Pfizer Announces a Research Grant RFP

I&I REALE 2021

RhEumatoid Arthritis Italian ReaL World Experience

Competitive Grant Program - using Expert 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 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	• Italy
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). • Applicant must be affiliated with an Italian host institution • 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	• December 15, 2020
Clinical Area	• Real World Data (RWD) in Rheumatoid Arthritis (RA)

Area of Interest Focus	The intent of this Request for Proposal (RFP) is to fund **observational** research projects in RA (mono or multicentric), with an exclusive focus on Real World Data (RWD) and Real world evidence (RWE), in relation to one or more of the following topics**:**
	• Treat-to-Target strategies in RA patients treated with JAK inhibitors (JAKis)
	• Efficacy and safety of treatment optimization with JAKis (e.g. monotherapy - in case of intolerance to methotrexate (MTX) or when MTX is inappropriate -, MTX and/or glucocorticoids (GCs) management)
	• Treatment strategies:
	  ○ temporary discontinuation,
	  ○ switching from biological disease-modifying antirheumatic drugs (bDMARDs) to targeted synthetic disease-modifying antirheumatic drugs (tsDMARDs) or between JAKis

	• Safety and efficacy of JAKis in sub-populations and comorbidities, including but not limited to history of malignancies, high cardiovascular (CV) risk, interstitial lung disease (ILD)
	• CV and venous thromboembolism (VTE) outcomes in RA patients on Tofacitinib compared with bDMARDs and/or other JAKis
	• Response and safety signals in patient subtypes such as, but not limited to, patients:
	  ○ With Extra-articular manifestations
	  ○ over 65 years old vs younger
	  ○ ACPA and/or RF-positive vs negative
	  ○ With Early RA vs longstanding RA
	• Tofacitinib, bDMARDs and/or other JAKis treatment persistence in RA patients (both monotherapy and combination therapy)
	• RWE from RA patient perspectives on tofacitinib, including but not limited to
	  ○ efficacy profile (e.g. RAPID3, HAQ-DI, EQ5, SF36, etc.)
	  ○ time to onset of efficacy,
	  ○ patient satisfaction / adherence /compliance

Expected Approximate Monetary Range of Grant Applications	• Individual projects requesting up to € 50.000 will be considered. Pfizer anticipates awarding up to 6 grants • 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: December 15, 2020 • Full Proposal Deadline: February 18, 2021 • Review of Full Proposals by ERP: March 2021 • Anticipated Full Proposal Notification Date: May 2021 • The projects should last no longer than 24 months • Grants will be distributed following a fully executed agreement **IMPORTANT:** *Grant funding will be distributed following execution of fully signed contract. The execution of fully signed contract must be completed within 90 days from receipt of the Approval Letter. Pfizer considers these terms non-negotiable for grant projects*
How to Apply	• **Please go to www.cybergrants.com/pfizer/Research 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 - REALE 2021 - RhEumatoid Arthritis Italian ReaL World Experience** • 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, Ai Ping Lee (AiPing.Lee@pfizer.com), with the subject line "REALE 2021 - RhEumatoid Arthritis Italian ReaL World Experience." • 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 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, 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 peer-reviewed 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.