The Japan Spondyloarthritis Society and Pfizer Announce
a Quality Improvement Grant RFP

Establishment of an Appropriate Network of Medical Care and Education for Axial Spondyloarthritis by Doctors in Practice and Experts in Spondyloarthritis

Competitive Grant Program – using Expert Review Panel

日本語版はこちらをクリックしてください⇓
Note this RFP is also available in Japanese for your convenience

I. Background

Pfizer Japan entered into a collaboration agreement with The Japan Spondyloarthritis Society (JSAS) to implement an innovative learning and change strategy. JSAS aims to contribute to society by improving the contents of medical care for axial spondyloarthritis (including related diseases) 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 external 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.

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. • 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. For projects offering continuing education credit, the requesting organization must be accredited. *Note: From the viewpoint of conflict of interest, people who are a board member of JSAS involved in the selection for this medical and educational project grant or who belong to the same medical institution as the member preparing open recruitment cannot apply for this program.*

III. Requirements

Date RFP Issued	November 5, 2021
Clinical Area	Axial Spondyloarthritis
Specific Area of Interest for this RFP:	This program will recruit a program for establishment of an appropriate network of medical care and education for axial spondyloarthritis by doctors in practice and spondyloarthritis experts. The purpose of this program is to establish a system that allows doctors in practice and spondyloarthritis experts to work together to establish an appropriate network of medical care and education for axial spondyloarthritis through the implementation of this 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 Investigator Sponsored Research More information can be found at Quality Improvement Grants

Target Audience:	Doctors in practice, spondyloarthritis experts, etc. *NOTE: Projects whose target is "Patients only" are not eligible.*
Disease Burden Overview:	To establish the medical care system for axial spondyloarthritis, the education and enlightenment for doctors in practice and spondyloarthritis experts are urgently needed to improve the level of medical care for axial spondyloarthritis based on the actual situation, while taking into account the evidence1), 2). This will require an educational system for doctors in practice (such as a system that indicates what kind of clinical signs or test results require referral to a spondyloarthritis expert, etc.) and establishment of a network to introduce patients to spondyloarthritis experts as well as establishment of a system for collaboration between doctors in practice and spondyloarthritis experts. Thus, a model program to achieve these goals is required.
Recommendations and Target Metrics:	1) Guidelines for the Diagnosis and Management of Spondyloarthritis in Clinical Practice 2020 (edited by the Japanese Society for Spondyloarthritis, published by SHINDAN TO CHIRYO SHA) 2) Diagnostic Guidance for Non-Radiographic Axial Spondyloarthritis in Japan 3) Updated 2016 ASAS/EULAR Management Recommendations for Axial Spondyloarthritis 4) Updated 2019 ACR/SAA/SPARTAN Recommendations for Treatment of Ankylosing Spondylitis and Non-Radiographic Axial Spondyloarthritis
Barriers:	In 2015, axial spondyloarthritis, a representative disease of ankylosing spondylitis, was designated as an intractable disease and many molecular targeted drugs were introduced. In addition, the indication of molecular targeted drugs for non-radiographic axial spondyloarthritis was also approved. However, because axial spondyloarthritis presents various clinical symptoms, attention needs to be paid to differential diagnosis and delay from the onset to diagnosis has also been pointed out. In Japan, the Guidelines for the Diagnosis and Management of Spondyloarthritis in Clinical Practice 2020 have been published and recommendations have been announced by ASAS/EULAR3) and ACR/SAA/SPARTAN4), but no clear research issues have been mentioned in these recommendations yet. In other words, the establishment of evidence for treatment with axial spondyloarthritis seems to be still on the way of development compared to rheumatoid arthritis, etc. However, the introduction of molecular targeted drugs has progressed and the new concept of non-radiographic axial spondyloarthritis has also appeared. As a result, it is necessary to improve the contents of medical practice for axial spondyloarthritis. In Japan, the concept of axial spondyloarthritis has not been fully penetrated and it is assumed that even if a patient has some suspicious symptoms or findings, he/she will not be referred from a doctor in practice to a spondyloarthritis expert. Therefore, the improvement of a system such as establishment of a network in medical care and education/enlightenment have become urgent.

	As current issues, the following contents are considered: Current issues (1) Development and practice of education system for doctors in practice (2) Establishment of a network for referral to spondyloarthritis experts (3) Establishment of a system that enables doctors in practice and spondyloarthritis experts to work together
Expected Approximate Monetary Range of Grant Applications:	The total available budget related to this RFP is 9,000,000 JPY. Individual projects requesting up to 3,000,000 JPY will be considered. The grant applications received from this open recruitment will be eventually determined by an external review committee. The external review committee is composed mainly of experts selected by the JSAS.
Key Dates:	• RFP release date: November 5, 2021 • LOI due date: January 31, 2022 Please note the deadline is midnight Eastern Time (New York, GMT -5). • Review of LOIs by External Review Panel: February 2022 • Anticipated LOI Notification Date: February 2022 • Full Proposal Deadline: April 2022* *Only accepted LOIs will be invited to submit full proposals • Review of Full Proposals by External Review Panel: May 2022 • Anticipated Full Proposal Notification Date: June 2022 • Grants distributed following execution of fully signed Letter of Agreement Anticipated Project Start and End Dates: 1-3 years (August 2022 - July 2025)
How to Submit:	• Please go to www.cybergrants.com/pfizer/loi 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: “*Rheumatoid Arthritis*” o Select the following Competitive Grant Program Name: “*2022 I&I L-Establishment of an Appropriate Network of Medical Care and Education for Axial Spondyloarthritis”* • 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 “*2022 I&I L-Establishment of an Appropriate Network of Medical Care and Education for Axial Spondyloarthritis*.”
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 external review committee is composed mainly of experts in the field of rheumatism selected by JSAS.
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) Guidelines for the Diagnosis and Management of Spondyloarthritis in Clinical Practice 2020, Edited by Research Group of "Large-scale Multicenter Study Aiming at the Preparation of Epidemiological Survey/Diagnostic Criteria and Medical Care Guidelines for Spondyloarthritis Represented by Ankylosing Spondylitis", Japanese Society for Spondyloarthritis, Health and Labour Sciences Research Grant (Research Project for Intractable Disease Policy), Published by SHINDAN TO CHIRYO SHA

2) Non-radiographic axial spondyloarthritis. Mod Rheumatol. 2021 Mar;31(2):277-282. doi: 10.1080/14397595.2020.1830512. Epub 2020 Oct 12.

3) 2016 update of the ASAS-EULAR management recommendations for axial spondyloarthritis. Ann Rheum Dis. 2017 Jun;76(6):978-991. doi: 10.1136/annrheumdis-2016-210770. Epub 2017 Jan 13.

4) 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Care Res (Hoboken). 2019 Oct;71(10):1285-1299. doi: 10.1002/acr.24025. Epub 2019 Aug 21.

IV. Terms and Conditions

Please take note every Request for Proposal (RFP) released by Pfizer Independent Grants for Learning & Change (IGLC), as well as a RFP released jointly with a Partner(s), is governed by specific terms and conditions. Click **here** to review these terms and conditions.

Appendix A

Letter of Intent Requirements

The Letter of Intent (LOI) will be accepted via the online application. When answering the LOI questions in the application please keep the following in mind:

Note: Complete each item within 2000 characters.

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. 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	• 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. • 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.