

# Pfizer Research Grant RFP

## *Diversity in Postmarketing Drug Safety Surveillance*

Competitive Grant Program –Pfizer Internal Review Process



### Overview

Through this RFP we aim to support research studies, either original research or reviews of published literature, that aim to enhance the diversity of postmarketing drug safety surveillance programs. Specifically, Proposals should focus on identifying, quantifying, and defining potential disparities in the safety and effectiveness of medications, vaccines, and medical devices across diverse populations.



### Geographic Scope

United States



### Project Types and Area of Interest

The objective of this RFP is to improve the quality of postmarketing drug safety surveillance programs by incorporating diverse perspectives, data sources, help improve the overall quality of healthcare, and promote health equity.

We are particularly interested in research involving populations who are at greatest risk due to disparities and social determinants of health. This may include projects that address the effect that structural barriers (e.g., access), social determinants (e.g., racial and ethnic inequities, geography, economics, health literacy, history), and attitudes (e.g., fear, trust) have on postmarketing drug safety surveillance diversity.



### Key Milestones

- Application submission deadline: **September 14, 2023**
- Anticipated decision notification date: **October 31, 2023**
- Anticipated project start date: **on or after December 1, 2023**



### Funding Range and Project Length

Individual projects requesting up to \$50,000 for one year will be considered.

## I. Eligibility

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### Geographic Scope:

- United States

### 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.
- The applicant (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.
- Applicant must be affiliated with a host institution

## II. Requirements

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### Date RFP Issued

- August 4, 2023

### Clinical Area

- Postmarketing Drug Safety Surveillance

### General Area of Interest for this RFP:

Through this RFP we aim to support research studies, either original research or reviews of published literature, that aim to enhance the diversity of postmarketing drug safety surveillance programs.

Postmarketing drug safety surveillance generates evidence to further quantify the safety and effectiveness of products when they transition out of the clinical trial space and into post approval (real world) use. In this transition, there is the opportunity to generate evidence on populations who may not have been as robustly represented in the pre-approval research. This lack of information may contribute to hesitancy, mistrust, or lack of access to care.

Proposals should focus on identifying, quantifying, and defining potential disparities in the safety and effectiveness of medications, vaccines, and medical devices across diverse populations. The objective is to improve the quality of postmarketing drug safety surveillance programs by incorporating diverse perspectives, data sources, help improve the overall quality of healthcare, and promote health equity.

We are particularly interested in research involving populations who are at greatest risk due to disparities and social determinants of health. This may include projects that address the effect that structural barriers (e.g., access), social determinants (e.g., racial and ethnic inequities, geography, economics, health literacy, history), and attitudes (e.g., fear, trust) have on postmarketing drug safety surveillance diversity.

Disadvantaged populations often shoulder the greatest burden of the disease for which a drug is under development, suffer disproportionately from adverse events associated with a product if/when they arise, and are underrepresented as a population in clinical trial research.

Potential areas of focus may include, but are not limited to:

- Identifying disparities in the postmarketing drug surveillance safety and effectiveness of medications, vaccines, and medical devices across diverse populations
- Identifying strategies to enhance the diversity of postmarketing drug safety surveillance programs
- Summarizing best practices for the inclusion of diverse populations in postmarketing drug safety surveillance programs

### Expected Approximate Monetary Range of Grant Applications:

- Individual projects requesting up to \$50,000 will be considered. The estimated total available budget related to this RFP is \$100,000
- Award amounts include direct costs, institutional overhead costs (capped at 28% per Pfizer policy), and indirect costs.

### Key Dates:

- RFP release date: 8/4/2023
- Grant Application due date: 9/14/2023  
Please note the deadline is 23:59 Eastern Standard Time (e.g., New York, GMT -5).
- Anticipated Grant Award Notification Date: 10/31/2023
- 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 Dates: on or after 12/1/2023, not exceeding one year in length

### 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](http://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: 2023 WWS US Drug Safety Surveillance RES
- Select the following Primary Area of Interest: Postmarketing Drug Safety Surveillance
- 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, Derek Warnick ([derek.warnick@pfizer.com](mailto:derek.warnick@pfizer.com)), with the subject line "2023 WWS US Drug Safety Surveillance RES."
- 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.
- Pfizer has drafted the terms of these agreements to be balanced and reasonable and to further the goals of both parties. Negotiating grant agreements requires significant resources, so please ensure that your institution (including your legal department) is able and willing to abide by these terms before proceeding with submission of your application as they will need to be accepted in their entirety.
- Payment will only be made to requesting Institution.

## 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.

## About Pfizer Global Medical Grants

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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

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### 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
- 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.