Pfizer Announces

Adapting Patient Reported Outcome (PRO) Tools to Include Patient Preference Measures

Competitive Grant Program- using External Review Panel

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 research, practice or care as outlined in the specific RFP.

For all Investigator Sponsored Research (ISRs) and general research grants, the grant requester (and ultimately the grantee) is responsible for the design, implementation, sponsorship, and conduct of the independent initiative supported by the grant, including compliance with any regulatory requirements. Pfizer must not be involved in any aspect of study protocol or project development, nor the conduct or monitoring of the research program.

Competitive Grant Program Eligibility

Geographic Scope	• United States
Applicant Eligibility Criteria	To be eligible: • The institution and principal investigator (PI) must be based in the eligible country noted above. • Only organizations are eligible to receive grants, not individuals or medical practice groups. • The applicant (PI) must have a medical or postdoctoral degree (MD, PhD, or equivalent), an advanced nursing degree (BSN with a MS/PhD), or a degree in Pharmacy, Physiotherapy, or Social Work. • Applicant must be affiliated with a host institution.

Requirements

Date RFP Issued	• June 26, 2019
Clinical Area(s)	• Rheumatology
Area of Interest Focus	Despite advances in the management, treatment, and available therapy options for Rheumatoid Arthritis (RA), achieving remission in clinical practice is not as common as in clinical trials.[1] Recent studies have shown that, even with early aggressive combination therapy, only a fraction of patients met the criteria for clinical remission of RA.[2] Research supports the use of aggressive, high-dose, multiple drug therapy as the best approach to managing RA, however, this is not common in practice.[3] One reason aggressive therapy is not chosen reflects issues or preferences important to patients but not accounted for in expert recommendations or clinical trials.[3] Many methods have been studied to address this gap between guideline recommendations and treatment experiences. Known as a “treat-to-target” (or T2T) approach, these approaches have largely focused on the development of tools the institution or individual health care practitioner (HCP) can utilize to track and score a patient’s experience with their perception of disease activity. These scores can inform well-timed treatment plan changes to keep patients at or near agreed upon targets. Utilization of Patient Reported Outcome (PRO) tools is common in clinical trials, yet few of these are used in the clinical setting. Additionally, PROs seem to be largely

	focused on validated scoring or screening tools, but these instruments may lack the ability to capture information on pain, fatigue, and other quality of life measures that patients rank as most important in their daily life.[4] As a result, patients may not be achieving outcomes that are meaningful to them and patient and physician goals may be misaligned. Furthermore, it is not clear whether HCPs consider patient preference for different types of therapies and/or route(s) of administration when engaging in shared decision-making conversations, which could contribute to patient hesitancy to change therapy when a treatment target is not being met. It is of interest to understand how a wholistic approach focused on clinical outcomes, PROs, and patient preferences impacts overall quality of care, patient satisfaction, and remission. Please note the intent of this RFP is to support health services research (HSR) projects to develop or validate a mechanism for examining both the use of PROs in practice, while also studying the decisional conflict that exists in patients with high disease activity who are reluctant to adjust their treatment to match the recommended algorithms or guidelines. Partnerships are encouraged when appropriate. During review the intended outcomes of the study will be given careful consideration and, if appropriate based on the program goal, programs with the highest likelihood to directly impact patient care will be given priority. One other aspect should be stressed. Pfizer is not seeking to support educational projects through this grant mechanism. Educational efforts alone (targeted at healthcare providers and/or patients), while potentially useful/necessary, are not likely to be sufficient in and of themselves to produce substantial increases in the use of patient reported outcome measures in clinical practice, as part of shared decision-making, goal-setting, and monitoring of response to treatment.
Expected Approximate Monetary Range of Grant Applications	• Individual projects requesting up to $350,000 will be considered. Pfizer anticipates awarding up to 3 grants. • 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 26, 2019 • LOI due date: August 5, 2019 Please note the deadline is midnight Eastern Time (New York, GMT -5). • Review of LOIs by ERP: August 30, 2019 • Anticipated LOI Notification Date: September 13, 2019 • Full Proposal Deadline: *October 14, 2019 • *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 ERP: November 8, 2019 • Anticipated Full Proposal Notification Date: November 29, 2019 NOTE: Grant funding will be distributed following execution of fully signed Letter of Agreement. Please review the contract language here and before submitting a proposal for consideration, confirm with your institution that you can accept all contract terms. Pfizer considers these terms non-negotiable for grant projects.
How to Apply	• Please go to www.cybergrants.com/pfizer/loi and sign in. First-time users should click "REGISTER NOW". Requirements for submission: • Select the following Competitive Grant Program Name: Adapting PROs to Patient Preference • Complete all required sections of the online application. See Appendix A for additional details • If you encounter any technical difficulties with the website, please click the "Technical Questions" link at the bottom of the page
Questions:	• If you have questions regarding this RFP, please direct them in writing to the Grant Officer, Amanda Solis at Amanda.solis@pfizer.com with the subject line "Adapting PROs to Patient Preference." • Please click here to view Frequently Asked Questions regarding the Competitive Grant Program
Review and Approval Process	• Grant requests received in response to a specific RFP are reviewed by an external 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	• All applicants will be notified via email by the dates noted above

Applicants will be Notified:	• Applicants may be asked for additional clarification during the review period

References:

1. Mierau M, Schoels M, Gonda G, Fuchs J, Aletaha D, Smolen JS. Assessing remission in clinical practice. *Rheumatology* (Oxford). 2007 Jun;46(6):975-9.
2. Schipper LG, Vermeer M, Kuper HH, Hoekstra MO, et al. A Tight Control Treatment Strategy Aiming for Remission in Early Rheumatoid Arthritis is More Effective than Usual Care Treatment in Daily Clinical Practice: A Study of Two Cohorts in the Dutch RA Monitoring Registry. Ann Rheum Dis 2012;71:845-850.
3. Wolfe F, Michaud K. Resistance of RA Patients to Changing Therapy. *Arthritis Rheum.* 2007;56:2135-2142.
4. Fautrel B, Alten R, Kirkham B, de la Torre I, et al. Call for action: how to improve use of patient-reported outcomes to guide clinical decision making in rheumatoid arthritis. *Rheumatology International.* 2018; 38:935–947.

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:

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 U.S. dollars (USD).
	• 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 GMG 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