# Pfizer Research Grant RFP

# *2023/2024 Global NASH ASPIRE**

Competitive Grant Program – using Expert Review Panel

## Overview

This competitive grant program is part of Pfizer's ongoing commitment to translate scientific discoveries into innovative medicines for patients with cardiovascular disease. It aims to support basic science, pre-clinical research, and clinical research that advances medical knowledge and clinical knowledge of nonalcoholic steatohepatitis (NASH) pathophysiology, co-morbidities associated with the disease and innovative approaches to diagnose, manage and treat NASH as well as support academic research development of promising emerging and established scientists around the globe.

## Geographic Scope

Global

## Project Types and Area of Interest

The NASH ASPIRE program will evaluate submitted research proposals that cover areas in basic, clinical and translational sciences. Innovative, feasible, rigorous research proposals with the potential of high impact in advancing the learning about NASH will be prioritized.

## Key Milestones

- Application submission deadline: **January 4, 2024**
- Anticipated decision notification date: **May 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.

## Funding Range and Project Length

Individual projects requesting up to USD $140,000 will be considered. Pfizer anticipates awarding up to 3 grants and a total fund of USD $420,000.

Research is expected to be completed and submitted for presentation/publication within 2-3 years of study start.

# I. Eligibility

## Geographic Scope:

- Global

## Applicant Eligibility Criteria

- 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.
- Both early career and experienced investigators are encouraged to apply and consideration will be given to all proposals meeting the selection criteria.

# II. Requirements

## Date RFP Issued

- September 5, 2023

## Clinical Area

- Nonalcoholic steatohepatitis (NASH)

## Specific Area of Interest for this RFP:

The NASH ASPIRE program will evaluate submitted research proposals that cover areas in basic, clinical and translational sciences. Innovative, feasible, rigorous research proposals with the potential of high impact in advancing the learning about NASH will be prioritized.

The following are the main areas of priority with high unmet needs.

In adult patients with NASH:

- Biopsy-confirmed NASH prevalence, clinical outcomes, and healthcare utilization
- Innovations in the use of non-invasive tools in the care of patients with NASH
- Understanding genetic drivers of NASH and identification of risk factors for disease progression in NASH
- Real world evidence on current unmet need in patients with NASH and type 2 diabetes and/or obesity

Out of scope research includes:

- Studies involving investigational products or medical devices including Pfizer's
- Pediatric studies
- Dietary intervention studies
- Stem cell therapy studies
- Studies comparing a competitor drug vs. a Pfizer product
- Highly invasive studies and studies that may have an ethical concern
- Mere replication of existing studies (i.e., lack of innovation)

## Expected Approximate Monetary Range of Grant Applications:

- Individual projects requesting up to USD $140,000 will be considered. The estimated total available budget related to this RFP is USD $420,000
- 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.
- Research is expected to be completed and submitted for presentation/publication within 2-3 years of study start.

## Key Dates:

- RFP Release Date: **September 5, 2023**
- Full Proposal Due Date: **January 4, 2024**
  - Please note the deadline is 23:59 Eastern Standard Time (e.g., New York, GMT -5).
- Review of Full Proposals by ERP: **April 2024**
- Anticipated Full Proposal Notification Date: **May 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.

## 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 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 IM Global NASH ASPIRE**
  - Select the following Primary Area of Interest: CVM- Nonalcoholic steatohepatitis (NASH)

- 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, Jessica Romano (jessica.romano@pfizer.com), with the subject line “2024 IM Global NASH ASPIRE RFP.”
- Please click here 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 here 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 specific RFP are reviewed by an expert review panel (ERP) to make final grant decisions.
- 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, continuing professional development or quality improvement.

## 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.

## 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 expert review panel (ERP) 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

## Specific RFP Submission Requirements

Applications will be accepted via the online portal listed in the How to Submit section. Please click here to download a Proposal Template which addresses the fields listed below. This document should be formatted as noted in the template.

### 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 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 click here for details.