Pfizer Research Grant RFP

Global Awards for Research in DMD-*AWARD*

Competitive Grant Program – using Expert Review Panel

Overview

This competitive program aims to fund innovative and novel research proposals that seek to advance the understanding and management of Duchenne muscular dystrophy (DMD).

Geographic Scope

Global

Project Types and Area of Interest

Pfizer is interested in supporting proposals that advance our understanding of the basic science, treatment and assessment of DMD through research. See **Area of Interest** section of RFP for further details.

Key Milestones

- Application submission deadline: July 10, 2023
- Anticipated decision notification date: September 2023
- Anticipated project start date: December 2023

Funding Range

Individual projects requesting up to $100,000 will be considered. Pfizer anticipates awarding up to 5 projects.

Pfizer

I. Eligibility

Geographic Scope:

- Global

Applicant Eligibility Criteria

- 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.
- 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

- April 27, 2023

Clinical Area

- Duchenne muscular dystrophy (DMD)

Area of Interest for this RFP:

- Research projects that will be considered for support include the following basic and clinical research of gene therapy for DMD:
  - What is the prevalence of Adeno-associated virus (AAV) neutralizing antibodies within a DMD patient population
  - Strategies that can circumvent pre-existing neutralizing antibodies (nABs) to AAV that may allow future re-dosing or enabling eligibility for gene therapy for those patients with pre-existing nABs
  - What mechanism underpin the immunologic adverse effects of gene therapy and strategies that can be used to mitigate the risk and treat adverse responses
  - What mechanisms influence the durability of response to gene therapy and what factors predict response to guide decision making
  - Innovative and novel approaches that can support assessment and long-term follow-up for those DMD boys receiving gene therapy
  - Establish Minimal Clinically Important Difference (MCID) for relevant assessment used in DMD
  - Identify novel risk factors and potential management strategies for rapid DMD disease progression, cognitive impairment or development of other co-morbidities
  - Understand and predict response to treatment and the disease course of DMD
  - Develop and/or validate diagnostic, prognostic or response biomarkers in DMD
  - Understanding the clinical, economic and societal burden of DMD
  - How changes in motor function relate to changes in DMD patient and caregiver quality of life and/or activities of daily living
  - Treatment patterns in DMD, including the evolving use of steroids, exon-skippers, and gene therapy

Expected Approximate Monetary Range of Grant Applications:

- Individual projects requesting up to $100,000 USD will be considered. Pfizer anticipates awarding up to 5 projects.
- 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.

Key Dates:

- RFP Release Date: 4/27/2023
- Full Proposal Due Date: 7/10/2023
- Review of Full Proposals by ERP: August 2023
- Anticipated Full Proposal Notification Date: September 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.

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: **2023 RD G DMD Research**
  - Select the following Primary Area of Interest: Duchenne muscular dystrophy
- 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, Amanda Stein (amanda.j.stein@pfizer.com), with the subject line **2023 RD G DMD RESEARCH**
- 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.
- This RFP is supported by Pfizer Inc. and, if approved, payment will be sent from the United States.
- Payment will only be made to requesting Institution.

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. 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
- Please describe how the project submitted supports diversity, equity, and inclusion either through the study population targeted or through the project team that is directly involved

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.