

Pfizer Research Grant RFP

Improving Health Equity in IBD through
Disparities Research

Competitive Grant Program – Pfizer Internal Review Process

### **Overview**

This competitive program seeks to support health equity in IBD through disparities research based on findings from Pfizer's IBD Health Equity Summit at Digestive Disease Week on May 5, 2023 in Chicago, IL.

# **Geographic Scope**

Global

# **Project Types and Area of Interest**

Our intent with this RFP is to support IBD related research initiatives focused on following:

- Precision medicine approach which is the tailoring of medical treatment to the individual patient, encompassing a multitude of data-driven (including multi-omic) approaches to foster appropriate clinical decision-making.<sup>1</sup> Examples would include:
  - Identifying clinical or laboratory characteristics of patients who have mild disease or remain in long-term remission, and studying whether patients with comorbidities have a different disease course
  - Collecting data on access to care for patients from underserved communities in order to tailor treatments more specifically
  - Meta-analysis or Systematic Literature Review (SLR) to further characterise potential differences underrepresented groups vs. general population in terms of disease course or treatment response
- Research on ways to improve IBD management among underserved groups, such as treat to target approaches
- Studies quantifying the socio-economic and psycological burden of IBD and its correlation with social determinants of health

# **Key Milestones**

- Application submission deadline: October 11, 2023
- Anticipated decision notification date: December 10, 2023
- Anticipated project start date: January 10, 2024.

# **Funding Range and Project Length**

Grant range expected to be from \$10,000 to \$250,000 USD. Maximum project length is 2 years.



# I. Eligibility

# Geographic Scope:

Global

# Applicant Eligibility Criteria

- 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.
- If the project involves multiple departments within an institution and/or between different institutions / organizations / 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 postdoctoral 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 independent 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.

# **II. Requirements**

#### Date RFP Issued

July 26, 2023

#### Clinical Area

IBD

### Background

Under the auspices of the Chief Medical Officer, Pfizer held an IBD Health Equity Summit at DDW 2023 in Chicago, Illinois on May 5, 2023, with a group of 22 experts and advocates across the field of gastroenterology. The purpose of the summit was to uncover research gaps and quality of care gaps that will determine future directions in IBD research and contribute to achieving healthcare equity by addressing clinical care disparities. Based on the research and quality of care gaps identified during the summit, Pfizer plans to identify and support potential solutions.

Several overarching themes emerged at the Summit, such as personalizing the appropriate therapy based on patient characteristics, the need to better evaluate sequencing and combination of therapies, increasing representation of underserved populations in clinical trials, and understanding the incidence of disease across the globe. Addressing these challenges will require solutions tailored to local and regional contexts that consider factors such as race, ethnicity, socio-economic status, culture, diet, and sexual orientation.

A key research gap discussed was the lack of phenotyping of patients to identify the appropriate treatment. For example, randomized controlled trials collecting clinical and precision medicine data to phenotype patients who have mild disease, remain in long-term remission, present comorbidities such as obesity, or belong to underserved groups to determine optimal treatments and who would benefit most from select therapy. In addition, one could perform meta-analysis on underserved groups from existing



datasets of previous trials.

Care for patients with IBD is not one size fits all and risk prediction can assist in identifying the appropriate intervention based on stage of disease and patients' treatment goals. A 2017 Lancet publication by Kugathasan S et al. demonstrated that African American race on its own is not associated with a genetic risk factor for progressing to advanced disease, so phenotypic differences associated with race remain unknown. Often the appropriate treatments are not chosen at the onset, leading to repeated treatment failure and surgery, which cause patients to feel like failures. Lack of cultural competency in specialist care, especially in diagnosing dermatological conditions on darker skin tones and addressing quality-of-life impacts of IBD on LGBTQIA+ patients. A strategy to pursue may be to consider randomized controlled trials collecting clinical and omics data (genomics, proteomics, phenomics etc.) to phenotype patients based on characteristics such as mild non-progressing disease, presence of comorbidities, and race and to evaluate the possibility of performing a meta-analysis of data on minority groups from existing datasets of previous trials to overcome this gap.

Globally, in regions where prevalence of infectious diseases is high, IBD is often misdiagnosed by primary care providers as an infectious disease such as tuberculosis and treated accordingly. Attendees highlighted the lack of equity in clinical trial participation and lack of phenotyping of minority groups to inform diagnosis and treatment strategies.

The group discussed a phenomenon called unmasking of disease which highlighted that the increasing incidence of IBD in several regions is due to recognition of the disease rather than a true increase in prevalence. Increasing incidence globally in the aging population increases the need for multispecialty care to address comorbidities. The increase in incidence will surpass economic growth making IBD very expensive to manage in developing countries such as China and India. The lack of community education and healthcare literacy contributes to the stigmatization of symptoms and delays the seeking of treatment in patients with IBD, especially in Asian cultures; effective education must be tailored to each community/culture and delivered at the local level by trusted sources. The gap in underserved communities across the globe in affordability of treatments and food security, including affording diets recommended for management of IBD.

# Specific Area of Interest for this RFP

The intent of this Request for Proposal (RFP) is to support research initiatives related to IBD such as:

- Precision medicine approach which is the tailoring of medical treatment to the individual patient, encompassing a multitude of data-driven (including multi-omics) approaches to foster appropriate clinical decision-making.<sup>1</sup> Examples include, but are not limited to, the following:
  - Identifying clinical or laboratory characteristics of patients who have mild disease or remain in long-term remission, and studying whether patients with comorbidities have a different disease course
  - Collecting data on access to care for patients from underserved communities in order to tailor treatments more specifically
  - Meta-analysis or Systematic Literature Review (SLR) to further characterise potential differences underrepresented groups vs. general population in terms of disease course or treatment response
- Research on ways to improve IBD management specifically treat to target approach among underserved groups, such as treat to target approaches
- Studies quantifying the socio-economic burden of IBD in the world stratified by ethnicity, race, socio-economic status, age, health literacy, sexual orientation, comorbitidies, mental and emotional burden of IBD



## Expected Approximate Monetary Range of Grant Applications:

• Individual projects requesting up to \$250,000 USD will be considered. The estimated total available budget related to this RFP is \$500,00 USD.

Award amounts include direct costs, institutional overhead costs (capped at 28% per Pfizer policy), and indirect costs.

## **Key Dates:**

- RFP release date: July 26, 2023
- Grant Application due date: October 11, 2023
- Please note the deadline is 23:59 Eastern Standard Time (e.g., New York, GMT -5).
- Anticipated Grant Award Notification Date: December 10, 2023
- 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.
- Anticipated Project Start and End Dates: January 10, 2024 to January 10, 2026

#### 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 <u>www.cybergrants.com/pfizer/Research</u> 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:
  - o For the question "Competitive Grant?" select Yes
  - Select the following Competitive Grant Program Name: 2023 I&I G IBD Disparities Research
  - Select the following Primary Area of Interest: IBD
- 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 after the due date will not be reviewed.

### Questions:

- If you have questions regarding this RFP, please direct them in writing to the Grant Officer, Sarthak Pandit (sarthak.pandit@pfizer.com), with the subject line "2023 I&I G IBD Disparities Research."
- Please click <u>here</u> to view Frequently Asked Questions regarding the Competitive Grant Program.

### **Grant Agreements:**

- If your grant is approved, your institution will be required to enter into a written grant agreement with Pfizer. Please click <u>here</u> to view the core terms of the agreement.
- 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**

 Grant requests received in response to a general RFP are reviewed by Pfizer to make final grant decisions.

## 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.

#### References

 Borg-Bartolo SP, Boyapati RK, Satsangi J, Kalla R. Precision medicine in inflammatory bowel disease: concept, progress and challenges. F1000Res. 2020 Jan 28;9:F1000 Faculty Rev-54. doi: 10.12688/f1000research.20928.1. PMID: 32047622; PMCID: PMC6993839.

#### **About Pfizer Global Medical Grants**

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 general Request for Proposal (RFP) that provides detail regarding a general area of interest, sets timelines for review and approval, and uses an internal Pfizer review process to make final grant decisions. Organizations are invited to submit an application addressing the research gaps 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. An ISR grant request cannot be submitted for a study that has already commenced and was not originally supported by Pfizer.



# **Appendix**

### **General 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.
- 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 insurances, heating, lighting, rent, building
    maintenance may be included. 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.
  - The inclusion of these costs cannot cause the amount requested to exceed the budget limit set forth in the RFP.
  - It should be noted that grants awarded through GMG 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 <u>click here</u> for details.

