Global Healthy Living Foundation and Pfizer Independent Grants for Learning & Change Request for Proposals (RFP) *Rheumatoid Arthritis Shared Decision Making*

I. Background

Pfizer and the Global Healthy Living Foundation (GHLF) are collaborating to offer a new grant opportunity focused on improving shared decision making among adults with rheumatoid arthritis and their providers.

The mission of Pfizer Independent Grants for Learning & Change (IGLC) is to partner with the global healthcare 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 recipient organization. Pfizer has no influence over any aspect of the projects and only asks for reports about the results and the impact of the projects in order to share them publicly.

CreakyJoints®, now in its 18th year, has evolved into the go-to source for more than 100,000 arthritis patients and their families world-wide who are seeking education, support, advocacy and patient-centered research. Co-founded in 1999 by arthritis patient Seth Ginsberg and social entrepreneur Louis Tharp, the CreakyJoints patient community is part of the GHLF, whose mission is to improve the quality of life for people with chronic illness. GHLF will lead the grant application evaluation process and oversee a proposal review committee that will make funding decisions.

In 2014, CreakyJoints created a patient-focused registry, ArthritisPower™ , one of the 20 Patient-Powered Research Networks (PPRNs) with support from the Patient-Centered Outcomes Research Institute (PCORI). ArthritisPower™ is the first-ever patient-led, patient-centered research registry for arthritis, bone, and inflammatory skin conditions. ArthritisPower is part of PCORnet, the National Patient-Centered Clinical Research Network (www.pcornet.org), a large, highly representative, national network for conducting patient-focused comparative effectiveness research.

The ArthritisPower mobile and Web application (App) allows patients to track, measure, and share their symptoms and treatments outcomes while simultaneously participating in arthritis research via informed consent. ArthritisPower Patient Governors serve as gatekeepers for researchers seeking to access registry data or solicit the community to participate in unique, voluntary studies. Patient Governors also help to prioritize research requests and will help to disseminate research findings to members of the CreakyJoints patient community. To learn more about the ArthritisPower Research Network, visit www.ArthritisPower.org.

Patients in the CreakyJoints patient community and the ArthritisPower registry have indicated that information about RA treatment options is a priority[2] and can represent a gap in care. For some medication decisions, there is strong evidence from research that can help guide patients and providers[1], although patients sometimes have differing interpretation of the evidence[3]. However, when a patient is not achieving their goals, the guidelines suggest that prescribers have a choice between several different treatments; the recommendation is to make a decision based on the patients' values and preferences[1]. When faced with such decisions, sufficient data relevant and comprehensible to both the patient and provider is not readily available. This RFP aims to improve the RA shared decision

making process by improving communications between provider and patient, specifically by making individual patient data available to clinicians. Collection of retrospective and/or prospective patient data from the ArthritisPower registry can be made available if desired to project investigators at no charge. However, app development costs associated with linking ArthritisPower data to clinical data should be coordinated with GHLF and budgeted for. Integration with clinical data collected in physician offices (e.g. via a registry, or electronic health record) for the purposes of shared decision-making is likely to maximize shared decision-making opportunities.

The intent of this document is to encourage organizations with a focus in healthcare provision or quality improvement to submit a letter of intent (LOI) in response to a Request for Proposal (RFP) that is related to quality improvement in shared decision making for rheumatoid arthritis treatment. The RFP model is a two-stage process. Stage 1 is the submission of the LOI. After review of the LOI, you may be invited to submit your Full Grant Proposal. 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 our grants system. Some RFPs may also be posted on the websites of other relevant organizations, as deemed appropriate.

II. Eligibility

Geographic Scope:	☑ United States Only ☐ International(specify country/countries)_____
Applicant Eligibility Criteria:	U.S. health care institutions, large and small; health care professional organizations and other organizations with a mission related to healthcare improvement; government agency partners with the capacity to reach patients with rheumatoid arthritis. More information on organizations eligible to apply directly for a grant can be found at http://www.pfizer.com/files/IGLC_OrganizationEligibility_effJuly2015.pdf. Collaborations within institutions (e.g., between departments and/or inter-professional), as well as between different institutions/organizations/associations, are encouraged. Please note all partners must have a relevant role and the requesting organization must have a key role in the project. For programs offering educational credit, the requesting organization must be the accredited grantee.

III. Requirements

Date RFP Issued:	November 11, 2016
Clinical Area:	Rheumatoid Arthritis (immunology and rheumatology)

Specific Area of Interest for this RFP:	It is our intent to support projects that focus on improving shared decision making with adults with rheumatoid arthritis (RA) in partnership with a patient community and using ArthritisPower™ data collected with online tools and/or mobile (e.g., smartphone) applications. The review process will prioritize funding projects that focus on using the infrastructure developed for ArthritisPower™ patient-powered research network, including, but not limited to, consultation with the network's Patient Governor Group on project design, implementation and dissemination, and use of the network's mobile app or equivalent web-based platform. Programs should focus on shared decision making for RA treatment in general. Programs limited to a focus on one treatment will not be eligible for consideration. However, projects may choose to select a focus for shared decision making that incorporates the combined use of data from a registry and/or electronic health records (EHR), if available to the project investigators and linkable to ArthritisPower data. Ideally, linkage would entail direct integration with ArthritisPower patient data (consistent with all HIPPA requirements), including patient-reported outcome (PRO) measures and other patient-related health concerns (e.g., patient goal setting, treat-to-target, reproductive health, or vaccination). For more information about examples of ArthritisPower registry data elements, a data dictionary can be viewed here http://arthritispower.creakyjoints.org/data-dictionary. It is expected that the proposed project will be evidence-based and the proposed research/evaluation will follow generally accepted scientific principles. During review the intended outcome of the project is given careful consideration and, if appropriate based on the project goal, projects with the maximum likelihood to directly impact patient care in a measurable way will be given high priority. Projects including an educational element can find more information on principals of learning and behavior change for health professionals at www.pfizer.com/files/HealthProfessionalsLearningandBehaviorChange_AFewPrinciples.pdf. There is a considerable amount of interest in receiving responses from projects that utilize system-based changes. Although educational efforts directed at physicians and/or patients may be entirely appropriate components in responses to this RFP, projects that include an overt description of system changes will be given high priority. *It is not our intent to support clinical research projects. 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.

Target Audience:	Adults living with rheumatoid arthritis (RA) and their healthcare providers.
Disease Burden Overview:	Rheumatoid arthritis (RA) is a chronic, systemic, often disabling, autoimmune disease affecting 1% of adults and 2-3% of older individuals[4-7]. This debilitating condition typically strikes younger people (median age 30s and 40s), in the prime of work and family productivity, and is usually lifelong. There are genetic and environmental factors associated with its onset, but there is no known cure. According to the Center for Disease Control, arthritis is the leading cause of disability in the U.S.[8]. New biologic medications that target specific components of the immune system have proved effective for most patients, with major improvements in quality of life[9]. Many RA patients with RA have not achieved remission or low disease activity despite the availability of effective treatments.
Recommendations and Target Metrics:	**Related Guidelines and Recommendations** • ACR Clinical Practice Guidelines for RA http://www.rheumatology.org/Portals/0/Files/ACR%202015%20RA%20Guideline.pdf • Patient Panel Recommendations for the Treatment of Rheumatoid Arthritis http://www.rheumatology.org/Portals/0/Files/When%20Patients%20Write%20the%20Guidelines.pdf • CreakyJoints Patient Guidelines for RA https://creakyjoints.org/ra-patient-guidelines/
Gaps Between Actual and Target, Possible Reasons for Gaps:	Achieving low disease activity or remission is considered a primary therapeutic target of RA treatment[10-12]. Remission can be achieved in RA patients receiving routine follow-up care[13], but many patients have moderate- to high-disease activity despite the availability of effective treatments. For some RA medication decisions, there is strong evidence from research that can help guide patients and providers[1-2], though patients sometimes have differing interpretations of the evidence[3]. Patients may choose to remain on a current but inadequate regimen rather than escalate treatment and others may not adhere to RA treatment even when treatment is available[14]. When a patient is suboptimally treated, the ACR guidelines for RA treatment usually indicate that prescribers have a choice between several different treatments[1]. In cases like these, the recommendation is for the patient and provider to determine which medication is best[1]. This requires open communication between patient and provider. And though roughly half of RA patients acknowledge that dialogue with their health care provider would improve their condition management, a majority felt uncomfortable raising treatment and disease concerns with their provider[15-16].

Barriers:	There are at least three barriers to shared decision making for optimal management of RA: lack of open communication between patients and providers[15-16], lack of providers' access to patient data between visits, and lack of patients' access to and comprehension of providers' clinical evaluation. Patients consider treatment success to include reduction of pain and/or swelling, improvements in quality of life, and control of disease progression, but may not adhere to a current treatment due to its inconvenience or side effects[15-16]. This RFP seeks to fund projects that aim to improve patient-provider communication for shared decision making and patient behavior to achieve optimal management of RA using data provided by both the patient and provider.
Current National Efforts to Reduce Gaps:	Treat-to-target studies in RA have suggested better disease activity control is achievable and results in improved patient outcomes. However, recent evidence suggests that when implemented in real-world settings, treat-to-target (T2T) studies sometimes fail to achieve their objective, in many cases because patients are not fully engaged in the process[17].
Expected Approximate Monetary Range of Grant Applications:	Individual projects requesting up to $500,000 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 project will depend upon the external review panel's evaluation of the proposal and costs involved, and will be stated clearly in the approval notification.
Key Dates:	RFP release date: November 11, 2016 LOI due date: January 20, 2017 Please note the deadline is 11:59 pm Eastern Time (New York, GMT -5). Review of LOIs by External Review Panel: January/February 2017 Anticipated LOI Notification Date: February 2017 Full Proposal Deadline: May 1, 2017 *Only accepted LOIs will be invited to submit full proposals Please note the deadline is midnight Eastern Time (New York, GMT -5). Review of Full Proposals by External Review Panel: May 2017 Anticipated Full Proposal Notification Date: June 2017 Grants distributed following execution of fully signed Letter of Agreement Period of Performance: July 1, 2017 to June 30, 2019

How to Submit:	Please go to www.cybergrants.com/pfizer/loi and sign in. First-time users should click "REGISTER NOW". Select the following Area of Interest: Rheumatoid Arthritis Shared Decision Making Requirements for submission: Complete all required sections of the online application and upload the completed LOI template (see Appendix). If you encounter any technical difficulties with the website, please click the "Need Support?" link at the bottom of the page. **IMPORTANT:** Be advised applications submitted through the wrong application type and/or submitted after the due date will not be reviewed by the committee.
Questions:	If you have questions regarding this RFP, please direct them in writing to the Grant Officer, Susan Connelly (susan.connelly@pfizer.com) or GHLF Research Director, Ben Nowell (bnowell@ghlf.org) with the subject line "Rheumatoid Arthritis Shared Decision Making RFP 11/11/2016."
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.

References:

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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).

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.

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. Project Classification
    1. There are multiple project types that are eligible for funding through this RFP. Please indicate which of the following best represents your project. More information on these classifications can be found in the Decision Matrix posted on the Tips & Templates tab the IGLC website.
        - Dissemination and Implementation (D&I) Research
        - Quality Improvement
        - Education or Educational research
    2. Background Information
        - It is expected that D&I research projects follow generally accepted principals. For all research projects the institution(s) must agree to assume all responsibilities as sponsor of the study as outlined in the proposal. These are listed in the **RFP Terms and Conditions (#9)**.
            - At the time of approval of a full proposal, applicants will be required to sign a research contract, submit IRB approval and a research protocol.
        - Quality improvement projects should be described in terms of generally accepted principles of improvement science such as those described by the IHI model for improvement or LEAN.
            - At the time of approval of a full proposal, applicants will be required to sign a letter of agreement.
        - Educational projects should be planned 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.
            - At the time of approval of a full proposal, applicants will be required to sign a letter of agreement.

C. 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.

D. 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. The RFP includes a national assessment of the need for the project. Please do not repeat this information within the LOI (you may reference the RFP, if necessary). Only include information that impacts your specific project, linking regional or local needs to those identified on the national basis, if appropriate.

E. 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

F. Project Design and Methods
    1. Describe the planned project and the way it addresses the established need.
    2. If your methods include educational activities, please describe succinctly the topic(s) and format of those activities.

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

H. 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.

I. Anticipated Project Timeline

J. 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.

K. Additional Information
    1. If there is any additional information you feel Pfizer should be aware of concerning the importance of this project, please summarize it in within the page limitations.

Organizational Detail (not to exceed 1 page)

Describe the attributes of the institutions/organizations/associations that will support and facilitate the execution of the project and the leadership of the proposed project. Articulate the specific role of each partner in the proposed project. Letters of support from partner organizations will be required at the Full 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****.*