Japanese Dermatological Association and Pfizer Announce
a Quality Improvement Grant RFP

Accelerate Promotion and Dissemination of Appropriate Atopic Dermatitis Diagnosis, Treatment, and Management Guidance

Competitive Grant Program – using Expert Review Panel

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Note this RFP is also available in Japanese for your convenience

I. Background

Pfizer Japan entered into a collaboration agreement with the Japanese Dermatological Association (JDA) to implement an innovative learning and change strategy. JDA aims social contribution through improvement of atopic dermatitis treatment and has similar goals to GMG with respect to promoting high quality education and change management initiatives that enable healthcare professionals to practice at an appropriate standard of care, thereby improving patient outcomes.

Pfizer Global Medical Grants (GMG) supports the global healthcare community's independent initiatives (e.g., research, quality improvement or education) to improve patient outcomes in areas of unmet medical need that are aligned with Pfizer's medical and/or scientific strategies.

Pfizer's GMG competitive grant program involves a publicly posted Request for Proposal (RFP) that provides detail regarding a specific area of interest, sets timelines for review and approval, and uses an expert review panel (ERP) to make final grant decisions. Organizations are invited to submit an application addressing the specific gaps in practice as outlined in the specific RFP.

For all quality improvement grants, the grant requester (and ultimately the grantee) is responsible for the design, implementation, and conduct of the independent initiative supported by the grant. Pfizer must not be involved in any aspect of project development, nor the conduct or monitoring of the quality improvement program.

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II. Eligibility

Geographic Scope:	Japan
Applicant Eligibility Criteria	• The following may apply: medical, dental, nursing, allied health, and/or pharmacy professional schools; healthcare institutions (both large and small); Medical academic societies (excluding branches of the Japan College of Rheumatology); and other entities with a mission related to healthcare improvement. From the viewpoint of conflict of interest, a person belonging to a medical institution, to which any director of the Japan College of Rheumatology belong, cannot apply. • If the project involves multiple departments within an institution and/or between different institutions / organizations / associations. all institutions must have a relevant role and the requesting organization must have a key role in the project.

III. Requirements

Date RFP Issued	April 4, 2022
Clinical Area	Atopic Dermatitis
Specific Area of Interest for this RFP:	This program is intended to support efforts to correct various imbalances among clinical sites providing atopic dermatitis treatment (e.g. differences in available information/knowledge, healthcare professionals' workload, etc.). Furthermore, through the practice and assessment of the support project, we are expected to improve the medical care system by coming up with new approaches that would contribute significantly to the correction of imbalance regarding treatment and improve prognosis among the patients 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 Investigator Sponsored Research. In addition, it is not also our intent to support guideline development (e.g., clinical treatment guidelines) from the viewpoint of COI. More information can be found at Quality Improvement Grants

Target Audience:	Healthcare professionals involved in atopic dermatitis treatment and management (physicians, nurses, dieticians, pharmacists, clinical psychologists, nursing teachers, etc.) *NOTE: Projects whose target is "Patients only" are not eligible.*
Disease Burden Overview:	Atopic dermatitis (AD) is a disease that primarily manifests as itchy eczema with repeated episodes of worsening and remission. Infantile AD may be resolved during childhood, or may become chronic with eczema remaining well into adulthood[1, 2]. AD can also develop (or worsen) during adolescence or adulthood[3-5]. Strong itching, associated sleep disorder and other symptoms significantly reduce the QoL of patients as well as their families, remarkably affecting their social life[6]. Thus, it is extremely important to provide accurate diagnosis of AD promptly following onset as well as treatment that enables early induction of remission and an appropriate management guidance to maintain the state of remission[7]. Various efforts are being made to enable appropriate AD diagnosis, treatment, and management guidance, such as release of AD treatment guidelines[7] jointly prepared by dermatologists, pediatricians/allergists and others, interdepartmental cooperation, promotion for team medicine comprising various healthcare professionals (physicians, nurses, pharmacists, etc.), and hospital-clinic cooperation involving university hospitals, regional core hospitals and local clinics, etc. Yet, there are still many AD patients who are not given adequate treatment. This competitive grant pertinent to the Program to Accelerate Promotion and Dissemination of Appropriate Atopic Dermatitis Diagnosis, Treatment, and Management Guidance is intended to discover, nurture, and disseminate approaches that can potentially be a new model case for AD treatment in line with the progress of medicine and to contribute to improved outcomes of patients.
Recommendations and Target Metrics:	Atopic Dermatitis Treatment Guideline 2021 Guidelines for Actions against Allergic Diseases in School (Revised in 2019) Guidelines for Handling Allergies at Nursery (Revised in 2019)
Barriers:	Although AD is a widely known disease, its etiology comprises multiple factors such as atopic predisposition, skin barrier vulnerability, and environmental factors; its symptoms and forms of manifestation vary among patients. Therefore, no single diagnostic criteria or treatment method can be applied uniformly to all AD patients. In addition, it is necessary to close the information gaps among clinical departments and healthcare professionals, and promote for correction of treatment imbalance since AD diagnosis, treatment, and management guidance are often provided by physicians not specializing in AD treatment. For topical treatment which is the standard treatment for AD, the dose amount of topical drugs, moisturizers, etc. and how to apply them make differences in therapeutic outcomes. It has been shown that patient education on topical drugs (sufficient explanation and periodical guidance by physicians, nurses, pharmacists, etc.) contributes to improved treatment

	adherence and patient outcomes[8-10]. Furthermore, proper management of AD symptoms is important in daily life, including nursery school, kindergarten, etc. for early childhood and school life for school-age children, and for which, guidelines for childcare workers and teachers have been issued[11, 12]. In addition, appropriate explanation to and follow-up on patients are essential pertinent to selection of new AD treatment methods such as systemic drugs. Thus, for better AD diagnosis, treatment, and management guidance, it is essential to build a team medicine scheme including cooperation among various staff members within a medical institution, as well as hospital-clinic collaborations involving local hospitals and core hospitals (including university hospitals), cooperation between nursing teachers and nurses at schools/nursery centers, and school doctors and local hospitals, etc. Finally, overwork and labor shortage are becoming serious problems for doctors and other medical staff not only in dermatology but also in all therapeutic areas. Therefore, cooperation of healthcare professionals playing various roles, task shifting, and efficiency improvement using digital tools are urgent issues in providing necessary and sufficient support to AD patients. By the way, "task shifting" is, for example, to have a person other than a physician (nurses, clerical assistant for physicians, etc.) who performs interviews and preliminary examinations on behalf of the physician[13, 14]. [1] Correction of treatment gaps (e.g., between departments, between medical institutions [universities/core hospitals - clinics], between healthcare professionals, etc.) [2] Establishment of team medicine scheme [3] Overwork/task shifting at medical institutions
Expected Approximate Monetary Range of Grant Applications:	The total available budget related to this RFP is 10,000,000 JPY. Individual projects requesting up to 5,000,000 JPY will be considered. The amount of the grant Pfizer will be prepared to fund for any project will depend upon the expert review panel's evaluation of the proposal and costs involved and will be stated clearly in the approval notification.
Key Dates:	• RFP release date: April 4, 2022 • LOI due date: July 4, 2022 Please note the deadline is midnight Eastern Time (New York, GMT -5). • Review of Full Proposals by Expert Review Panel: August 2022 • Anticipated Full Proposal Notification Date: September 2022 • Grants distributed following execution of fully signed Letter of Agreement Anticipated Project Start and End Dates: 1-3 years (December 2022 – November 2025)

How to Submit:	• Please go to www.cybergrants.com/pfizer and sign in. First-time users should click "Create your password". • In the application: o Select the following Project Type: "*Quality Improvement*". o Select the following Primary Area of Interest: "*Atopic Dermatitis*" o Select the following Competitive Grant Program Name: "*2022 I&I JP: Accelerate Promotion and Dissemination of AD Diagnosis, Treatment, and Management Guidance*" • Requirements for submission: Complete all required sections of the online application and upload the completed Full Proposal template (see Appendix). • If you encounter any technical difficulties with the website, please click the "Technical Questions" 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, Akihiro Kamina (meg.japan@pfizer.com), with the subject line "*2022 I&I JP: Accelerate Promotion and Dissemination of AD Diagnosis, Treatment, and Management Guidance*."
Grant Agreements:	• If your grant is approved, your institution will be required to enter into a written grant agreement with Pfizer. Please click here to view the core terms of the agreement. • Pfizer has drafted the terms of these agreements to be balanced and reasonable and to further the goals of both parties. Negotiating grant agreements requires significant resources, so please ensure that your institution (including your legal department) is able and willing to abide by these terms before proceeding with submission of your application as they will need to be accepted in their entirety.
Review and Approval Process:	• The panels are comprised of professionals from the medical community with advanced degrees and expertise in particular clinical areas, or specific needs of a geographic region/learner group, or expertise in research, continuing professional development or quality improvement • The expert review committee is composed mainly of experts in the field of rheumatism selected by JDA.
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. • Pfizer must complete payment procedure by the end of November 2022. Please confirm the procedure of your institution for receiving our grant before proceeding with submission of your application.

References:

1) Kusunoki T. et al: Changing prevalence and severity of childhood allergic diseases in Kyoto, Japan, from 1996 to 2006, Allergol Int, 2009; 58: 543—548.

2. Yamamoto-Hanada K. et al: Four phenotypes of atopic dermatitis in Japanese children: A general population birth cohort study, Allergol Int, 2019; 68: 521—523.

3. Ricci G. et al: Long-term follow-up of atopic dermatitis: retrospective analysis of related risk factors and association with concomitant allergic dis¬eases, J Am Acad Dermatol, 2006; 55: 765—771.

4. Illi S. et al: The natural course of atopic dermatitis from birth to age 7 years and the association with asthma, J Allergy Clin Immunol, 2004; 113: 925—931.

5. Sandström MH. et al: Prognosis and prognos¬tic factors in adult patients with atopic dermatitis: a long term follow-up questionnaire study, Br J Dermatol, 2004; 150: 103—110.

6. Murota H. et al. Evaluating the burden of pruritus due to atopic dermatitis in Japan by patient-reported outcomes, J Med Econ, 2021;24:1280-1289

7. Atopic Dermatitis Treatment Guideline Preparation Committee, Atopic Dermatitis Treatment Guideline 2021, Japanese Journal of Dermatology: 131 (13), 2691-2777, 2021

8. Hideki Mukai et al., Benefits of Inpatient Treatment for Atopic Dermatitis - Questionnaire Survey to Investigate Improvement of Skin and Psychiatric Symptoms -, Skin Research, Vol. 11 (2012) Suppl. 18

9. Sakae Kaneko et al., Questionnaire to Pharmacists on Guidance Given to Patients with Atopic Dermatitis, Japanese Journal of Allergology: 63 (9), 1250-1257, 2014

11. Japan Society of School Health (Committee for Revision of Guidelines for Allergic Diseases in School), Guidelines for Actions against Allergic Diseases in School (Revised in 2019), p61-70

12. Ministry of Health, Labour and Welfare (Study Group for Review of Guidelines for Handling Allergies at Nursery), Guidelines for Handling Allergies at Nursery (Revised in 2019), p57-64

13. Roles in the Process of Treatment and Diagnosis, Reference Material for the 4th Meeting of Review Committee on Promotion of Tasks/Shifts/Shares to Promote Work Style Reform for Physicians, December 25, 2019

14. Promotion of Tasks/Shift/Share within the Scope Feasible Under the Current System, HPB Notification No. 0930-16, September 30, 2021

Appendix A

Quality Improvement Project Full Proposal

Applications will be accepted via the online portal. Full Proposal documents should be no longer than 10-15 pages in length (12-point font and 1-inch margins) excluding Organization Detail and References. When uploading your Full Proposal please ensure it addresses the following*:

Goals and Objectives	• 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). • 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.
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.
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
Project Design and Methods	• Describe the planned project and the way it addresses the established need. • If your methods include educational activities, please describe succinctly the topic(s) and format of those activities
Innovation	• Explain what measures you have taken to assure that this project idea is original and does not duplicate other projects or materials already developed. • 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.
Evaluation and Outcomes	• 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.

	• Quantify the amount of change expected from this project in terms of your target audience. • Describe how the project outcomes will be broadly disseminated.
Anticipated Project Timeline	• Provide an anticipated timeline for your project including project start/end dates
Additional Information	• If there is any additional information you feel Pfizer should be aware of concerning the importance of this project, please summarize here
Organization Detail	• 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.
Budget Detail	• The budget amount requested must be in Japanese YEN (JPY). • While estimating your budget please keep the following items in mind: o 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. o The inclusion of these costs cannot cause the amount requested to exceed the budget limit set forth in the RFP. o It should be noted that grants awarded through GMG cannot be used to purchase therapeutic agents (prescription or non-prescription). o Consumption tax should be included in your budget. • Pfizer maintains a company-wide, maximum allowed overhead rate of 28% for independent studies and projects.