

Japanese Society for Inflammatory Bowel Disease and Pfizer Announce a Quality Improvement Grant RFP

Providing Appropriate Medical Care for IBD Patients Competitive Grant Program – using Expert Review Panel

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Note this RFP is also available in <u>Japanese</u> for your convenience

I. Background

Pfizer Japan entered into a collaboration agreement with Japanese Society for Inflammatory Bowel Disease (JSIBD) to implement an innovative learning and change strategy. JSIBD aims to promote research into the etiology, pathology, and treatment of inflammatory bowel diseases (IBD) such as ulcerative colitis and Crohn's disease, thereby contributing to improvement of the quality of life (QOL) of patients, 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.

II. Eligibility

Geographic Scope:	Japan
Applicant Eligibility Criteria	 Only organizations are eligible to receive grants, not individuals or medical practice groups.
	 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.
	 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.

III. Requirements

Date RFP Issued	November 8, 2022
Clinical Area	Inflammatory Bowel Disease
Specific Area of Interest for this RFP:	 This grant program will seek educational programs for healthcare professionals to provide appropriate medical care for IBD. The purpose of this program is to establish a system that can address appropriate medical care/education for IBD and establishment of networks by aiming to improve the skills of healthcare professionals engaged in IBD through implementation of the program.
	 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>Investigator Sponsored Research</u>. 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 <u>Quality Improvement Grants</u>
Target Audience:	 Healthcare professionals (e.g., IBD specialists and community healthcare professionals)
Disease Burden Overview:	 In recent years, medical treatment for IBD has made dramatic progress, but with changes in lifestyle such as westernization of meals, the number of patients with IBD is steadily increasing.¹⁻² As a result,





Recommendations and Target Metrics:	 diversification of IBD patients,³ increasing burdens on the institutions specialized in IBD, and delay in the development of healthcare professionals are becoming problems. To solve these problems, it is required to establish hospital-clinic/hospital-hospital cooperation with institutions specialized in IBD, to educate/enlighten specialists and healthcare professionals, and to expand team medical care including cooperation with other departments.⁴⁻⁵ Diagnostic Criteria and Treatment Guidelines for Ulcerative Colitis and Crohn's Disease in 2021 Ministry of Health, Labour and Welfare, Grants-in-Aid for Scientific Research, Research on Policy Planning for Intractable Diseases "Research Group for Intractable Inflammatory Bowel Disease" Evidence-based Clinical Practice Guidelines for Inflammatory Bowel Disease (IBD) 2020 Edited by the Japanese Society of Gastroenterology
Barriers:	 "Education for healthcare professionals regarding support for integrating work and treatment in IBD treatment" Outline: In Japan, various initiatives and support systems have been established under the initiative of the Ministry of Health, Labour and Welfare (MHLW) to support "integrating treatment and work" for patients with cancer, heart diseases, intractable diseases, etc. As the personnel playing an important role in such support, a system to nurture "integrating support coordinators" has been established. However, its utilization and dissemination in the IBD area are not yet sufficient. Since many patients with IBD develop their disease before or at working age and require continued treatment throughout their working age, it is particularly important for healthcare professionals treating patients with IBD to have a good understanding of the efforts and systems related to 'the integration of treatment and work' and to have the skills to plan individual treatment plans with appropriate support.
Current National Efforts to Reduce Gaps:	 The Ministry of Health, Labour and Welfare issued the "guidelines of support for integrating treatment and work," in which measures for intractable diseases including IBD are indicated as "measures based on the characteristics of treatment for intractable diseases."⁸ Training of integrating support coordinators is conducted as a project for supporting the integration of treatment and work by the Japan Organization of Occupational Health and Safety (JOHAS). If a medical institution provides appropriate support for integrating treatment and work, the expense can be added to the medical fee. (B001-9 Guidance fee for support for integrating treatment and work, 1000 points)





Expected Approximate Monetary Range of Grant Applications:	 Individual projects requesting up to 2,500,000 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 grant agreement.
Key Dates:	RFP release date: November 8, 2022
	Full Proposal Deadline: January 6, 2023
	Please note the deadline is 23:59 Eastern Time (New York, GMT -5).
	Review of Full Proposals by Expert Review Panel: February 2023
	Anticipated Full Proposal Notification Date: March 2023
	 Grants distributed following execution of fully signed Letter of Agreement
	 Anticipated Project Start and End Dates: April 1, 2023 to March 31, 2025 (Up to 2 years)
How to Submit:	 Please go to <u>www.cybergrants.com/pfizer/QI</u> and sign in. First-time users should click "Create your password".
	Click the "Start A New Quality Improvement Application" button.
	 For the question "Competitive Grant?" select Yes
	 Select the following Competitive Grant Program Name: "2023 I&I JP: Providing Appropriate Medical Care for IBD Patients"
	Requirements for submission:
	Complete all required sections of the online application (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 "Providing Appropriate Medical Care for IBD Patients".
Grant Agreements:	 If your grant is approved, your institution will be required to enter into a written grant agreement with Pfizer. Please click <u>here</u> 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	 A specific grant program RFP uses an expert review panel (ERP) to make final grant decisions. 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
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 during the review period.

References:

- 1) Website of the Japan Intractable Diseases Information Center, Ministry of Health, Labour and Welfare
- 2) Increased Incidence of Inflammatory Bowel Disease in Association with Dietary Transition (Westernization) in Japan, Mitsuro Chiba et.al,2021, JMA Journal
- 3) Inflammatory Bowel Disease: Complexity and Variability Need Integration. Fiocchi,2018, Front Med (Lausanne)
- 4) Lead to team medicine! Visual text for IBD treatment, Yodosha (issued in November 2016)
- 5) IBD Research June 2020 Issue, SENTAN IGAKU-SHA (Issued in June 2020)
- 6) Diagnostic Criteria and Treatment Guidelines for Ulcerative Colitis and Crohn's Disease in 2021

Ministry of Health, Labour and Welfare, Grants-in-Aid for Scientific Research, Research on Policy Planning for Intractable Diseases "Research Group for Intractable Inflammatory Bowel Disease"

- 7) Evidence-based Clinical Practice Guidelines for Inflammatory Bowel Disease (IBD) 2020. Edited by the Japanese Society of Gastroenterology
- 8) Ministry of Health, Labour and Welfare "Guidelines of support for integrating treatment and work at workplace" (revised in March 2022)





Appendix

Quality Improvement Full Proposal Requirements

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 <i>overall</i> 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 <i>your</i> 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. Letters of support from partner organizations will be required at the Full Proposal stage only and should not be included with the LOI.
Budget Detail	 The budget amount requested must be in Japanese Yen (JPY). While estimating your budget please keep the following items in mind: General organizational running costs such as insurances, heating, lighting, rent, building maintenance may be included. Pfizer does not provide funding for capital purchases (infrastructure expenses such as equipment, purchases of software or software licenses, technology or bricks and mortar). Equipment hire/leasing is acceptable and may be included in project budget. 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 GMG cannot be used to purchase Pfizer therapeutic agents (prescription or non-prescription). Pfizer maintains a company-wide, maximum allowed overhead rate of 28% for independent studies and projects. Please click here for details.



