 page):

1. **Title:** *Please include the project title, Grant ID number and main collaborators.*
2. **Abstract:** *Please include an abstract summary of your proposal including the overall goal, target population, methods and assessment. Please limit this to 250 words.*

**B. Table of Contents** (no page limit)

**C. Main Section of the proposal** (not to exceed 15 pages):

1. **Overall Goal & Objectives:** *Describe the overall goal for this project. Describe how this goal aligns with the focus of medication optimization for patients with rheumatoid arthritis, the goals of the applicant organizations and the proposed project. List the **key** objectives and how they are intended to address the established need for this project.*
2. **Current Assessment of need in target area**
  - a. *Describe the need for medication optimization in your target area. Only include information that impacts your specific project, linking regional or local needs to those identified on the national basis if appropriate. Describe the need for your project in terms of “what is” versus “what should be”.*

- b. 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) 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.
3. **Target Audience:** Describe the primary audience(s) targeted for this project.
- Describe the level of commitment from the potential participants including your plan for recruitment as necessary.
  - Demonstrate the scope of your target audience has a potential to impact the goal established in this proposal.
  - Describe who will directly benefit from the project outcomes. Include in this description whom, beyond the primary target, would potentially benefit from the project in terms of this being a model for others to replicate or expand. To be considered, all proposals must indicate how the applicant will identify and address equity in the population it serves.
4. **Project Design and Methods:** Describe your project design and methods.
- Include a description of the overall strategy, methodology and analysis linking them to the goal of the project. Articulate which of the four key areas for medication optimization will be impacted by your project: 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.
  - Describe the way the project planned addresses the established need and produces the desired results.
  - Indicate how you will determine if the target audience was fully engaged in the project.
  - Articulate how you intent to address disparities in health and health care through this work.
  - Include a description of the measures you have taken to assure that this project idea is original and does not duplicate other projects or materials already developed.
  - If appropriate, show how this project builds upon existing work, pilot projects, or ongoing projects developed either by your institution or other institutions related to this project.
  - If your project includes the development of tools note if they be available publically at no cost.
5. **Evaluation Design**
- In terms of the metrics used to assess the need for this project, describe how you will determine if the practice gap was addressed for the target group.
    - Identify the sources of data that you anticipate using to make the determination.
    - Describe how you expect to collect and analyze the data.
    - Describe how you will determine if the results evaluated are directly related to the intervention described in this proposal.
    - Describe how you will track balancing measures to ensure your work does not unintentionally impact another area.

- Describe how you will know if your changes are leading to an improvement over time rather than at a single point in time at the conclusion of the proposal time period.
  - b. Quantify the amount of change expected from this project in terms of your target audience (e.g., a 10% increase over baseline or a decrease in utilization from baseline between 20-40%)
  - c. Describe how you plan for the project outcomes to be broadly disseminated. This includes scaling up within your organization and spread beyond your organization.
6. **Detailed Workplan and Deliverables Schedule:** Include a narrative (which counts toward the 15-page limit) describing the workplan and outlining how the project will be implemented over the X-year period. Using a table format (no page limit), list the deliverables and a schedule for completion of each deliverable.

**D. References (no page limit)**

**E. Organizational Detail (not to exceed 3 pages)**

1. **Organizational Capability:** Describe the attributes of the institution(s)/organization(s)/association(s) that will support and facilitate the execution of the project.
2. **Leadership and Staff Capacity:** Include the name of the person(s) responsible for this project (PI/ project lead (PL) and/or project manager). The project manager, whether a current staff member or someone to be hired, is essential to the work outlined in your proposal. Demonstrate the PI/PL and project manager's availability, commitment, and capability to plan, implement, and evaluate the proposed project; describe how the project manager will oversee the project activities, including ensuring that tasks are accomplished as planned.
  - a. List other key staff members proposed on the project (e.g., healthcare provider champion, medical advisor, statisticians, IT lead, etc.), if relevant, including their roles and expertise. Please list out key staff for each institution/organization/association the specific role that they will undertake to meet the goals of this project.
  - b. Please describe how you will include the voice of the patient in your planning and execution.
  - c. When listing staff, please include staff first name, last name, professional credentials, and Country of Residence.
  - d. NOTE Regarding Proposed Speakers: Pfizer shall not provide funding of CME when Pfizer has knowledge at the time of the decision to fund CME that a proposed CME faculty member has conducted a promotional speaking engagement on similar topic(s) on behalf of Pfizer in the past 12 months.

**F. Detailed Budget** (Refer to/Complete **Budget Template**; no page limit for the Excel file or the narrative):

1. Upload a detailed budget, using the Excel template provided. Applicants are expected to customize the budget for their proposal, adding additional details and deliverables as appropriate.
2. Provide **a written narrative** that contains a detailed explanation of each cost element proposed. Budget narratives should include a justification for all personnel, indicating the percentage of time allocated to the project. The budget should demonstrate appropriate and reasonable costs for project expenses.
3. Pfizer maintains a company-wide, maximum allowed overhead rate of 28% for independent studies and projects.
  - *Institutional Overhead Costs: Costs to the institution for the support of your project. Examples include human resources department costs, payroll processing and accounting costs, janitorial services, utilities, property taxes, property and liability insurance, and building maintenance.*
4. Some examples of what awarded funds may **not** be used for are listed below:
  - Office equipment (e.g., furniture, computers)
  - Registration and travel costs for professional development meetings or courses not related to this project
  - Health care subsidies for individuals
  - Construction or renovation of facilities
  - Therapeutic agents (prescription or non-prescription)
  - Food and/or beverages for learners and/or participants in any capacity
  - Lobbying

**G. Staff Biosketches** (no page limit):

*Applicants must provide brief biosketches of all individuals listed in section E in an appendix. NIH Biosketches are an acceptable format but not required.*

**H. Letter(s) of Commitment** (no page limit):

*Letter(s) must be provided from all organizations listed in section E documenting their support and commitment to the project. Letters should be issued from an institutional authority or authorities and collaborators guaranteeing access, resources and personnel (as the case may be) for proposed project.*

**Submission:** Proposals should be submitted online via the Pfizer Independent Grants for Learning & Change website [www.pfizer.com/independentgrants](http://www.pfizer.com/independentgrants)

**Proposals should be single-spaced using Calibri 12-point font and 1-inch margins. Please adhere to the page limits listed for each section.** There is no page limit for the reference section. Tables and Figures should be included in the main section of your proposal and do count to the page count. Only sample forms or other full page documents can be included as an appendix. Please consult with the Grant Officer before submitting such additional documents.

All required sections (aside from the budget) 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 full proposal. Budgets should be submitted in a separate excel file.

## Appendix B: Full Proposal Review and Scoring

Below please find a table illustrating the general guidance the review panel uses when evaluating your submission.

	<b>Maximum Score</b>	<b>Guiding Questions for Evaluation Criteria</b>
<b>Project Goals and Objectives</b>	15%	<ul style="list-style-type: none"> <li>• Is the goal in line with the specific area of interest for the RFP?</li> <li>• Is the goal clearly stated?</li> <li>• Does the project goal address an important problem or a critical barrier to progress in the field?</li> <li>• Does the goal illustrate an innovative approach that does not replicate other efforts?</li> <li>• Are SMART (specific, measurable, attainable, relevant and time-bound) objectives used?</li> </ul>
<b>Target Audience Alignment</b>	10%	<ul style="list-style-type: none"> <li>• Is the primary audience(s) targeted for this project well described and appropriate?</li> <li>• Does the description adequately address the commitment of the potential participants?</li> <li>• As described, is the proposed scope of the target audience large enough to significantly impact the gap identified?</li> <li>• Beyond the primary target audience, will others potentially benefit from the project in terms of this being a model for others to replicate or expand?</li> <li>• Are issues of health and health care equity addressed by this proposal?</li> </ul>
<b>Project Design and Methods</b>	20%	<ul style="list-style-type: none"> <li>• Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific goal(s) of the project?</li> <li>• Did the request adequately describe the way the project planned addresses the established need and produces the desired results?</li> <li>• Is the project designed in a way that will fully engage the target audience?</li> <li>• Does the proposal explain what measures have been taken to assure that this project idea is original and does not duplicate other programs or materials already developed?</li> <li>• Does the proposal describe how this initiative builds upon existing work, pilot projects, or ongoing programs, etc., developed either by the sponsoring institution or other institutions related to this program?</li> <li>• If the proposal includes the development of tools, will they be available publically at no cost?</li> </ul>
<b>Assessment Methodology (Needs Assessment and Program</b>	30%	<ul style="list-style-type: none"> <li>• Does the proposal build upon the need described in the RFP and identify specific regional or local needs relevant to the target group?</li> <li>• Does the proposal describe the data source, method and</li> </ul>

	<b>Maximum Score</b>	<b>Guiding Questions for Evaluation Criteria</b>
<b>Evaluation)</b>		<p>analysis used to determine that a gap exists?</p> <ul style="list-style-type: none"> <li>• Does the proposal include quantitative baseline data summary, initial metrics, or project starting point in the target area?</li> <li>• Does the proposal describe how the practice gap identified in the needs assessment will be addressed for the target group?</li> <li>• Will the project achieve measurable outcomes in terms of improved clinical practice or patient impact?</li> <li>• Does the proposal quantify the amount of change expected from this project in terms of their target audience?</li> <li>• Does the proposal describe the data source, method and analysis that will be used to evaluate the impact of this project?</li> <li>• Does the proposal identify the method used to control for other factors outside this project (e.g., use of a control group)?</li> <li>• Does the proposal include a plan for the project outcomes to be broadly disseminated?</li> </ul>
<b>Detailed Workplan and Deliverables Schedule</b>	5%	<ul style="list-style-type: none"> <li>• Is the completion schedule for each deliverable realistic?</li> <li>• Is the tactical project plan detailed and appropriate?</li> </ul>
<b>Organizational Capability, Leadership &amp; Staff Capacity</b>	10%	<ul style="list-style-type: none"> <li>• Are the project lead/Pis, collaborators, and other researchers well suited to the project?</li> <li>• If the project is collaborative do collaborators have complementary and integrated expertise?</li> <li>• Is there evidence to indicate that the project lead will oversee the project activities, including ensuring that tasks are accomplished as planned?</li> <li>• Does the proposal include a solid method for inclusion of the voice of the patient?</li> <li>• How will the roles and expertise provided by the key staff members support the execution of the initiative?</li> <li>• Is there sufficient evidence to indicate the applicants have the staff capacity to facilitate the execution of the project?</li> <li>• Do the attributes of the requesting organization and their collaborative partners support and facilitate the execution of the project?</li> <li>• What is the evidence of institutional commitment to support the initiative?</li> <li>• Is institutional infrastructure available to sustain the initiative?</li> </ul>
<b>Budget</b>	10%	<ul style="list-style-type: none"> <li>• Does the total amount requested seem appropriate compared to other requests?</li> <li>• Is the budget fully justified and reasonable in relation to the</li> </ul>

	Maximum Score	Guiding Questions for Evaluation Criteria
		<p>proposed initiative?</p> <ul style="list-style-type: none"> <li>• Does the allocation for specific activities seem realistic?</li> <li>• Are the budget categories consistent with the proposed initiative?</li> <li>• Is the overhead within the limits set in the RFP?</li> </ul>

Each category has been assigned a weight. The scores listed for each area will add up to a score with a maximum of 100 and a minimum of 0. This information, along with the Strengths and Weaknesses identified during the review period will be provided in aggregate form back to the applicant.

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- <sup>13</sup> [Koecheller et al \(1989\)](#), "Indicators for the selection of ambulatory patients who warrant pharmacist monitoring," *American Journal of Hospital Pharmacy*
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## Appendix C: Criteria for Distinguishing Rigorous QI from Research Requiring Full IRB Review

### A Guide for Quality Improvers

1. HIPPA privacy criteria must be met
  - a. Note that HIPPA criteria have to do with privacy and confidentiality and apply to research and QI in general. HIPPA requirements should be met regardless of the nature of the project.
2. The intervention must be “minimal risk”
  - a. Even if the project is believed to be “minimal risk,” project leaders still must formally consider the risk of unintended consequences or harm, perform appropriate monitoring, and have a plan for mitigating any unintended consequences.
3. Projects are exempt from IRB review as “research” if they are designed to improve care so as to conform more reliably to established or accepted standards (evidence-based or supported by consensus)
  - a. Important considerations:
    - i. Evaluation is intrinsic to improvement; It is counterintuitive to suggest that evaluating QI efforts is “research” in the traditional sense. Failure to evaluate is incompatible with learning.
    - ii. Feedback of data (both process and outcome data) in real time is essential; withholding data from participants so as not to “contaminate” the evaluation converts QI to research
    - iii. Intent to publish no longer is considered an automatic classification of QI and traditional “research.” However, journals will require a statement that the project was deemed “exempt” by an IRB or classified as QI without formal review by institutional IRB policy. In general, it is prudent to have an expedited review and an exemption waiver from the institutional IRB.
    - iv. The inclusion of a comparison group does not automatically convert QI to traditional research if there is minimal risk and procedures are in place to anticipate, monitor and mitigate unintended consequences. It may be prudent to include an oversight body (similar to a data safety and monitoring board in traditional research) to determine if and when an intervention clearly is superior and patients/providers in the comparison group should be crossed over to receive the intervention.
4. Surveys
  - a. Surveys designed to gauge the opinions and perceptions of external customers, patients, staff, and trainees are considered integral to an organization’s quality oversight and operational activities
  - b. Privacy and confidentiality must be respected
  - c. To avoid perception of coercion or possible repercussions, include language such as: “This is an anonymous survey. Results will be presented only as aggregate data, with complete protection of individual anonymity. Completion is entirely voluntary.”
  - d. If there is intent to publish, those being surveyed are informed that they can opt out by returning a blank survey

Note: OHRP currently is considering revisions to the Common Rule that would exempt QI studies based on specific criteria. Drafts that have been posted for public commentary make the appropriate distinction between studies designed to bring care closer to accepted standards *versus* studies that are designed to compare the safety and effectiveness of two or more practices. This is exemplified by the SUPPORT randomized study, which sought to determine which of two ranges of oxygenation targets was safer and more effective in neonatal intensive care (e.g., guiding oxygen delivery to avoid retinopathy of prematurity). This clearly is “research.” Had the study examined interventions (e.g., team care and daily audits) designed to increase the percentage of babies meeting the established acceptable range of oxygenation targets, it could have been considered rigorous quality improvement.

Useful guidance can be found in:

<https://nam.edu/wp-content/uploads/2015/12/NAM-CERIC-CommonRule.pdf>

[http://www.nationalacademies.org/hmd/Activities/Quality/~media/Files/Activity%20Files/Quality/VSR/T/Discussion%20Papers/CommonRule.pdf](http://www.nationalacademies.org/hmd/Activities/Quality/~/media/Files/Activity%20Files/Quality/VSR/T/Discussion%20Papers/CommonRule.pdf)