Pfizer Independent Grants for Learning & Change
Request for Proposals (RFP)
Quality improvements in the Management of Atopic Dermatitis

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 an 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:	The following may apply: medical, 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. 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 continuing education credit in any component, the requesting organization must be the accredited grantee.

III. Requirements

Date RFP Issued:	June 5, 2017
Clinical Area:	Atopic Dermatitis
Specific Area of Interest for this RFP:	This quality improvement project RFP is focused on patients with atopic dermatitis, and it has the overall goal to improve patient quality of life and health outcomes. This includes individuals with atopic dermatitis that receive no treatment as well as those with severe atopic dermatitis who may not be taking advantage of all available treatment options. Additionally, since children represent the majority of individuals diagnosed with atopic dermatitis, this quality improvement RFP looks to impact caregiver education and awareness. 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. *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:	Healthcare professionals caring for patients with or at risk for atopic dermatitis (dermatology, allergy). Projects that extend to pediatric or the family practice settings may also be considered.
Disease Burden Overview:	Atopic dermatitis (eczema) is an inflammatory skin disease resulting in itchy, red, swollen, and cracked skin. It generally begins in childhood and changes in severity over time.[1] Atopic dermatitis is a major public health problem that impacts roughly 10.7% of the US population, with many cases undiagnosed by a physician.[2]
Recommendations and Target Metrics:	**Related Guidelines and Recommendations** • Guidelines of care for the management of atopic dermatitis, updated in February 2014.

Gaps Between Actual and Target, Possible Reasons for Gaps:	Over 70 % of atopic dermatitis (AD) patients have mild disease, and approximately 20% and 2% having moderate and severe disease, respectively.[4] Practice gaps have been identified in diagnosing and treating patients in AD, and possible reasons for these gaps include a wide range of assessment tools with no clear consensus on the optimal method to assess severity and outcomes.[5] This may result in practice variations for the assessment and recording of AD severity. With several new and emerging therapeutic options available it is important that clinicians have an ability to assess the best option for patient care.[6,7,8] Assessing the severity of disease over time is becoming more critical for choosing a treatment regimen and evaluating the effectiveness of the therapy, in order to provide optimized patient care.
Barriers:	Barriers to achievement of the appropriate assessment of AD severity including; 1. The broad range of AD symptomatology [9,10] 2. No serologic markers accurately reflect AD severity [3] 3. Multiple clinical assessment tools with no clear consensus [11] 4. Lack of knowledge of reliable scales which can be considered for practical use [12,13,14] 5. Lack of integration of severity assessment into electronic medical records [15] 6. Time and overhead costs required for the assessment and recording of AD severity in the practice [13]
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 Dates:	RFP release date: June 5, 2017 LOI due date: July 17, 2017 Please note the deadline is midnight Eastern Time (New York, GMT -5). Review of LOIs by External Review Panel: late August 2017 Anticipated LOI Notification Date: September 1, 2017 Full Proposal Deadline: October 6, 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: late-October 2017 Anticipated Full Proposal Notification Date: November 10, 2017 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: Quality Improvements in AD 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, Amanda Solis (amanda.solis@pfizer.com), with the subject line "QI in AD June 5, 2017."
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:

1. Handout on Health: Atopic Dermatitis (A type of eczema). *National Institute of Arthritis and Musculoskeletal and Skin Diseases*. May 2013. Retrieved May 1, 2017.
2. Hanifin JM. Reed, ML, Impact Working Group. A population-based survey of eczema prevalence in the United States." *Dermatitis* 18.2(2001):82-91.
3. Eichenfield LF, Tom WL, Chamlin SL et al. Guidelines of care for the management of atopic dermatitis: section 1. Diagnosis and assessment of atopic dermatitis*. J Am Acad Dermatol*. 2014; 70(2):338-351. doi: 10.1016/j.jaad.2013.10.010 https://www.aad.org/practicecenter/quality/clinical-guidelines/atopic-dermatitis#sthash.3jww7sir.dpuf
4. Arkwright PD, Motala C, Subramanian H, et al. Management of difficult-to-treat atopic dermatitis. *J Allergy Clin Immunol Pract*. 2013; 1(2): 142-151. doi: 10.1016/j.jaip.2012.09.002
5. Hill MK, Kheirandish Pishkenari A, Braunberger TL, Armstrong AW, Dunnick CA. Recent trends in disease severity and quality of life instruments for patients with atopic dermatitis: A systematic review. *J Am Acad Dermatol*. 2016; 75(5): 906-917. doi: 10.1016/j.jaad.2016.07.002
6. Food and Drug Administration. FDA approves Eucrisa for eczema. *FDA News Release.* December 14, 2016. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm533371.htm. Accessed May 17, 2016.
7. Kaufman MB. Pharmaceutical approval update. *Pharm and Therap.* 2017; 42(2): 90-91. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5265233/
8. Mullard A. FDA approves dupilumab for severe eczema. *Nat Rev Drug Discov.* 2017; 16(5): 305. doi: 10.1038/nrd.2017.90
9. Simpson El. Atopic dermatitis: a review of topical treatment options. *Curr Med Res Opin.* 2010; 26(3): 633-640. doi: 10.1185/03007990903512156
10. Novak N, Leung DY. Advances in atopic dermatitis. *Curr Opin Immunol.* 2011; 23(6): 778-783. doi: 10.1016/j.coi.2011.09.007
11. de Bruin Weller MS, Knulst AC, Meijer Y, Bruijnzeel-koomen CA, Pasmans SG. Evaluation of the child with atopic dermatitis. *Clin Exp Allergy.* 2012; 42(3): 352-362. doi: 10.1111/j.1365-2222.2011.03899.x
12. Chalmers JR, Simpson E, Apfelbacher CJ, et al. Report from the fourth international consensus meeting to harmonize core outcomes measure for atopic eczema/dermatitis clinical trials (HOME initiative). *Br J Dermatol.* 2016; 175(1): 69-79. doi: 10.1111/bjd.14773
13. Wolkerstorfer A, de Waard van der Spek FB, Glazenburg EJ, Mulder PG, Oranje AP. Scoring the severity of atopic dermatitis: three item severity score as a rough system for daily practice and as a pre-screening tool for studies. *Acta Derm Venereol.* 1999; 79(5): 356-359. https://www.ncbi.nlm.nih.gov/pubmed/10494710
14. Finlay AY. Measurement of disease activity and outcome in atopic dermatitis. *Br J Dermatol.* 1999; 135(4): 509-515. https://www.ncbi.nlm.nih.gov/pubmed/8915137
15. Abuabara K, Magyari AM, Hoffstad O, et al. Development and validation of an algorithm to accurately identify atopic eczema patients in ptimary care electronic health records from the UK. *J Invest Dermatol.* 2017. doi: 10.1016/j.jid.2017.03.029

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**.*