



Pfizer Announces
Inflammation ASPIRE 2019 Atopic dermatitis
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 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 programme.



Competitive Grant Programme Eligibility

Geographic Scope	<ul style="list-style-type: none"> Europe, 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

Requirements

Date RFP Issued	<ul style="list-style-type: none"> February 1st, 2019
Clinical Area	<ul style="list-style-type: none"> Pfizer invites investigators to apply for the Inflammation ASPIRE 2019 Research Awards through submission of research proposals with the primary objective to increase understanding of the effect of inhibition of the PDE4 pathway on specific clinical effects – looking at either efficacy and/or safety outcomes in AD, as well as the role of the PDE4 pathways in inflammation.
Area of Interest Focus	<p>The intent of this Request for Proposal (RFP) is to fund clinical research in AD, in relation to one or more of the following topics:</p> <p><u>Programme-Wide Areas of Interest (available to applicants from ALL eligible countries)</u></p> <ul style="list-style-type: none"> Defining the effect of PDE4 inhibitors on atopic dermatitis pathophysiology: <ul style="list-style-type: none"> Effects on innate and adaptive immunity at different stages of the disease Effects on skin barrier repair Assessment of PDE4 inhibitors' effect on skin microbiome

	<ul style="list-style-type: none"> ○ Defining the MoA of PDE4 inhibition on itch neural mechanism ● Clinical studies with PDE4 inhibitors: <ul style="list-style-type: none"> ○ Evaluation of PDE4 inhibitors' impact on PROs, SCORAD index, quality of life, sleep and itch ○ Analyses of compatibility/effect of PDE4 inhibitors: <ul style="list-style-type: none"> - With commonly used topical agents (e.g., sunscreen) - In combination with other treatments modalities (e.g., phototherapy) - In combination with systemic treatments - In concomitant use with topical corticosteroids as acute treatment in mild to moderate AD <p>In addition to the programme-wide areas of interest listed above, there are also special country-specific grants available Italy. There are no additional areas of interest, but additional funding is available for grant applications from Italy (please see "Expected Approximate Monetary Range of Grant Applications" section below for more information)</p>
<p>Expected Approximate Monetary Range of Grant Applications</p>	<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 €60,000 for AD will be considered. Overall, €300,000 has been allocated to the AD programme. ● Country-specific special grants - monetary range: <ul style="list-style-type: none"> - Italy – one additional grant of up to €90,000 is available for Italian applicants for the programme-wide areas of interest ● 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

<p>Key Dates</p>	<ul style="list-style-type: none"> • RFP release date: February 1st, 2019 • LOI due date: April 1st, 2019 <p>[Please note the deadline is midnight Eastern Time (New York, GMT -5).]</p> <ul style="list-style-type: none"> • Review of LOIs by ERP: Mid-May 2019 • Anticipated LOI Notification Date: Mid-May 2019 • Full Proposal Deadline: Four weeks from LOI notification date <p>*Only accepted LOIs will be invited to submit full proposals. [Please note the deadline is midnight Eastern Time (New York, GMT -5).]</p> <ul style="list-style-type: none"> • Review of Full Proposals by ERP: July 2019 • Anticipated Full Proposal Notification Date: August 2019 <p>NOTE: Grant funding will be distributed following execution of fully signed Letter of Agreement.</p>
<p>How to Apply</p>	<ul style="list-style-type: none"> • Please go to CyberGrants 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: IDM AD ASPIRE 2019 • For the country-specific special project grants, select the appropriate Competitive Grant Program Name (IDM AD ASPIRE Italy 2019). Please remember that for the country-specific special grants, the budget caps differ to the programme-wide grants. • 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
<p>Questions:</p>	<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 2019 enquiry.”
<p>Mechanism by which Applicants will be Notified:</p>	<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
<p>Frequently Asked</p>	<p>What are the ASPIRE Research Grants? ASPIRE are a subset of Pfizer’s competitive research grants . The ASPIRE</p>

Questions (FAQs)

subset of the competitive grants programme aims 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.

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).

Who is eligible to apply for ASPIRE Research Grants?

In 2019, 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.

Why are there special opportunities for some countries?

In previous years, some countries have had country-specific competitive grant programmes. In 2019, to maximise the available funds to be spent on grants rather than administration, the country specific programmes have been incorporated into the regional programmes leading to additional grant opportunities for some countries

When will the ASPIRE Research Grants be announced?

The successful awardees 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 a ASPIRE Research Grant?

Applications are to be submitted to Pfizer through an online submission website in a 2-step process. Visit www.cybergrants.com/pfizer/LOI, follow the process and submit your letter of intent (LOI). These letters of intent are summary proposals, which will be evaluated by a LOI review panel. The LOI review panel will decide which proposals can continue and submit a full proposal through the same website.

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

Receive assistance by contacting globalmedicalgrants@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 in due course to all applicants.

	<p>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.</p> <p>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.</p> <p>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).</p>
<p>Previous ASPIRE winners</p>	<p>ASPIRE 2018 Awarded proposals in Inflammation Research</p> <p>Ernest Choy (Cardiff University, UK) Tofacitinib on pain processing in rheumatoid arthritis (ToPPRA)</p> <p>James Bluett (University of Manchester, UK) Development and validation of a tofacitinib adherence assay in rheumatoid arthritis - oral adherence</p> <p>Costantino Pitzalis (Barts and the London School of Medicine and Dentistry, UK) Phosphoproteomic profiling of tofacitinib response in rheumatoid arthritis (Phospho-Tof-RA)</p> <p>Harald Burkhardt (Goethe-University Frankfurt/Main & Fraunhofer Institute for Molecular Biology and Applied Ecology, Germany) Comparison of the capability to taper non-steroidal anti-inflammatory drugs and of treat-to-target guided de-escalation of corticosteroids in newly initiated Tofacitinib or Etanercept therapy to accelerate the clinical relevant decrease of accompanying NSAID and corticosteroid treatment in patients with active Rheumatoid Arthritis and inadequate response to previous csDMARD</p> <p>Michael Nurmohamed (Reade, Netherlands) Increased thromboembolic risk during antirheumatic treatment, fact or fiction</p> <p>Denis Poddubnyy (Clinic of Gastroenterology, Infectiology and Rheumatology, Campus Benjamin Franklin, Charite - Universitätsmedizin Berlin, Germany) A 24-week, prospective, open-label, proof-of-concept study to evaluate the efficacy of tofacitinib in reducing inflammation detected on MRI in patients with</p>

psoriatic arthritis presenting with axial involvement

Sander W. Tas (Academic Medical Center/University of Amsterdam, Netherlands)

The contribution of JAK-STAT signaling to pathological endothelial responses in psoriatic arthritis

Ursula Fearon (Trinity College Dublin, Ireland)

To elucidate the effect of tofacitinib on specific polyfunctional T-cells within the PsA-inflamed synovium

Stefan Schreiber (Medical Department, University Hospital Schleswig Holstein, Campus Kiel & Institute of Clinical Molecular Biology, University Hospital Kiel and Christian-Albrechts-University Kiel, Germany)

TofaCID_A systems medicine approach to dissect tofacitinib dependent modulation of signatures of disease and response in chronic inflammatory disease

Christien van der Woude (Erasmus MC, Netherlands)

Deep profiling of lipid changes in patients with active ulcerative colitis treated with either tofacitinib or infliximab

Alessandro Armuzzi (Fondazione Policlinico Universitario A. Gemelli Università Cattolica del Sacro Cuore, Italy)

Predictive value of colonic mucosal and synovial tissues profiles for response to JAKs inhibitor in patients affected by ulcerative colitis and concomitant peripheral arthritis

Massimo Fantini (Università Degli Studi di Roma «Tor Vergata», Italy)

(A)nalysis of immunological (VA)riables in ex vivo (T)ofacitinib-treated human biopsies from (A)ctive ulcerative colitis patients to predict clinical (R)esponse (the AVATAR study)

Europe ASPIRE 2017 Awarded Proposals in Inflammation Research:

Thierry Schaeffer (University Hospital of Bordeaux, France)

Impact of Tofacitinib on Pain sensitization in Rheumatoid Arthritis patients (TOPRA study)

Maya H Buch (Leeds Institute of Rheumatic and Musculoskeletal Medicine, United Kingdom)

Investigating JAK-STAT intracellular signalling in peripheral blood cell subsets using multi-parameter flow cytometry and synovial tissue JAK-STAT to tailor

JAK inhibitor therapy in patients with refractory rheumatoid arthritis

Arthur G Pratt (Newcastle University, United Kingdom)

Refining a Predictive Biomarker for Effective JAK-STAT Inhibition in Rheumatoid Arthritis

Silvia D'Alessio (Humanitas Research Hospital, Milano, Italy)

Unravelling the mechanism of action of Tofacitinib on immune cell trafficking through IBD-associated microvasculature

Keren M Rabinowitz (Felsenstein Research Medical Center, Petach Tikva, Israel)

Mechanistic insights into modification of human intestinal immune responses by Janus kinase (JAK) modulation

Bas Oldenburg (University Medical Centre Utrecht, Netherlands)

Novel tools to assess mucosal JAK-STAT activity and the effect of therapeutic compounds in patients with Crohn's disease and ulcerative colitis

Europe ASPIRE 2016 Awarded Proposals in Inflammation Research:

Helen L. Wright (Institute of Ageing and Chronic Diseases, University of Liverpool, United Kingdom)

The effect of JAK inhibition on neutrophil killing, NETosis and metabolism in rheumatoid arthritis

Marta Rizzi (University Medical Centre Freiburg, Germany)

Impact of Janus kinase inhibition on human early and late B cell development

Giovanni Almanzar (University Hospital Wuerzburg, Germany)

Varicella-zoster-virus-(VZV)-specific cellular immune response of in vitro tofacitinib-treated lymphocytes derived from patients with autoimmune arthritis

Sergei Nedospasov (Deutsches Rheuma-Forschungszentrum Berlin, Germany)

Combined blockade of TNF and JAK-STAT pathways in murine models of autoimmune arthritis

Thomas Karonitsch (Medical University of Vienna, Austria)

Epigenetic reprogramming of rheumatoid fibroblast-like synoviocytes (RA-FLS) with JAKinibs

Elisabetta Botti (University of Rome "Tor Vergata", Italy)

JAK-STAT signaling inhibition on autoantigen driven psoriatic inflammation

Friederike Berberich-Siebelt (University of Würzburg, Germany)

A novel Jakinib in the dichotomy of mucosal healing and inflammation-

associated cancer resolution

Prof. dr. Maikel P. Peppelenbosch (Erasmus MC, Rotterdam)

The effect of the microbiome on JAK/STAT/SOCS signaling in the intestinal epithelial compartment of IBD patients

Konrad Aden (Christian-Albrechts-Universität zu Kiel, Germany)

Dissecting the role of tofacitinib on epithelial stem cell function and intestinal repair

Europe ASPIRE 2015 Awarded Proposals in Inflammation Research:

Thomas Huizinga (Leiden University Medical Center, Netherlands)

Exploring the disease modifying effects of tofacitinib: Does tofacitinib affect intracellular signalling pathways involved in the regulation of autoantibody production in rheumatoid arthritis?

Cristina Albanesi (Istituto Dermopatico dell'Immacolata IDI-IRCCS, Italy)

Immunomodulatory effects of tofacitinib on psoriatic keratinocytes and on its capability to mimic SOCS inhibitory circuits

Rik Lories (KU Leuven, Belgium)

Control of cartilage damage by inhibition of JAK-STAT signalling: Identifying signalling networks

Janneke Nicoline Samsom (Erasmus University Medical Center, Netherlands)

Tofacitinib to treat inflammatory bowel disease which is driven by defective antigen presenting cell function

Axel J. Hueber (Friedrich-Alexander University Erlangen-Nuernberg, Germany)

Dissecting JAK-STAT dependent bone-turnover in autoimmune arthritis

Europe ASPIRE 2014 Awarded Proposals in Inflammation Research:

Dirk Foell (University of Muenster, Germany)

Regulatory monocytes induced by blocking JAKs in inflammatory diseases

Antonio Costanzo (Sapienza University of Rome, Italy)

Effects of JAK3 inhibition on transcriptional landscapes in psoriasis

Ursula Fearon (St Vincent's University Hospital, Ireland)

Tofacitinib inhibits synovial invasiveness, bioenergetics and bone resorption in RA

Eniko Sonkolty (Karolinska University Hospital, Sweden)

Investigation of the role of microRNAs in the mechanism of action of JAK/STAT inhibitors in psoriasis

Markus F. Neurath (University of Erlangen-Nuernberg, Germany)

Effects of tofacitinib on intestinal epithelial cells and mucosal healing in inflammatory bowel diseases

Europe ASPIRE 2013 Awarded Proposals in Inflammation Research:

Marie-Christophe Boissier (University of Paris 13, France)

Translational study of tofacitinib-mediated JAK inhibition on neutrophil activation and apoptosis in TNF-alpha-transgenic mice and rheumatoid arthritis

João Eurico Fonseca (Instituto de Medicina Molecular, Portugal)

Inhibition of bone and cartilage degradation in rat-induced arthritis treated with tofacitinib

Thomas Harder (University Hospital Erlangen, Germany)

Pharmacodynamic risk assessment of immunodeficiency during treatment with JAK3-inhibitors

Gabriel Herrero-Beaumont (Joint and Bone Research Unit. IIS-Fundación Jiménez Díaz, Spain)

Effect of tofacitinib in the systemic and trisula inflammatory profile in an experimental model of rheumatoid cachexia

Jens Thiel (University Hospital Freiburg, Germany)

Effect of inhibiting JAK-STAT pathways by tofacitinib on B cell differentiation and function

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	<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 here
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