Pfizer Independent Grants for Learning & Change Request for Proposals (RFP) Shared Management of Psoriatic Arthritis

I. Background

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.

The intent of this document is to encourage organizations with a focus in healthcare professional education and/or quality improvement to submit a letter of intent (LOI) in response to a Request for Proposal (RFP) that is related to education in a specific disease state, therapeutic area, or broader area of educational need. The RFP model is a two-stage process. Stage 1 is the submission of the LOI. 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 (<u>www.pfizer.com/independentgrants</u>) 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	The following may apply: medical, nursing, allied health, and/or
Criteria:	pharmacy professional schools; healthcare institutions (both large and
	small); professional associations; government agencies; and other
	entities with a mission related to healthcare improvement.
	More information on organizations eligible to apply directly for a grant
	can be found at
	http://www.pfizer.com/files/IGLC_OrganizationEligibility_effJuly2015.p
	<u>df</u> .
	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 continuing education credit in any component,
	the requesting organization must be the accredited grantee.
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II. Eligibility

III. Requirements	
Date RFP Issued:	May 8, 2017
Clinical Area:	Psoriatic Arthritis
Specific Area of Interest for this RFP:	Evidence indicates that many patients with Psoriatic Arthritis (PsA) remain undiagnosed, and those who have been diagnosed are not receiving optimal care. ¹ It is our intent to support projects that focus on the coordinated management and identification of patients with psoriatic arthritis (PsA) by both rheumatology and dermatology healthcare professionals.
	Patients with Psoriatic Arthritis experience symptoms that involve both the skin and the joints, impacting their quality of life. ² Given the nature of the disease, patients may seek care from both dermatologists and rheumatologists, as the disease progresses through periods of flare and remission. A collaborative approach to treatment by a combined team of rheumatology and dermatology clinicians allows for a unique blend of expertise and provides the opportunity for comprehensive care for the PsA patient. ³
	It is expected that projects will be evidence-based and the proposed 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 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_action_action_action_com/state_bare
	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 <u>www.Pfizer.com/iir</u> .
Target Audience:	Rheumatology and Dermatology healthcare professionals caring for patients with or at risk for psoriatic arthritis.
Disease Burden Overview:	Psoriatic arthritis (PsA) is a chronic inflammatory arthritis in the setting of skin or nail psoriasis. The exact prevalence is unknown and has been difficult to estimate, however; researchers agree that PsA impacts 2-3% of the general population. PsA is a well-recognized cause of chronic joint damage, disability and poor Quality of Life (QoL). ⁴ The condition is often undiagnosed and treatment algorithms are poorly defined. ⁵

Recommendations and Target Metrics:	 Related Guidelines and Recommendations European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update. Ann Rhoum Dis, 2016 Mar; 75(2):499-510
Gaps Between Actual and Target, Possible Reasons for Gaps:	 Ann Rheum Dis. 2016 Mar;75(3):499-510 Psoriatic arthritis is often underdiagnosed and undertreated. A rising trend is the establishment of combined rheumatology and dermatology practices for the management of various diseases, including PSA. One such center in Vancouver recently conducted a patient satisfaction survey and concluded that 88% of their patients find the combined clinic setting to be beneficial.⁶
Barriers:	In 2016 the American College of Rheumatology re-examined their 2005 Workforce Study to estimate the number of practicing rheumatologists in the US and identified a growing shortage in the number of clinicians. Due to an increase in the aging population they anticipate a continuing shortage of rheumatologists, with to the gap reaching 1,900 by 2025. ⁷ Results in 2010 showed that shortages were beginning to appear in underserved areas and are projected to worsen. ⁸ Several factors also impact the workforce challenges in the dermatology field. Since 1999, a stable undersupply of dermatologic services has been reported, amplified by a broadening scope of practice into surgical and cosmetic dermatology. At the same time, there has been increased demand for dermatologic care, driven by the aging population and prevalence in skin diseases. Dermatology practices have adapted with an increased number of physician assistant and nurse practitioners being employed in the field. ⁹
Current National Efforts to Reduce Gaps:	There is an ongoing trend to combine dermatology and rheumatology care through dual clinics. Workforce shortages in all specialty areas are being addressed through efforts to increase the number of medical school and residency seats. ¹⁰
Expected Approximate Monetary Range of Grant Applications:	Individual projects requesting up to \$350,000 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 Deter	DED valages data, May 9, 2017
Key Dates:	RFP release date: May 8, 2017
	LOI due date: June 23, 2017
	Please note the deadline is midnight Eastern Time (New York, GMT -5).
	Review of LOIs by External Review Panel: July 2017
	Anticipated LOI Notification Date: August 11, 2017
	Full Proposal Deadline: September 18, 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: mid-October 2017
	Anticipated Full Proposal Notification Date: November 13, 2017
	Crants distributed following execution of fully signed Letter of
	Grants distributed following execution of fully signed Letter of Agreement
	Period of Performance: Beginning on or after January 1, 2018.
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: PsA Shared Management
	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.
	IMPOPTANT: Readvised applications submitted through the wrong
	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, Amanda Solis (<u>amanda.solis@pfizer.com</u>), with the
	subject line "[Shared Management of PsA May 8]."
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. Armstrong, AW, Robertson AD, Wu J, Schupp C, Lebwohl MG. Undertreatment, treatment trends, and treatment dissatisfaction among patients with psoriasis and psoriatic arthritis in the United

States: findings from the National Psoriasis Foundation surveys, 2003-2011. *JAMA Dermatol* 2013;149:1180-1185.

- 2. Betteridge N, Boehncke WH, Bundy C, Gossec L, Gratacos J, Augustin M. Promoting patient-centric care in psoriatic arthritis: a multidisciplinary European perspective on improving the patient experience. *JEADV* 2015;30, 576-585.
- 3. Velez NF, Wei-Passanese EX, Husni ME, Mody EA, Qureshi AA (2012) Management of psoriasis and psoriatic arthritis in a combined dermatology and rheumatology clinic. *Arch Dermatol Res* 304:7-13.
- 4. Leung YY, Tam LS, Lee KW, Leung MH, Li Ek. Involvement, satisfaction and unmet health care needs in patients with Psoriatic Arthritis. *Rheumatology*. 2009 Oct;(49):53-56.
- 5. Helliwell P. et al, Arthritis Care Res(Hoboken). 2014 Dec;66(12):1759-66.
- 6. Samycia M, McCourt C, Shojania K, Au S. Do collaborative clinics work? Patient satisfaction in a combined dermatology/rheumatology clinic. *J Am Acad Derm*. 2016 May;74(5)sAB80.
- 7. 2015 Workforce Study of Rheumatology Specialists in the United States. (2015). American College of Rheumatology. <u>http://www.rheumatology.org/portals/0/files/ACR-Workforce-Study-2015.pdf</u>.
- "Regional distribution of adult rheumatologists" John D. FitzGerald MD, PhD, LaTanya Benford BS, Michael Battistone MD, Calvin R. Brown Jr. MD, Amy C. Cannella MD, Eliza Chakravarty MD, David A. Elashoff PhD, Allan C. Gelber MD, Carlos J. Lozada MD, Marilynn Punaro MD, Barbara Slusher PA-C, MSW, Abby Abelson MD DOI: 10.1002/art.38167 - See more at: <a href="http://www.rheumatology.org/About-Us/Newsroom/Press-Releases/ID/29/Shortage-of-RheumatologistsIn-Some-US-Regions-Closest-Doctor-May-Be-200-Miles-Away#sthash.ngUNHQDH.dpuf
- 9. Kimball AB, Resneck JS. The US Dermatology Workforce: A specialty remains in shortage. J Am Acad Dermatol. 2008 Nov;(59):741-45.
- The Complexities of Physician Supply and Demand: Projections from 2014 to 2025. (April 5, 2016). Association of American Medical Colleges. <u>https://www.aamc.org/download/458082/data/2016_complexities_of_supply_and_demand_projec_tions.pdf</u>.

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 (<u>http://www.pfizer.com/files/IGLCsunshineFAQ_updatedJan2016.pdf</u>).

- 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

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
 - 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
 - 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.