Japanese Society for Inflammatory Bowel Disease and Pfizer Quality Improvement RFP *Providing Appropriate Medical Care for IBD Patients*

Competitive Grant Program - using Expert Review Panel

Overview

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Japanese Society for Inflammatory Bowel Disease (JSIBD) and Pfizer invite applications for this educational grant program targeting initiatives for healthcare professionals to provide appropriate medical care for patients with inflammatory bowel disease (IBD). The program will help build systems allowing appropriate clinical practice/education and establish networks by aiming to improve the skills of healthcare professionals engaged in IBD treatment through implementation of the selected projects.

Geographic Scope

Japan

Project Types and Area of Interest

This grant program will seek Quality Improvement projects 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.

Key Milestones

- Application submission deadline: January 5, 2024
 Extended Due Date: Junary 31, 2024
- Anticipated decision notification date: March 31, 2024
- Anticipated project start date: June 1, 2024

Funding Range and Project Length

Individual projects requesting up to 2,000,000 JPY will be considered.

Anticipated Project Start and End Dates: June 1, 2024 to May 31, 2026 (Up to 2 years)

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



I. Eligibility

Geographic Scope:

• Japan

Applicant Eligibility Criteria

- Only legal 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.

II. Requirements

Date RFP Issued

• October 10, 2023

Clinical Area

• Inflammatory Bowel Disease (IBD)

Specific Area of Interest for this RFP:

It is our intent to support projects that focus on seeking educational projects 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.

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, 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⁾

Recommendations and Target Metrics

- Diagnostic Criteria and Treatment Guidelines for Ulcerative Colitis and Crohn's Disease in 2022
- 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

Specific areas of interest for the program:

The grant program will seek projects on the following topics:

- Education for healthcare professionals on establishment of regional collaboration systems and interprofessional teams in IBD treatment
- Education facilitating seamless transition
- Education for healthcare professionals on pregnancy and childbirth in IBD treatment

Overview:

• With the growing number of IBD patients making it a challenge to provide adequate care for IBD within specialized medical institutions, it has become imperative to maintain the quality of IBD treatment with limited medical resources by establishing IBD care systems through collaborations with regional medical institutions and role-sharing among different professionals. While there are expectations for "medical care" tailored to life events and lifestyles of individual IBD patients, transitions of pediatric IBD patients to adult care settings and provision of appropriate medical care during pregnancy and after childbirth are also considered important issues. With the 2019 enactment of the "Act on Comprehensive Promotion of Measures for Providing Seamless Child-Rearing Support" (Basic Act on Child and Maternal Health and Child Development), pediatric to adult care transitions are now specified in the basic policies. However in reality, differences in practice style between pediatric and adult care can often hinder smooth transfer. In regard to pregnancy and childbirth, educational opportunities on the characteristics of therapeutic drugs and vaccination are necessary for not just female patients but male patients as well. To provide appropriate education according to individual IBD patients' lifestyles, it is vital to establish patient-centered comprehensive team-based medical care comprising various professionals such as pediatricians, adult doctors, nurses, pharmacists, nutritionists, certified public psychologists, and medical social workers.

Current National Efforts to Reduce Gaps

- In Hokkaido, Professor Hiroshi Nakase at Sapporo Medical University led the efforts to construct a remote collaborative medical care network, which was awarded by the Cabinet Office as an outstanding initiative utilizing digital technology.
- JSIBD has been conducting education seminars (MS education seminars) for medical staff based on multidisciplinary collaboration. In addition, "IBD Center" has been placed in key institutions and operated as a framework to facilitate multidisciplinary collaboration.
- Project groups of "Research on Intractable Inflammatory Bowel Disease" funded by the Ministry of Health, Labour and Welfare Grants-in-Aid for Scientific Research on Intractable Diseases and others have been working on transitions of pediatric IBD patients, which have so far resulted in the publication of the "Guidelines for Supporting Independence of Pediatric IBD Patients Transitioning to Adult Care" and consensus statements on transitions of patients with childhood-onset IBD.
- Educational efforts targeting healthcare professionals and patients regarding pregnancy and childbirth in IBD treatment include the development of "Treatment Strategies for Women of Child-Bearing Age with Systemic Lupus Erythematosus (SLE), Rheumatoid Arthritis (RA), Juvenile Idiopathic Arthritis (JIA), or IBD" (issued in March 2018), treatment strategies for women of childbearing age with RA or IBD, and patient handbooks.

Expected Approximate Monetary Range of Grant Applications:

• Individual projects requesting up to 2,000,000 JPY will be considered.



- Award amounts include direct costs, institutional overhead costs (capped at 28% per Pfizer policy), and indirect costs.
- 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: 10/10/2023
- Full Proposal Due Date: 1/5/2024 Extended Due Date: 1/31/2024
 - Please note the deadline is 23:59 Eastern Standard Time (e.g., New York, GMT -5).
- Review of Full Proposals by ERP: 2/29/2024
- Anticipated Full Proposal Notification Date: 3/31/2024
- Grants will be distributed following a fully executed agreement and submission of Final Protocol, documentation of IRB/IEC approval, regulatory approval (if applicable), exemption or waiver.

How to Submit:

Note: Please read this section carefully since applications submitted not following these instructions will not be accepted and will be cancelled

- Please go to <u>www.cybergrants.com/pfizer/Ql</u> and sign in. First-time users should click "Create your password".
- Click the "Start a New Quality Improvement Application" button.
- In the application:
 - For the question "Competitive Grant?" select Yes
 - Select the following Competitive Grant Program Name:" 2024 I&I JP JSIBD Providing Appropriate Medica Care for IBD Patients QI"
 - Select the following Primary Area of Interest: Inflammatory Bowel Disease (IBD)
- Requirements for submission:

Complete all required sections of the online application and upload your project proposal (see Appendix) in the Full Proposal Submission field.

• 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 after the due date will not be reviewed.

Questions:

 If you have questions regarding this RFP, please direct them in writing to Pfizer Japan MEG-J office (meg.japan@pfizer.com), with the subject line "Providing Appropriate Medica 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.
- Payment will only be made to requesting Institution.

Review and Approval Process



- A specific grant program RFP uses an expert review panel (ERP), which consists mainly of JSIBD members, 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) 2021. Edited by the Japanese Society of Gastroenterology



Japanese Society of Inflammatory Bowel Disease (JSIBD) aims to help "improve research activities, education, and clinical practice in IBD such as ulcerative colitis and Crohn's disease and contribute to the health and welfare of Japanese people." To achieve these objectives, JSIBD is engaged in the following activities:

- 1. Organizing academic conferences, lecture meetings, workshops, etc.
- 2. Publishing newsletters, journals, academic books, etc.
- 3. Communicating and collaborating with related academic organizations in Japan and overseas
- 4. Fostering IBD specialists
- 5. Carrying out educational activities for healthcare professionals involved in IBD treatment
- 6. Informing and educating the public on IBD
- 7. Providing grants for researchers studying IBD
- 8. Providing support for multicenter research on IBD
- 9. Undertaking clinical research on IBD
- 10. Other projects necessary for the achievement of JSIBD's objectives

About Pfizer Global Medical Grants

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.



Specific RFP Submission Requirements

Applications will be accepted via the online portal listed in the How to Submit section. Project Proposals/Protocols should be single-spaced using Calibri 12-point font and 1-inch margins. Note there is a 15-page limit exclusive of references. When uploading your Full Proposal please ensure it addresses the following sections:

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:
 - 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 <u>click here</u> for details.

