

Pfizer Research Grant RFP

Real World Evidence of Abrocitinib in Patients with Moderate-to-Severe Atopic Dermatitis

**Competitive Grant Program – Pfizer Internal Review Process** 

#### **Overview**

This competitive program seeks to generate new Real World Evidence (RWE) in the management of atopic dermatitis (AD) with abrocitinib. Research projects to be supported should be retrospective and focus on effectiveness and/or safety profile of abrocitinib data generated in real world settings.

# **Geographic Scope**

The Geographic Scope is Global; all countries where abrocitinib is approved are included, multiple site studies preferred.

# **Project Types and Area of Interest**

Potential applicants are encouraged to develop retrospective general research studies for abrocitinib in the management of atopic dermatitis (AD) resuting in RWE and publication of these results. The grant can be used for conducting a retrospective chart review analysis, and/or medical writing support.

# **Key Milestones**

- Application submission deadline: January 11, 2024
- Anticipated decision notification date: February 29, 2024
- Anticipated project start date: April 2024

# **Funding Range and Project Length**

Up to \$150,000 -175,000, project length can be up to nine months.



# I. Eligibility

### Geographic Scope:

• Global; all countries where abrocitinib is approved. Multiple site studies preferred.

### 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 parties 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

October 23, 2023

#### Clinical Area

Atopic Dermatitis

#### General Area of Interest for this RFP:

• The use of JAK-1-inhibitors in AD: Retrospective general research studies for abrocitinib in the management of atopic dermatitis resulting in RWE and publication of results will be considered for Pfizer support, which include patients with moderate-to-severe AD treated with abrocitinib. Specific topics of interest may include, but not limited to, clinician-reported outcomes, patient-reported outcomes (PROs), epidemiology, adherence, prior treatments, concomitant treatments, dosing, safety, and tolerability. The grant can be used for conducting a retrospective chart review analysis, and/or medical writing support.

#### **Expected Approximate Monetary Range of Grant Applications:**

• Individual projects requesting up to \$150,000-175,000 will be considered. The estimated total available budget related to this RFP is \$300,000 Award amounts include direct costs, institutional overhead costs (capped at 28% per Pfizer policy), and indirect costs.



### **Key Dates:**

- RFP release date: October 23, 2023
  - Grant Application due date: January 11, 2024
  - Please note the deadline is 23:59 Eastern Standard Time (e.g., New York, GMT -5).
- Anticipated Grant Award Notification Date: February 29, 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.
- Anticipated Project Start and End Dates: April 1, 2024 to January 31, 2025.

#### 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 <a href="www.cybergrants.com/pfizer/Research">www.cybergrants.com/pfizer/Research</a> 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 G RWE AD RES
  - Select the following Primary Area of Interest: Atopic Dermatitis
- 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, Beth Brillinger (beth.brillinger@pfizer.com), with the subject line "RWE for AD September 15, 2023."
- 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.
- **Delete if not a Global RFP:** 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

Bibliography of relevant references.

### **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.
- 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, effectiveness, and/or other 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.

