

Accelerating Advancements in Women's Health

An Innovative Research Grant Program

REQUEST FOR PROPOSALS

MARCH 28, 2023



INTRODUCTION

Myovant Sciences and Pfizer are launching this Request for Proposals (RFP) as part of their combined commitment to improve the lives of women.

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.

Myovant Sciences aspires to redefine care for men and women through purpose-driven science, empowering medicines, and transformative advocacy.

Relugolix Combination Therapy [Rel-CT], commercially available as Myfembree[®], is a fixed-dose combination of relugolix (a gonadotropin-releasing hormone receptor antagonist) estradiol, and norethindrone acetate. It is a once-daily oral medication indicated in premenopausal women for the management of heavy menstrual bleeding associated with uterine leiomyomas or for moderate to severe pain associated with endometriosis.

Key Dates: Letter of Intent Due May 10, 2023 **LOI DEADLINE EXTENDED: June 20, 2023**
If selected, Full Proposals will be due September 2023

Funding: \$1,000,000 is available for funding with an estimated 5-7 grants awarded

I. Eligibility

Geographic Scope:

- United States

Applicant Eligibility Criteria

- The institution and principal investigator (PI) must be based in the United States.
- Only organizations are eligible to receive grants, not individuals or medical practice groups.
- The applicant (PI) must have a medical or postdoctoral degree (MD, DO, PhD, or equivalent), an advanced nursing degree (BSN with a MS/PhD or DNP), or a degree in Pharmacy (PharmD), Physician Associate (PA), 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

March 28, 2023

Clinical Area

Women's Health

Specific Area of Interest for this RFP:

The intent of this Request for Proposal (RFP) is to support research in the following areas:

- Rel-CT as preoperative therapy and/or for surgery avoidance
- Rel-CT effect on uterine fibroids prior to surgical intervention (e.g.: alteration of dissection planes in myomectomy, fibroid shrinkage, etc.)
- Rel-CT in conjunction with surgery
- Rel-CT in patients with infertility
- Rel-CT and health-related quality of life (HRQOL), patient reported outcomes (PROs), or patient satisfaction in estrogen-driven diseases
- Examination of patient preference and health disparities on medical vs surgical options for management of UF/EM
- Rel-CT and UF- or EM-related healthcare utilization including but not limited to hospitalizations, office visits, emergency department visits, cost to patients, and absenteeism
- Rel-CT and premenstrual dysphoric disorder (PMDD)
- Rel-CT and female sexual dysfunction
- Rel-CT for heavy menstrual bleeding of idiopathic etiology (excludes uterine fibroids, endometriosis, and adenomyosis)
- Rel-CT use in perimenopausal patients
- Rel-CT for pelvic pain of idiopathic etiology
- Rel-CT for induction of amenorrhea

OUT OF SCOPE for this RFP:

- Placebo-controlled studies (only open-label studies will be considered)
- Studies using relugolix monotherapy (commercially available as “Orgovyx”)
- Animal studies (only human trials will be considered)
- Pre-clinical research
- Concepts that are already being evaluated in company-sponsored Phase 1–4 clinical studies
- Ex-US (only submissions within the United States will be considered)

Expected Approximate Monetary Range of Grant Applications:

- Individual projects requesting up to \$200,000 will be considered. The estimated total available budget related to this RFP is \$1,000,000.
- Award amounts include direct costs, institutional overhead costs (capped at 28% per Pfizer policy), and indirect costs.
- Research is expected to be completed within 18 months and submitted for presentation/publication within 6-12 months post completion.
- 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: March 28, 2023
- LOI Due Date: ~~May 10, 2023~~

LOI DEADLINE EXTENDED: June 20, 2023

Please note the deadline is 23:59 Eastern Standard Time (e.g., New York, GMT -5).

- Review of LOIs by ERP: ~~June 2023~~ **August 2023**
- Anticipated LOI Notification Date: ~~July 2023~~ **September 2023**
- Full Proposal Due Date: ~~September 2023~~ **October 2023**

Only accepted LOIs will be invited to submit full proposals.

Please note the deadline is 23:59 Eastern Standard Time (e.g., New York, GMT -5).

- Review of Full Proposals by ERP: December 2023
- Anticipated Full Proposal Notification Date: ~~December 2023~~ **January 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/loi 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 LOI" button.
- In the application:
 - For the question “Competitive Grant?” select **Yes**
 - Select the following Competitive Grant Program Name: **2023 IM US PFE-MYO Women’s Health RES**
 - Select the following Primary Area of Interest: **Women’s Health – Uterine Fibroids/Endometriosis**

- 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 Officers, Jessica Romano (Jessica.Romano@pfizer.com) and Jennifer Smith (Jennifer.Smith@myovant.com), with the subject line “PFE-MYO 2023 Women’s Health Research 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/Myovant. Please click [here](#) to view the core terms of the agreement.
- Pfizer/Myovant have 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 specific RFP are reviewed by an expert review panel (ERP) to make final grant decisions.
- The panels comprise 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.

This RFP does not commit Pfizer, Myovant, or their partners to award a grant or a grant of any particular size if one is awarded, nor to pay any costs incurred in the preparation of a response to this request. Pfizer/Myovant reserve the right to accept or reject any or all applications received as a result of this request, or to cancel this RFP in part or in its entirety, if it determines it is in the best interest of Pfizer/Myovant to do so.

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

1. Myfembree [Prescribing Information]. Brisbane, CA: Myovant Sciences, Inc. January 2023.

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 and Myovant's medical and/or scientific strategies.

The 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 and Myovant 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 or Myovant.

Appendix

Specific RFP Submission Requirements

The Letter of Intent (LOI) will be accepted via the online application. When answering the LOI questions in the application please keep the following in mind:

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. The expected timeline for these projects is up to 18 months of research followed by 6-12 months to publish results (maximum 2.5 years).
- 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.
- Please describe how your proposal and/or your team seek to promote diversity, equity, and inclusion in this study.

- Early-career applicants: Describe the support the applicant will receive from mentor(s) and collaborators and how the award will advance the applicant's career. Letter(s) of support will be requested at the Full Proposal stage.

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

- A total amount requested is the only information needed for the LOI stage. Full Budget is not required. This amount can be adjusted at the Full Proposal stage as applicable.
- 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 or Myovant 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.