Pfizer Announces a Research Grant RFP 2021 Rheumatology Competitive Grant Program – using Expert Review Panel

, Ir=

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 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 one of the eligible countries 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
	 [Optional] Both early career and experienced investigators are encouraged to apply and consideration will be given to all proposals meeting the selection criteria

Requirements

Date RFP Issued	• November 2, 2020
Clinical Area	Rheumatology
Area of Interest Focus	The intent of this Request for Proposal (RFP) is to support both clinical and basic science research on the pathogenesis and treatment of Rheumatoid Arthritis (RA), Psoriatic Arthritis (PsA), and/or Ankylosing Spondylarthrosis (AS) with a specific focus on projects that are most relevant to improving patient care.
	All US investigators are encouraged to apply, including young investigators who are in the early stages of their career.
	Specific areas of interest include:
	 General/RA: Thrombosis and Inflammation – elucidating the mechanism by which the immune system contributes to the pathophysiology of VTE formation





	 Influence of JAK/STAT pathways on the pathophysiology of VTE, e.g., platelet function and coagulation factors, endothelial factors, humoral factors Understanding how and which risk factors and combination thereof in rheumatoid arthritis patients contribute to outcomes (mortality, MACE, VTE)
	 Pediatrics/JIA: Clinical, genomic, and or biomarker profiles to predict treatment response in JIA Uveitis in JIA: pathogenesis, outcomes/HRQoL, predictors/risk factors
	 Connective Tissue Diseases: The role of JAK/STAT pathway in the cutaneous manifestations of selected rheumatologic disease: SLE, dermatomyositis, scleroderma JAK/STAT signaling in the pathogenesis of the cutaneous manifestations of autoimmune diseases The role of JAKi in the treatment of cutaneous manifestations of autoimmune disease
	 SpA: Understanding pathophysiology-relationship between gut microbiome and the onset of spondyloarthritis Epidemiology of axSpA including risk factors, spectrum/progression from nr-axSpA to r-axSpA/AS Efficacy and safety of tofacitinib in spondyloarthritis including nr-axSpA and in PsA as monotherapy v. combination with csDMARDs Evidence for reduced inflammation (MRI, US) and inhibition of structural progression (x-ray) in spondyloarthritis Response in patient subtypes/dominant SpA features (e.g., peripheral SpA, uveitis, enthesitis, dactylitis, IBD)
Expected Approximate Monetary Range of Grant Applications	 Individual projects requesting up to \$150,000 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: November 2, 2020
	Submission Deadline: *January 22, 2021
	[Please note the deadline is 23:59 Eastern Time (New York, GMT -5).]
	Review of Full Proposals by ERP: March 2021
	Anticipated Full Proposal Notification Date: May 2021
	NOTE: Grant funding will be distributed following execution of fully signed contract. 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 <u>www.cybergrants.com/pfizer/Research</u> and sign in. First- time users should click "Create your password".
	Requirements for submission:
	 Select the following Competitive Grant Program Name: 2021 I&I L: Rheumatology Competitive Research
	 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 (<u>amanda.solis@pfizer.com</u>) with the subject line "2021 I&I L: Rheumatology Competitive Research."
	 Please click <u>here</u> 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 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





Appendix A Full Proposal/Protocol

Applications will be accepted via the online portal. Full Proposal/Protocol 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/Protocol please ensure it addresses the following:

Goals and Objectives	 Provide the main goal of the study and the study population (if applicable). Provide a detailed definition that is directly linked to the primary objective.
Assessment of Need for the Project	• This should reflect your study rationale. Provide a brief description of the medical/scientific question and the rationale of how this trial or study addresses the question.
Target Audience	 Describe the primary audience(s) targeted for this project. For Investigator Sponsored Clinical Trials, please specify the age, gender and other demographic information for trial population. 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 concisely the research design and methods for achieving the stated goals. For a clinical interventional study, include inclusion/exclusion criteria, treatment plan and statistical plan.
Innovation	• Explain what measures you have taken to assure that this project idea is original and does not duplicate other projects. 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	 Specify type and frequency of safety, efficacy, and/or outcome measures. Also indicate the method(s) used to assess measures. Provide a publication plan describing intended submission of abstracts to (a) congress(es) or intended submission of (a) publication(s) to peerreviewed journals. All publications must follow ICH guidelines.
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. Early-career applicants: Letter(s) of support from mentor(s) and collaborators describing how the award will advance the applicant's career.
Organization Detail	• This information is used to assess the capability of the organizational resources available to perform the effort proposed. Identify the facilities to be used [laboratory, animal, clinical and "other"]. If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project.
References	Bibliography of relevant references.



