Research Grant Request for Proposals

New Research Areas to Improve Diagnosis and Treatment of Inflammatory Bowel Disease

Overview:

Pfizer Inc. and the American Gastroenterological Association (AGA) are collaborating to offer a new grant opportunity to proposals focused on new research areas that could improve the diagnosis and treatment of inflammatory bowel disease (IBD).

This Pfizer competitive grant program involves a publicly posted general Request for Proposal (RFP) that provides details regarding specific areas of interest, sets timelines for review and approval. AGA will select the Expert Review Panel (ERP) to make final grant decisions, create a community of practice for the selected Grantees and share existing knowledge and tools.

Organizations are invited to submit an application addressing the research gaps as outlined in this 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. An ISR grant request cannot be submitted for a study that has already commenced and was not originally supported by Pfizer.

About American Gastroenterological Association (AGA):

The American Gastroenterological Association is the trusted voice of the GI community. Founded in 1897, AGA represents members from around the globe who are involved in all aspects of the science, practice, and advancement of gastroenterology. The AGA Institute administers the practice, research, and educational programs of the organization.

About Pfizer ER&G:

Pfizer External Research & Grants (ER&G) 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.

Geographic Scope:

United States

Key Milestones:

Funding Range and Project Length:

Individual projects requesting up to $60,000 will be considered.

Maximum project length is 1 year.

I. Eligibility

Geographic Scope:

- United States

Applicant Eligibility Criteria:

- The PI is a member of the American Gastroenterological Association.
- 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 (i.e., an independent group of physicians not affiliated with a hospital, academic institution, or professional society). Pfizer cannot provide grants to individuals, individually owned private physician practices or informal groups which are not legal entities.
- If the project involves multiple departments within an institution and/or between different institutions / associations, all institutions must have a relevant role, and the requesting organization must have a key role in the project.
- The PI must have a medical or doctoral degree (MD, PhD, or equivalent), an advanced nursing degree (BSN with a MS/PhD), or a degree in Pharmacy, Physiotherapy, or Social Work.
- The applicant must be the PI or an authorized designee of such individual (e.g., PI's research coordinator).
- The PI must be an employee or contractor of the requesting organization.
- Requesting organization must be legally able to receive award funding directly from Pfizer Inc. We strongly recommend that applicants confirm this with their organization or institution prior to submitting an application. Grants awarded to organizations that are subsequently found to be unable to accept funding directly from Pfizer Inc. may be subject to rescission.
- Pfizer grants support a wide variety of organizations, all of which are legal entities. These include accredited medical schools or academic hospitals; other medical centers focused on patient care and residency training, not necessarily affiliated with universities; medical, scientific, or professional associations, non-profit patient organizations, non-profit civic organizations that advocate for patients, support research, and improve healthcare.

II. Requirements

Primary Area of Interest:

- Gastroenterology - IBD (Inflammatory Bowel Disease) - RES

Specific Area of Interest for this RFP:

The Request for Proposals (RFP) from the AGA-Pfizer collaboration seeks submissions that are focused on new research areas that could improve the diagnosis and treatment of inflammatory bowel disease (IBD). Specific areas of interest include:

1. Use of real-world data to model IBD practice patterns.
2. Areas specific to S1P receptor modulators.
   - Elucidate the role of S1P receptor modulators in extra-intestinal manifestations of IBD.
   - Evaluation of S1P receptor modulators in IBD as combination or sequenced treatment with immunosuppressants/advanced therapies.
   - Evaluate efficacy and safety of S1P receptor modulators in other gastrointestinal (GI) conditions such as eosinophilic esophagitis, Crohn's disease, pouchitis, proctitis, pancolitis, microscopic colitis, and checkpoint inhibitor induced colitis.
3. Areas specific to innovative or novel methods of disease diagnosis and/or monitoring.

- Use of artificial intelligence/machine learning to identify or select patients with IBD who are likely to respond to specific therapeutics.
- Evaluate the effectiveness of intestinal ultrasound (IUS) in monitoring patient responses to treatment, with a focus on, but not limited to, S1P receptor modulators.
- Explore the clinical utility of IUS in monitoring disease activity and extent, as well as tracking changes in disease activity in conjunction with treatment.
- Investigate the role of IUS in guiding IBD care, supporting long-term clinical remission, and preventing complications, while addressing optimal techniques and limitations.
- Use of artificial intelligence (AI) in endoscopic assessments of the intestinal tract.
- Implementation of treat to target strategies in disease monitoring.
- Leverage rich clinical, biomarker and/or -omics data to predict treatment responses in IBD.

Clinical or pre-clinical proposals within the areas of interest above are within scope.

Expected Approximate Monetary Range of Grant Applications:

IMPORTANT: Grants will be distributed following a fully executed agreement and submission of Final Protocol, Documentation of IRB/IEC Approval, Regulatory Approval (if applicable), Exemption or Waiver.

Organizations must obtain approval from an Institutional Review Board (IRB) for their proposal to be eligible to receive the grant award, if the study design requires IRB approval. It is not mandatory to have IRB approval at the time of proposal submission. However, organizations are anticipated to secure an IRB evaluation after the award notification and must ensure that the approval is in place prior to 19 December 2025.

- Individual projects requesting up to $60,000 will be considered. The estimated total available budget related to this RFP is $120,000.
- Award amounts include direct costs, institutional overhead costs (capped at 28% per Pfizer policy), and indirect costs.
- 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 grant agreement.

Key Dates:

IMPORTANT: Be advised applications submitted after the due date will not be reviewed.

*Please note the deadline is 23:59 Eastern Standard Time (e.g., New York, GMT -5)

How to Submit:

IMPORTANT: Please read this section carefully since applications not following these instructions will not receive consideration for funding.

- Please go to www.cybergrants.com/pfizer/Research and sign in.
  - Note: there are individual portals for each grant application type. Please be sure to use the URL above.
  - First-time users should click "Create your password".
- Click the "**Start A New Research Grant Application**" button.
- Requirements for submission:
  - Complete all required sections of the online application.
  - **IMPORTANT:** Upload proposal (see Appendix) in the Proposal/Protocol field.
- In the application:
  - For the question "**Competitive Grant?**" select "**Yes**"
- Select the following Primary Area of Interest: **Gastroenterology - IBD (Inflammatory Bowel Disease) - RES**
- Select the following Competitive Grant Program Name: **2025 I&I US AGA IBD Diagnosis and Treatment RES**

Questions:

- If you encounter any technical difficulties with the website, please click here or the "Technical Questions" link at the bottom of the page in Cybergrants.
- Please click here to view "Frequently Asked Questions" regarding the Competitive Grant Program.
- If you have questions regarding this RFP, please direct them in writing to the Grant Officer, Talita Honorato-Rzeszewicz (Talita.Honorato-Rzeszewicz@pfizer.com) or Nick Tomeo (awards@gastro.org), with the subject line *"New Research Areas to Improve Diagnosis and Treatment of Inflammatory Bowel Disease 2025".*

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. AGA will select the Expert Review Panel (ERP).
- The panels are comprised of professionals from the medical community with advanced degrees and expertise in particular clinical or research areas, or specific needs of a geographic region/learner group, or expertise in research, continuing professional development or quality improvement.
- Standard score-driving criteria used to evaluate submissions include (1) investigator, (2) environment and institutional commitment, (3) significance, (4) approach, (5) innovation, and (6) fit with the areas of interest specified in this RFP.

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

IMPORTANT: RFP Submission Requirements

Applications will be accepted via the online portal listed in the How to Submit section. Project Proposals/Protocols should be single-spaced using Calibri 12-point font and 1-inch margins. Note there is a 15-page limit exclusive of references. When uploading your Full Proposal please ensure it addresses the following sections:

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 peer-reviewed journals.

Anticipated Project Timeline

- Provide an anticipated timeline for your project including project start/end dates.
- An ISR grant request cannot be submitted for a study that has already commenced and was not originally supported by Pfizer.

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.

Budget Detail

- The budget amount requested must be in U.S. dollars (USD).
- While estimating your budget please keep the following items in mind:
- General organizational running costs such as legal fees, insurance, heating, and lighting etc. should be included in an Institutional Overhead (if required). These costs are not specific to a grant request and therefore, should not appear as line items in budgets. However, costs that are specific to the study (e.g., some countries require insurance to be taken out on a per-study basis for clinical research) would be acceptable to be included as line items.
- The inclusion of these costs cannot cause the amount requested to exceed the budget limit set forth in the RFP.
- Pfizer does not provide funding for capital purchases (infrastructure expenses such as equipment, purchases of software or software licenses, technology or bricks and mortar). Equipment hire/leasing is acceptable and may be included in project budget.
- It should be noted that grants awarded through ER&G cannot be used to purchase Pfizer therapeutic agents (prescription or non-prescription).
- Pfizer maintains a company-wide, maximum allowed overhead rate of 28% for independent studies and projects. Please click here for details.

Required Documents

- Project Plan or Proposal
- Biosketches for the PI, key personnel, and, if applicable, mentor.
- Early career applicants: Mentor and other letters of support.
- Initial Study Protocol
- Organizations must obtain approval from an Institutional Review Board (IRB) for their proposal to be eligible to receive the grant award, if the study design requires IRB approval. It is not mandatory to have IRB approval at the time of proposal submission. However, organizations are anticipated to secure an IRB evaluation after the award notification and must ensure that the approval is in place prior to 19 December 2025.