



Pfizer Announces

Inflammation ASPIRE 2020 Ulcerative colitis International Developed Markets Competitive Grant Programme

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 grantees) 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 programme.

Competitive Grant Programme Eligibility

Geographic Scope	<ul style="list-style-type: none"> Europe (except Germany), Israel, Turkey, Russia, Australia, New Zealand, Japan and South Korea
Applicant Eligibility Criteria	<p>To be eligible:</p> <ul style="list-style-type: none"> The principal investigator (PI) and institution must be based in one of the eligible countries noted above. The applicant (PI) must hold an MD, PhD, PharmD or the equivalent 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 – however, preference will be given to early-career applicants (investigators in non-tenure-track positions, which includes fellows, post-docs, assistant professors, researchers without a position leading to permanent <tenure> professorship).

Requirements

Date RFP Issued	<ul style="list-style-type: none"> March 16, 2020
Clinical Area	<ul style="list-style-type: none"> Pfizer invites investigators to apply for the Inflammation ASPIRE 2020 Research Grants through submission of research proposals with the primary objective to increase understanding of the effect of inhibition of the JAK–STAT pathway on specific clinical effects – looking at either efficacy and/or safety outcomes in UC, as well as the role of the JAK–STAT pathways in inflammation.
Area of Interest Focus	<p>The intent of this Request for Proposal (RFP) is to fund clinical research in UC in relation to one or more of the following topics*:</p> <ul style="list-style-type: none"> ✓ Understanding treatment and efficacy: <ul style="list-style-type: none"> Disease management in UC using tofacitinib and new measures of efficacy (eg., treat to target, measures of efficacy <including faecal calprotectin>, development of new tools which includes PRO measurement using wearables/apps). Use of tofacitinib in: <ul style="list-style-type: none"> _ severe, acute flare UC patients _ ulcerative proctitis

	<ul style="list-style-type: none"> _ pouchitis _ other inflammatory GI conditions such as eosinophilic gastroenteritis and microscopic colitis _ patients with history of cancer (efficacy and safety) _ extraintestinal manifestations • Evaluation of the ability to restart tofacitinib therapy after interruption in UC patients • Dose increase and dose reduction • True tofacitinib monotherapy (no 5 ASA or Steroids) • Strategies to improve adherence to therapies in UC (and predictors of good adherence) • RWE studies are highly encouraged on all the above topics and will be preferentially valued if they combine several registries and /or generate rapid results through retrospective analysis and use of big data analysis techniques <p>✓ Personalized medicine:</p> <ul style="list-style-type: none"> • Predictors of Adverse events (e.g., lipids elevation, NMSC, HZ, serious infections, VTE) • Predictors of disease severity <p>✓ Mechanistic association of JAK inhibition with VTEs</p> <p>*Preference will be given to projects with a clear publication plan and timeline.</p>
Expected Approximate Monetary Range of Grant Applications	<p>Programme-wide grants monetary range:</p> <ul style="list-style-type: none"> • For the programme-wide areas of interest (available to ALL eligible countries, individual projects requesting up to €30,000 for mechanistic studies and €150,000 for clinical studies in UC will be considered. Overall, €0.96 million has been allocated to the UC programme. • 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	<ul style="list-style-type: none"> • RFP release date: March 16, 2020 • Full Proposals due date: May 1st, 2020 [Please note the deadline is midnight Eastern Time (New York, GMT -5).] • Review of Full Proposals by ERP: June 18th, 2020 (TBC) • Anticipated Full Proposal Notification Date: July 1st, 2020 <p>NOTE: Grant funding will be distributed following execution of fully signed Letter of Agreement.</p>
How to Apply	<ul style="list-style-type: none"> • Please go to www.cybergrants.com/pfizer/Research and sign in. First-time users should click "REGISTER NOW". <p>Requirements for submission:</p> <ul style="list-style-type: none"> • For programme-wide areas of interest applications, select the following Competitive Grant Program Name: R-2020-I&I IDM UC ASPIRE • 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 "Need Support?" link at the bottom of the page • Please note that applications must be submitted in English
Questions:	<ul style="list-style-type: none"> • If you have questions regarding this RFP, please direct them in writing to the Grant Officer, Jo Harbron (jo.harbron@pfizer.com), with the subject line "Inflammation ASPIRE 2020 enquiry."
Mechanism by which Applicants will be Notified:	<ul style="list-style-type: none"> • All applicants will be notified via email by the dates noted above. • Applicants may be asked for additional clarification during the review period.
Frequently Asked Questions (FAQs)	<p>What are the ASPIRE Research Grants?</p> <p>ASPIRE are a subset of Pfizer's competitive research grants. ASPIRE grants aim to fund research in the disease area of inflammation and immunology across Europe, Israel, Turkey, Russia, Australia, New Zealand, Japan and South Korea. Pfizer is fully funding the ASPIRE Research Grants. Additionally, Pfizer is providing the infrastructure and administrative support required to facilitate the review process, as well as notifying applicants and distributing the research grants. All applications will be formally reviewed by a committee of European medical/scientific experts in the field of the specific appropriate area.</p> <p>Due to Foreign Corrupt Practices Acts (FCPA) regulations, submissions selected for research grants by the review committee must go through an internal review at Pfizer to ensure provision of the grant is appropriate and relevant information regarding potentially influencing government official status, as well as beneficiaries and controllers' information, is captured (when applicable).</p>

Who is eligible to apply for ASPIRE Research Grants?

In 2020, the ASPIRE will focus on European countries, Israel, Turkey, Russia, Australia, New Zealand, Japan and South Korea. ASPIRE applications are possible for any investigator. To be eligible for a research grant, an applicant must hold an MD, PhD, PharmD or the equivalent and must reside in Europe, Israel, Turkey, Russia, Australia, New Zealand, Japan or South Korea.

What is the role of Pfizer in the ASPIRE Research Grants?

Pfizer will provide the administrative support required to facilitate the collation of applications and the review process, as well as notifying applicants and distributing research grants. All applications will be formally reviewed by the ASPIRE review committee including European and Asian medical and scientific experts, as well as one Pfizer voting panel member.

When will the ASPIRE Research Grants be announced?

The successful grantees will be notified about three months after the deadline. See home page for key dates.

Is the funding a per-annum or per-study amount?

Each research grant funds the entire research period and is not a sum paid per year.

Does the funding include Institutional overhead costs and indirect costs?

Yes, the maximum funding for each type of research grant includes indirect costs, and institutional overhead costs. Final budgets of those studies awarded a grant will be reviewed for fair market value before the contracting process begins.

Are the ASPIRE Research Grants open to researchers working outside one of the countries listed below?

No. The ASPIRE Research Grants are open only to researchers in these countries: Europe, Israel, Turkey, Russia, Australia, New Zealand, Japan and South Korea.

Are there any specific research areas that are excluded from ASPIRE funding?

The following topics fall outside of the scope of the ASPIRE Programme:

- General education and / or training
- Public health
- Support for research that is already underway
- Support for ongoing clinical programmes that are part of an organization's routine operations

Can an exception be made for certain applicants regarding the eligibility criteria to the ASPIRE Research Grants?

The eligibility requirements – academic, scientific, etc. – are designed and

maintained by the committee of experts. In keeping with the purpose and intention of the ASPIRE Research Grants, applicants must meet all the criteria in order to be considered for a research grant. Submissions outside these parameters will not be considered.

Is there a time limit for conducting the funded research?

Study results are expected three years maximum after the signature of the contract.

• How do I apply for an ASPIRE Research Grant?

Please go to www.cybergrants.com/pfizer/research and sign in. First-time users should click "REGISTER NOW".

Requirements for submission:

- Select the following Competitive Grant Program Name: Ulcerative Colitis
- 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 "Need Support?" link at the bottom of the page or contact gmg@pfizer.com.

I'm having difficulty submitting my application online, who do I contact for assistance?

Receive assistance by contacting gmg@pfizer.com

What is the deadline for application?

See information from above.

When will I hear whether my application has been successful?

See information from above.

If my application is successful, when will the funding commence?

Research Grants will commence about 2 months after the notification of the selection, pending receipt of all required documents noted in the application portal.

Will I receive a copy of the Review Committee's evaluation of my grant proposal?

The corresponding feedback will be provided upon request in due course only to applicants who had their proposals rejected.

Can Pfizer drugs be provided?

Upon request, and only for clinical research, Pfizer may provide both study drug and/or placebo. In this case drug cost must not be included in the budget template, must be clearly mentioned within the proposal.

For all translational research proposals, no drug will be provided, as in this case drug can easily be obtained from third party providers.

If I receive a research grant, will I become part of the press release in the public domain?

If your proposal is awarded a grant, then you will be informed personally before the press release.

I have a question that is not covered here

If you require clarification on an issue not addressed here, please contact the Grant Officer Jo Harbron (jo.harbron@pfizer.com).

Appendix A

Submission Requirements

Applications will be accepted via the online portal. When preparing your Full Proposal please ensure it addresses the following:

Goals and Objectives	<ul style="list-style-type: none"> Provide the main goal of the study and the study population. Provide a detailed definition that is directly linked to the primary objective
Assessment of Need for the Project	<ul style="list-style-type: none"> This should reflect your study rationale. Provide a brief description of the medical question and the rationale of how this trial addresses the question
Target Audience	<ul style="list-style-type: none"> Describe the primary audience(s) targeted for this project. For Investigator Sponsored 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Specify type and frequency of safety, efficacy, and outcome measures. Also indicate the method(s) used to assess measures
Anticipated Project Timeline	<ul style="list-style-type: none"> Provide an anticipated timeline for your project including project start/end dates
Additional Information	<ul style="list-style-type: none"> If there is any additional information you feel Pfizer should be aware of concerning the importance of this project, please summarize.
Organization Detail	<ul style="list-style-type: none"> 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 Early-career applicants: Letter(s) of support from mentor(s) and collaborators describing how the award will advance the applicant's career.

