## Global Healthy Living Foundation and Pfizer Independent Grants for Learning & Change Request for Proposal (RFP) Accelerating the Detection, Diagnosis and Initial Treatment of Psoriatic Arthritis (PsA)

#### I. Background

Pfizer and the Global Healthy Living Foundation (GHLF) are collaborating to offer a new grant opportunity focused on accelerating diagnosis and initial treatment of psoriatic arthritis (PsA) among patients in the U.S.

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 asks for reports about the results and the impact of the projects in order to share them publicly.

The Global Healthy Living Foundation is a 501(c)(3) non-profit organization whose mission is to improve the quality of life for people living with chronic illnesses, such as arthritis, osteoporosis, migraine, diabetes, psoriasis, cardiovascular disease and chronic pain, by advocating for improved access to care at the community, state, and federal levels, and amplifying education and awareness efforts within its social media framework. The Global Healthy Living Foundation is the parent organization of CreakyJoints®, 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 and ArthritisPower™, 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.

Patients in the CreakyJoints patient community and ArthritisPower registry have indicated that recognizing and communicating arthritis symptoms as early as possible to their physician is a priority in order to speed diagnosis and the provision of appropriate treatment. Moreover, there is increasing evidence that early diagnosis and treatment of PsA results in improved long-term outcomes. However, underdiagnosis and delays in PsA diagnosis represent substantial gaps in care that are not being adequately addressed. Integration with clinical data collected in physician offices (e.g. via a registry, or electronic health record) for the purposes of accelerating the detection and treatment of PsA is likely to optimize timely diagnoses. The ArthritisPower registration process and data collection tool (app) can be re-themed in order to appeal to a target audience that previously may not have identified themselves with arthritis (i.e., psoriasis patients). Screening tools that have been developed and validated for PsA

(e.g., the PEST or PASE; see Recommendations and Target Metrics below) can be embedded in the ArthritisPower app and registry at no charge to project investigators, if desired (NOTE: This does not include measure copyright charges where applicable). However, development costs associated with retheming app registration and data collection and/or linking ArthritisPower data to clinical data should be coordinated with GHLF and budgeted for.

The intent of this document is to inform organizations with a focus in healthcare provision or quality improvement about this grant opportunity and invite them to submit a letter of intent (LOI) in response to a Request for Proposal (RFP) that is related to the acceleration and improvement of the detection, diagnosis and initial treatment (0-6 months after diagnosis) of PsA. Appropriate projects may include the following: raising PsA awareness among physicians and patients, implementing PsA patient screening tools and longitudinal data capture via a mobile application (i.e., the ArthritisPower registry, or a derivative, e.g., PsoriasisPower), and tracking patients who are newly diagnosed and treated using longitudinal patient reported outcome (PRO) measures and clinical data via the registry (see www.ArthritisPower.org). 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
Applicant Eligibility Criteria:	The following may apply: medical, dental, nursing, allied health, and/or pharmacy professional schools; healthcare institutions (both large and small); professional associations; government agencies; and other entities with a mission related to healthcare improvement.  Or
	U.S. health care institutions; health care professional organizations and other organizations with a mission related to healthcare improvement; government agency partners with the capacity to reach patients with psoriasis or psoriatic arthritis (PsA).
	More information on organizations eligible to apply directly for a grant can be found at <a href="http://www.pfizer.com/files/IGLC">http://www.pfizer.com/files/IGLC</a> OrganizationEligibility effJuly2015.p <a href="mailto:df">df</a> .
	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:	April 24, 2018
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### Clinical Area:

## Specific Area of Interest for this RFP:

Psoriatic Arthritis (immunology and rheumatology; dermatology)

It is our intent to support projects that focus on improving the early detection, diagnosis and initial treatment (during the first six months following diagnosis) of adults with psoriatic arthritis (PsA) in partnership with health care providers in the community.

Priority will be given to proposals that are able to:

- Leverage ArthritisPower™ or other validated tools and/or mobile (e.g., smartphone) applications for screening and data collection;
- Ensure healthcare system-based changes; and
- Demonstrate a direct impact on patient care.

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Infrastructure developed for ArthritisPower™ patient-powered research network and available for this project includes, but is not limited to, use of the network's mobile app or equivalent web-based platform for deployment of screening tools and assessments, permission to integrate electronic health records (EHR), if available to the project investigators, with ArthritisPower™ data (ideally, linkage would entail direct integration with patient data from PsA screening tools and patient-reported outcome measures), and consultation with a Patient Governor Group on project design, implementation and dissemination. For more information about examples of ArthritisPower™ registry data elements, a data dictionary can be viewed here: <a href="https://arthritispower.creakyjoints.org/Data Dictionary ArthritisPower">https://arthritispower.creakyjoints.org/Data Dictionary ArthritisPower</a>

Programs should focus on accelerating detection, diagnosis and initial treatment of PsA by testing innovative healthcare system-based changes. Programs limited to a focus on one treatment will not be eligible for consideration.

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 <a href="https://www.pfizer.com/files/HealthProfessionalsLearningandBehaviorChange">www.pfizer.com/files/HealthProfessionalsLearningandBehaviorChange</a> AFewPrinciples.pdf.

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 <a href="https://www.Pfizer.com/iir">www.Pfizer.com/iir</a>.

Target Audience:	The target audience for the projects should include: 1) adults living with symptoms of psoriatic arthritis (PsA); 2)or adults that are_newly diagnosed with PsA; and 3) HCPs who reach these two patient populations.
Disease Burden Overview:	Psoriatic arthritis (PsA) is a chronic inflammatory musculoskeletal disease associated with psoriasis, with peripheral arthritis, dactylitis, enthesitis and spondylitis being the most common features. Previously, it has been reported that the incidence of PsA is ~6 per 100,000 per year, and the prevalence is ~1-2 per 1,000 in the general population. Among patients with psoriasis, the annual incidence of PsA is estimated to be approximately 3% and the reported prevalence of PsA among patients with psoriasis has varied between 6% and 41%. In the majority of patients, skin symptoms develop first, followed by arthritis; in 10-15% arthritis symptoms present first and in some patients skin and joint symptoms present at the same time.
Recommendations and	Related Guidelines and Recommendations
Target Metrics:	<ul> <li>New and existing (2015) <u>GRAPPA</u> and <u>EULAR</u> recommendations for the management of psoriatic arthritis<sup>9</sup></li> <li>Classification of Psoriatic Arthritis (CASPAR) criteria</li> <li>American College of Rheumatology (ACR) / National Psoriasis Foundation (NPF) Clinical Practice Guidelines for PsA (not yet released)</li> <li>Raising the Voice of Patients: A Patient's Guide to Living with Psoriatic Arthritis (GHLF/CreakyJoints)</li> <li>PsA Screening and Detection tools:         <ul> <li>Psoriasis Epidemiology Screening Tool (PEST)</li> <li>Psoriatic Arthritis Screening and Evaluation (PASE)</li> <li>Toronto Psoriatic Arthritis Screening (ToPAS)</li> <li>Early Arthritis for Psoriatic Patients (EARP)</li> </ul> </li> </ul>

# Gaps Between Actual and Target, Possible Reasons for Gaps:

PsA is underdiagnosed and undertreated. Diagnosis within the first 2 years of symptom onset is generally considered early PsA.<sup>2,10</sup> A recent survey of more than 200 PsA patients enrolled in CreakyJoints found that most (75%) sought treatment for symptoms such as joint pain and stiffness or rash within the first two years of noticing new symptoms. Nearly all reported receiving a misdiagnosis before PsA was identified. Fifty-one percent of respondents received a diagnosis of PsA a year or more after seeking medical attention; 17% and 15% received a PsA diagnosis 5 and 10 years after first reporting symptoms to a medical professional, respectively.<sup>11</sup> Patients who responded to the survey had consulted a range of medical professionals including general practitioners (80%), rheumatologists (66%), dermatologists (33%), and orthopedists (22%).<sup>11</sup>

Early diagnosis of PsA results in better outcomes. Diagnosing and treating patients within 6 months to 2 years of first symptom reporting prevents permanent damage such as bone or joint erosions.<sup>3,5,12</sup> Shorter symptom duration at diagnosis and start of therapy is also associated with remission or low disease activity at 5 years.<sup>13</sup>

#### **Barriers:**

There are at least five potential barriers to early diagnosis of PsA. First, PsA is difficult to diagnose. Unlike rheumatoid arthritis or systemic lupus erythematosus, PsA lacks definitive, goldstandard diagnostic markers and its presentation is heterogeneous. 7,14 Patients with psoriasis may seek treatment for joint pain and instead receive diagnoses for more common conditions such as gout, fibromyalgia or osteoarthritis. <sup>7</sup> Second, patients are under-exposed to information about PsA. PsA is not as well known among the general patient population as are other forms of arthritis, such as osteo- or rheumatoid arthritis. Patient organizations like the National Psoriasis Foundation (NPF) and GHLF/CreakyJoints offer patient education resources, but these may not reach all patients who are potentially affected. Third, early diagnosis of PsA has not always been a priority for rheumatologists. 10 Moreover, other providers such as nurse practitioners (NP), physician assistants (PA) and primary care physicians (PCPs) may lack familiarity with the signs and symptoms of PsA and thus misdiagnose or delay referrals to specialists. Fourth, securing a rheumatologist or dermatologist referral appointment in a timely manner may prove difficult for many patients and their referring providers. Fifth, dermatology practices may not routinely discuss PsA or screen their psoriasis (PsO) patients for PsA.

Current National Efforts to Reduce Gaps:	<ul> <li>Group for Research and Assessment of Psoriasis and Psoriatic         Arthritis (GRAPPA) http://www.grappanetwork.org/</li></ul>
Expected Approximate	Individual projects requesting up to \$500,000 will be considered. The
<b>Monetary Range of</b>	total available budget related to this RFP is \$1,000,000.
<b>Grant Applications:</b>	
	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
V D-t	notification.
Key Dates:	RFP release date: April 24, 2018  LOI due date: June 1, 2018  Please note the deadline is midnight Eastern Time (New York, GMT-5).
	Review of LOIs by External Review Panel: late June 2018
	Anticipated LOI Notification Date: July 9, 2018
	Full Proposal Deadline: August 10, 2018 *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: September 2018
	Anticipated Full Proposal Notification Date: September 21, 2018
	Grants distributed following execution of fully signed Letter of Agreement
	Period of Performance: January 1, 2019 to December 31, 2021

How to Submit:	Please go to <a href="https://www.cybergrants.com/pfizer/loi">www.cybergrants.com/pfizer/loi</a> and sign in. First-time users should click "REGISTER NOW".
	Select the following Area of Interest: Psoriatic Arthritis Accelerating Diagnosis
	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.
	<b>IMPORTANT:</b> 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, Amanda Solis (amanda.solis@pfizer.com) or GHLF Research Director, Ben Nowell (bnowell@ghlf.org) with the subject line "Psoriatic Arthritis Accelerating Diagnosis"
Mechanism by which	All applicants will be notified via email by the dates noted above.
Applicants will be	
Notified:	Applicants may be asked for additional clarification or to make a
	summary presentation during the review period.

#### References:

- 1. Nowell WB, Ginsberg S, Higginbotham P, Johnson B, O'Beirne R, Safford M, Willig J, Curtis JR. Patients' Prioritization of Patient-Centered Education and Research Topics in Rheumatic Disease. Abstract, European League Against Rheumatism Annual Meeting. 2015.
- 2. Gladman D. Early psoriatic arthritis. Rheum Dis Clin North Am 2012;38(2):373-86.
- 3. Gladman D, Thavaneswaran A, Chandran V, et al. Do patients with psoriatic arthritis who present early fare better than those presenting later in the disease? Ann Rheum Dis 2011;70(12):2152–4.
- 4. Tillett W, Jadon D, Shaddick G, et al. Smoking and delay to diagnosis are associated with poorer functional outcome in psoriatic arthritis. Ann Rheum Dis 2013; 72(8):1358–61.
- 5. Haroon M, Gallagher P, Fitzgerald O. Diagnostic delay of more than 6 months contributes to poor radiographic and functional outcome in psoriatic arthritis. Ann Rheum Dis 2015; 74:1045–50.
- 6. Mease P, Gladman D, Papp K, et al. Prevalence of rheumatologist-diagnosed psoriatic arthritis in patients with psoriasis in European/North American dermatology clinics. J Am Acad Dermatol 2013;69(5):729–35.
- 7. Ogdie A, Weiss P. The Epidemiology of Psoriatic Arthritis. Rheum Dis Clin North Am. 2015;41(4):545-68.
- 8. Ritchlin CT, Colbert RA, Gladman DD. Psoriatic Arthritis. N Engl J Med. 2017;376(21):2095-6.
- Laura C. Coates, Laure Gossec, Sofia Ramiro, Philip Mease, Désirée van der Heijde, Josef S. Smolen, Christopher Ritchlin, Arthur Kavanaugh; New GRAPPA and EULAR recommendations for the management of psoriatic arthritis, *Rheumatology*, Volume 56, Issue 8, 1 August 2017, Pages 1251–1253, https://doi.org/10.1093/rheumatology/kew390.
- 10. Kane D, Pathare S. Early psoriatic arthritis. Rheum Dis Clin N Am 31 (2005) 641–657. doi:10.1016/j.rdc.2005.07.009
- 11. Ogdie, A, Nowell WB, Applegate E, Gavigan K, Venkatachalam S, de la Cruz M, Flood E, Schwartz EJ, Romero B, Hur P. Diagnostic experiences of patients with psoriatic arthritis: misdiagnosis is common. European League Against Rheumatism Annual Meeting 2018 (abstract).
- 12. Kane D, Stafford L, Bresnihan B, et al. A prospective, clinical and radiological study of early psoriatic arthritis: an early synovitis clinic experience. Rheumatology 2003;42(12):1460.
- 13. Theander E, Husmark T, Alenius G, et al. Early psoriatic arthritis: short symptom duration, male gender and preserved physical functioning at presentation predict favourable outcome at 5-year follow-up. Results from the Swedish Early Psoriatic Arthritis Register(SwePsA). Ann Rheum Dis 2014;73(2):407–13.
- 14. McHugh, NJ. Early psoriatic arthritis. Rheum Dis Clin N Am 41 (2015); 615-622. http://dx.doi.org/10.1016/j.rdc.2015.07.005

#### **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 (<a href="http://www.pfizer.com/files/IGLCsunshineFAQ">http://www.pfizer.com/files/IGLCsunshineFAQ</a> 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 <u>single-spaced</u> using <u>Calibri 12-point font</u> and <u>1-inch margins</u>. Note there is a <u>3-page limit</u> 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
  - 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 <u>Decision Matrix</u> posted on the <u>Tips & Templates</u>
    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 <a href="www.pfizer.com/files/HealthProfessionalsLearningandBehaviorChange\_AFewPrinciples.pdf">www.pfizer.com/files/HealthProfessionalsLearningandBehaviorChange\_AFewPrinciples.pdf</a>.
      - 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**.