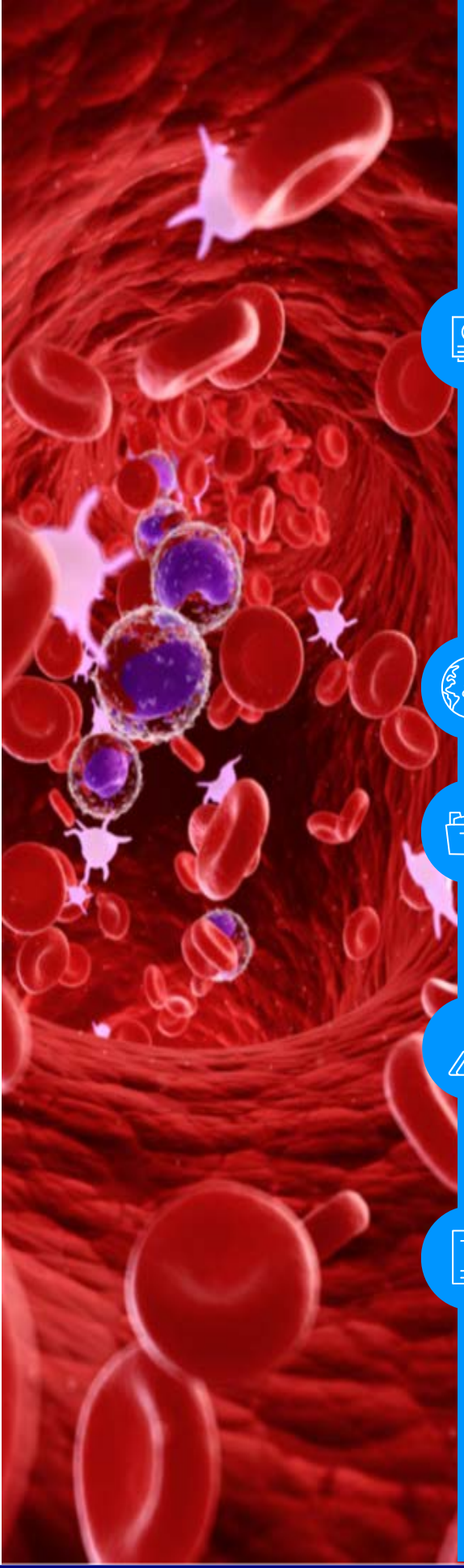

Pfizer Research Grant – Request for Proposals (RFP)

Real-World Data Generation with Elranatamab in Relapsed/Refractory Multiple Myeloma

Competitive Grant Program –Pfizer Internal Review Process

Overview

Pfizer supports Investigator Sponsored Research (ISR) projects that advance medical and scientific knowledge about our therapies.

An ISR is a type of grant that supports an independent research study where the investigator or organization is the sponsor of the study and where Pfizer provides financial and/or non-financial support for the development or refinement of specific and defined medical knowledge relating to a Pfizer asset. This program is open to all researchers who are interested in conducting their own research.

Geographic Scope

United States

Area of Interest

Studies that will be considered for Pfizer financial support will focus on generating evidence on the use of elranatamab in multiple myeloma in the real world setting. See full details in the General Area of Interest Section in the page below.

Key Milestones

- Application submission deadline: **August 12, 2024**
- Anticipated decision notification date: **September 10, 2024**
- Anticipated project start date: **January 2025**

Funding Range

Individual study grant requests up to $200,000 USD will be considered, although smaller requests (around $50,000) are also encouraged.

If there is strong scientific justification and well-supported in the budget details, applicants may request up to a maximum of $250,000 per study.

The estimated total available budget related to this RFP is $500,000 USD.

Pfizer

I. Eligibility

Geographic Scope/Location of Project/Study:

- United States

Applicant Eligibility Criteria

- PIs can be from US institutions.
  - Academic health care centers.
  - Community health care centers.
  - Health care professional organizations and other organizations related to health care improvement.
  - Health technology companies if partnered with a health care delivery organization who must serve as lead applicant. Collaboration between Institutions is strongly encouraged to foster interactive sharing of knowledge and expertise, and to utilize the combined clinical strengths of both Institutions.
  - Proposal submissions from junior faculty are encouraged.
  - Trainees may participate as a sub-investigator under appropriate mentorship from a PI.

II. Requirements

Date RFP Issued

- June 17, 2024

Clinical Area

- Oncology – Hematology – Multiple Myeloma

General Area of Interest for this RFP:

Projects eligible for Pfizer support under this RFP should reflect the real-world use of elranatamab in multiple myeloma in the United States. The aim is to generate clinical insights on the current treatment methodologies, including elranatamab use in difficult-to-treat populations, adverse event management, and dosing.

This RFP is not intended for interventional research.

For interventional proposals, please refer to this alternative RFP: 2024 ONC Global Interventional Research Studies with Elranatamab.pdf (pfizer.com). Please note the application deadline for this interventional RFP is July 18, 2024.

Expected Approximate Monetary Range of Grant Applications:

- Individual study grant requests up to $200,000 USD will be considered, although smaller requests (around $50,000) are also encouraged.

  If there is strong scientific justification and well-supported in the budget details, applicants may request up to a maximum of $250,000 per study.
- The estimated total available budget related to this RFP is $500,000 USD.

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

Key Dates:

- Grant Application due date: **Monday, August 12, 2024**
  Please note the deadline is 23:59 Eastern Standard Time (e.g., New York, GMT -5).
- Anticipated Grant Award Notification Date: **Monday, September 10, 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.
- Contracting and IRB Review Period: **September 2024 to December 2024**
- Anticipated Project Start Date: **January 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 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 ONC US RWD Generation with Elranatamab RES
  - Select the following Primary Area of Interest: Oncology – Hematology – Multiple Myeloma
- 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, Don Rodriguez (Don.Rodriguez@pfizer.com), with the subject line "RFP -- Real-World Data Generation with Elranatamab June 2024."
- 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 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

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 no page limit for this RFP. 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 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 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.