Pfizer Announces

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Inflammatory and Immune-Mediated Dermatologic Disorders

195, Ir=198 198, Au=19

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 |
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| 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 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 4, 2019 |
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| Clinical Area | Inflammatory and Immune-mediated Dermatologic Disorders |
| Area of Interest Focus | The intent of this Request for Proposal (RFP) is to support predinical, clinical and outcomes research through a competitive grant program with the intent to increase medical knowledge in the diagnosis and management of inflammatory and immune-mediated dermatologic disorders. |
| | Areas of Research Focus Pfizer is interested in supporting high quality basic science, translational, clinical and outcomes research in atopic dermatitis, alopecia areata, Phosphodiesterase 4-inhibition (PDE4), and Janus Kinase (JAK) pathways |
| | with special interest in the following topics: |





Atopic Dermatitis (AD)

- Approaches to improving adherence to pharmacologic topical therapies for atopic dermatitis
- Phenotypic differences in the clinical course and/or response to pharmacologic therapy for atopic dermatitis
- Exploring the caregiver burden in managing atopic dermatitis in children
- Exploring the cytokine profile of patients with atopic dermatitis across the age spectrum

Phosphodiesterase 4-inhibition

- Exploring the role of PDE4 in atopic dermatitis as it relates to skin barrier function, cytokine regulation, and related symptoms and signs of inflammation, itch and pain.
- Evaluating use of a topical PDE4 inhibitor in combination or in sequence with other agents for atopic dermatitis.
- Evaluating mitigation strategies for tolerability reactions associated with pharmacologic topical agents for atopic dermatitis

Janus Kinase Pathways

- Assessment of the role of JAK-1 dependent cytokines and the JAK/STAT pathway in the pathophysiology of atopic dermatitis or alopecia areata
- Understanding HCP treatment preferences for moderate-to-severe atopic dermatitis (i.e. MoA, RoA, possibility of drug holidays) and satisfaction with currently available therapies

Alopecia Areata (AA)

- Exploring and defining the burden of illness of AA and associated comorbidities
- Assessment of the impact of AA in mild, moderate and severe disease on healthcare resource utilization and patient perception
- Identifying the patient/caregiver/parent perception of current therapies for alopecia areata and factors affecting switching therapies or adherence
- Developing validated scales to measure patient-related outcomes for alopecia areata

Out of Scope

- Research proposals that conflict with ongoing Pfizer-sponsored trials or future development plans are out of scope.
- Research proposals that require drug supply for investigational JAK-





| | inhibitors |
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| 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 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: November 4, 2019 LOI due date: January 31, 2020 [Please note the deadline is 23:59 Eastern Time (New York, GMT -5).] Review of Full Proposals by ERP: Review will occur in March 2020 Anticipated Full Proposal Notification Date: Notifications of grant decisions will be communicated by May 2020 |
| How to Apply | Please go to <u>www.cybergrants.com/pfizer/Research</u> and sign in. First-time users should click "REGISTER NOW". Requirements for submission: Select the following Competitive Grant Program Name: 2019 I&I L Inflammatory and Immune-Mediated Dermatologic Disorders 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, Derek Warnick (<u>derek.warnick@pfizer.com</u>), with the subject line "Inflammatory and Immune-Mediated Dermatologic Disorders." |
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| | 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 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 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 |
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| 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 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 |
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| References | Bibliography of relevant references. |



