International Bowel Ultrasound Group and Pfizer Announce an Intestinal Ultrasound Grant Request For Proposal Closing the Gaps within Intestinal Ultrasound. Competitive Grant Program

I. Introduction
This Request for Proposals (RFP) is for research initiatives focused on intestinal ultrasound (IUS) in inflammatory bowel disease (IBD). The **International Bowel Ultrasound Group (IBUS)** and **Pfizer Global Medical Grants & Partnerships (GMGP)** are collaborating to offer a new competitive grant opportunity aimed at addressing critical research gaps in this field.

Through this collaboration with Pfizer GMGP, IBUS aims to leverage its expertise and knowledge to support innovative research projects that will advance the understanding and application of IUS in the care of IBD patients.

About the International Bowel Ultrasound Group (IBUS):
The IBUS is a non-profit association dedicated to research, training, and cooperation in the field of bowel diseases and intestinal ultrasound. Our mission is to improve patient care by promoting all efforts that enhance the diagnosis, treatment, and management of IBD. IBUS achieves this through:

- **Research:** Promoting, sponsoring, and overseeing international research in bowel diseases and intestinal ultrasound.
- **Collaboration:** Cooperating with other organizations interested in bowel diseases, including professional medical associations and industry partners.
- **Education:** Supporting and promoting the training of healthcare personnel in bowel diseases and ultrasound.
- **Knowledge Exchange:** Organizing international and regional scientific exchange and training programs.
- **Advocacy:** Influencing the investigation and management of bowel diseases through the use of ultrasound by developing, publishing, and disseminating best-evidence guidelines and educational materials.

About Pfizer Global Medical Grants & Partnerships (GMGP):
Pfizer Global Medical Grants & Partnerships (GMGP) 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.

For all 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.

Pfizer and IBUS are jointly issuing this RFP. Grant funding will be provided directly from Pfizer. IBUS will select the Expert Review Panel (ERP), create a community of practice for the selected Grantees and share existing knowledge related to the use of ultrasound in the care of patients with IBD.

Eligibility

Geographic Scope

Global

Applicant Eligibility Criteria

- **Applicant** must be **an IBUS Member** and may collaborate with another Organization or Institution.
- **Only organizations are eligible** to receive grants, not individuals or medical practice groups.

Requirements

Date RFP Issued

22 August 2024

Clinical Area

Inflammatory Bowel Disease and Intestinal Ultrasound

Project Types and Area of Interest

The IBUS-Pfizer GMG collaboration invites proposals for research projects that address the following priority areas within the field of intestinal ultrasound (IUS) in inflammatory bowel disease (IBD):

1. **IUS in Monitoring IBD:** Proposals should focus on the broader role of IUS in monitoring various aspects of IBD, including disease activity, treatment response (including, but not limited to, Etrasimod), and complications. The primary outcome should be IUS-based findings, and the study design should allow for a multi-center approach.
2. **Perianal IUS in Proctitis:** Proposals should investigate the impact of perianal IUS on monitoring proctitis across various treatment modalities (including but not limited to Etrasimod). Multi-center studies are encouraged to provide a comprehensive understanding of this under-researched area.
3. **IUS in Special Populations:** Proposals should explore the utility of IUS in monitoring ulcerative colitis and Crohn's disease in pregnant women, adolescents, and children. This area represents a significant gap in our knowledge and has the potential to improve care for these specific patient populations.
4. **IUS Education:** Proposals should investigate strategies for enhancing IUS competency development among healthcare professionals. This may include research on curriculum development (perianal, pediatric, advanced IUS, train-the-trainer), standardization of techniques (contrast-enhanced ultrasound, elastography), and evaluation of different learning modalities.
5. **IUS in monitoring treatment with Etrasimod in a real-world setting:** The use of IUS in monitoring the effectiveness of Etrasimod in UC.

We encourage proposals that utilize quantitative, qualitative, or mixed-methods approaches and involve primary data collection, secondary data analysis, or a combination of both. While formal cost-benefit or cost-effectiveness analyses are not required, proposals should demonstrate the potential value and impact of the proposed research for improving patient care and advancing the field of IUS in IBD.

Key Milestones

RFP Release Date: 22 August 2024
Proposal Due Date: 1 October 2024
Review of Proposals by ERP: October 2024
Anticipated Notification Date: October/November 2024

- 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.
- The **agreement** is expected to be signed by both parties within 2024 and **without change.**

Anticipated Project State Date: January 2025

Funding Range and Project Length

- **3 Grants** of up to **$100,000** for **12-month projects** are planned.
- Award amounts include direct costs, institutional overhead costs (capped at 28% per Pfizer policy), and indirect costs.

How to Submit

Note: Please read this section carefully since applications submitted not following these instructions will not be accepted and will be cancelled.

- Please go to https://www.cybergrants.com/pfizer/Research and sign in.
  - First-time users should click “Create your password”. [Note: there are individual portals for each grant application type. Please be sure to use the URL above.]
- Click the "**Start a New Research Grant Application**" button.
- In the application:
  - For the question “**Competitive Grant?**” select “**Yes**”
  - Select the following Competitive Grant Program Name: **2024 I&I Global IBUS Ultrasound in IBD RES**
- Requirements for submission:
  - Complete all required sections of the online application and upload your project proposal (see Appendix) in the Proposal/Protocol field.
  - If you encounter any technical difficulties with the website, please click the “Technical Questions” link at the bottom of the page.

IMPORTANT: Be advised applications submitted through the wrong application type and/or submitted after the due date will not be reviewed by the committee.

Questions

If you have questions regarding this RFP, please direct them in writing to the Pfizer Grant Officer, **Amanda Stein (amanda.j.stein@pfizer.com)** or to **office@bowel-ultrasound.org at IBUS**.

Grant Agreement

- If your grant is approved, your institution will be required to enter into a written grant agreement with Pfizer. Please click here to view the core terms of the agreement.
- The agreement is expected to be signed by both parties within 2024 and without change.
- Under Pfizer's competitive grant program, modifications to grant agreements will not be reviewed unless a genuine conflict exists as between applicable law and the terms of the relevant grant agreement. Applicant is encouraged to share the core terms with counsel for approval prior to submitting an application.
- Except where prohibited by applicable law and, in any case, subject to review by Pfizer Legal, payment of grant funding may only be paid to the grantee organization.
- This RFP is supported by Pfizer Inc. and, if approved, payment will be sent from the United States

Review and Approval Process

- A specific grant program RFP uses an expert review panel (ERP) to make final grant decisions. IBUS will select the Expert Review Panel
- 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. The panel will include 1 Pfizer Medical Affairs representative.

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

Specific 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 **5-page limit** exclusive of references. When uploading your Full Proposal please ensure it addresses the following sections:

Scientific Aim

- Provide clear description of the objectives of the project

Background/Significance

- This should reflect your study rationale/justification of the importance of the project.

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.

Additional Information

- If there is any additional information you feel Pfizer and IBUS should be aware of concerning the importance of this project, please summarize here.

Budget Detail

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 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

References

- Please include relevant references
- Note the 5-page limit does not include references