

Pfizer Research Grant RFP Patient Preferences for Drug Delivery: Literature Review

Competitive Grant Program - using Expert Review Panel

Overview

Through this RFP Pfizer seeks to solicit proposals to conduct a systematic review of patient preference studies that quantify preferences for alternative modes and frequencies of drug delivery or medication administration. This review will enable Pfizer and other researchers to incorporate what is already known about this topic in decisions related to drug delivery.

Geographic Scope

Global

Project Types and Area of Interest

This RFP has been developed to solicit proposals for a systematic literature review and summary of patient preference studies that include mode and frequency of treatment administration as attributes and provide quantitative estimates of the ranking or utility of different modes and frequencies of administration from the patient perspective. The specific focus of this study should be summarizing preferences for different types of non-oral/non-tablet modes of administration and the frequency with which they are used for drug administration.

The goal of this study will be to draw conclusions from the data that will allow for the generalization of these findings to indications within and across disease areas.

Key Milestones

- Application submission deadline: June 21, 2023
- Anticipated decision notification date: September 2023
- Anticipated project start date: November 1, 2023

Funding Range and Project Length

Approximately one year.



I. Eligibility

Geographic Scope:

Global

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.
- 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

Patient Preferences for Drug Delivery

Specific Area of Interest for this RFP:

Quantitative preference studies that examine the mode and frequency of drug administration are common in the literature. However, these studies have been conducted across multiple disease areas, and are found across a wide range of peer-reviewed journals. In addition, mode and frequency of administration are often not the primary focus of a patient preference study despite the fact the mode and frequency of administration may be the only feature that distinguishes among the products of interest.

This RFP has been developed to solicit proposals for a systematic literature review and summary of patient preference studies that include mode and frequency of treatment administration as attributes and provide quantitative estimates of the ranking or utility of different modes and frequencies of administration from the patient perspective. The specific focus of this study should be summarizing preferences for different types of non-oral/non-tablet modes of administration and the frequency with which they are used for drug administration. Non-oral/non-tablet modes of administration could include vial-and-syringe, pre-filled syringe, autoinjectors with different features, other injection devices or aids, intravenous infusions, drug implants, etc. Injections could be subcutaneous or intramuscular. Oral/tablet modes of administration can be included to the extent that they are compared directly with non-oral/non-tablet modes of administration. The goal of this study will be to draw conclusions from the data that will allow for the generalization of these findings to indications within and across disease areas.

The study should also address findings related to preference heterogeneity and the relationship between patient characteristics and preference for mode and frequency of administration. In addition, the study should identify challenges encountered as a result of lack of standardization in attribute descriptions, reporting of results, and/or availability of study materials as supplementary material.



Background:

Patient preference information is considered an important component to inform future decision-making across the medical product life cycle. However, often, discussions of patient preferences for treatment focus on benefits and risks even though many patient preference studies include attributes related to the mode and frequency of treatment administration. While there have been multiple systematic reviews of discrete choice experiments in health, none to date have focused on cataloguing results related to preferences for alternative approaches to drug delivery. A summary of this literature will enable researchers to leverage existing findings to generalize about patients' preferences for drug delivery in different diseases and different circumstances.

Pfizer Global Medical Patient Impact Assessment (GMPIA) and Global Medical Grants (GMG) have worked together to launch an RFP to address this matter. Through this RFP Pfizer seeks to solicit proposals to conduct a systematic review of patient preference studies that quantify preferences for alternative modes and frequencies of drug delivery or medication administration. This review will enable Pfizer and other researchers to incorporate what is already known about this topic in decisions related to drug delivery.

Purpose:

Patient preference studies have become a common approach to understanding patients' priorities and preferences, the importance of treatment features to treatment choice, and the tradeoffs patients are willing to make among treatment attributes.² A large number of patient preference studies includes attributes intended to elicit preferences related to the mode and frequency of administration^{3,4} and some studies explicitly examine preferences for attributes that differentiate among modes of administration.¹ However, there is no systematic review of these findings in the literature despite the fact that there likely is sufficient evidence in the literature to draw conclusions about patients' preferences for the features of drug administration modes, different types of injections and injection devices, injection volume, and the frequency of drug administration. Such a review would be of value to the pharmaceutical industry because it will provide information that can inform decisions related to treatment administration early in drug development to ensure that the methods and frequency of drug delivery used in later-stage clinical studies and post-marketing reflect the needs and preferences of patients.

Outcomes and Metrics:

The selected awardee will present a detailed list of search terms to be used in the literature search and a data abstraction form, completed data abstraction and summary tables, and a summary report. The awardee is encouraged to publish the results of this effort in a high-impact peer-reviewed journal that publishes patient preference studies (e.g., Value in Health, The Patient, PharmacoEconomics, etc).

References

- McNamara M, Turner-Bowker DM, Westhead H, Yaworsky A, Palladino A, Gross H, Pleil A, Loftus J. Factors Driving Patient Preferences for Growth Hormone Deficiency (GHD) Injection Regimen and Injection Device Features: A Discrete Choice Experiment. Patient Prefer Adherence. 2020 Apr 30;14:781-793. doi: 10.2147/PPA.S239196. PMID: 32431492; PMCID: PMC7198440.
- 2. Soekhai V, de Bekker-Grob EW, Ellis AR, Vass CM. Discrete Choice Experiments in Health Economics: Past, Present and Future. Pharmacoeconomics. 2019 Feb;37(2):201-226. doi: 10.1007/s40273-018-0734-2. PMID: 30392040: PMCID: PMC6386055.
- 3. Thieu VT, Robinson S, Kennedy-Martin T, Boye KS, Garcia-Perez LE. Patient preferences for glucagon-like peptide 1 receptor-agonist treatment attributes. Patient Prefer Adherence. 2019 Apr 17;13:561-576. doi: 10.2147/PPA.S187907. PMID: 31114170; PMCID: PMC6483112.



4. Visser LA, Louapre C, Uyl-de Groot CA, Redekop WK. Patient needs and preferences in relapsing-remitting multiple sclerosis: A systematic review. Mult Scler Relat Disord. 2020 Jan 2;39:101929. doi: 10.1016/j.msard.2020.101929. Epub ahead of print. PMID: 31924590.

Expected Approximate Monetary Range of Grant Applications:

- Individual projects requesting up to \$75,000 will be considered. The estimated total available budget related to this RFP is \$75,000
- 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, the costs involved, and will be stated clearly in the grant agreement.

Key Dates:

- RFP Release Date: 4/27/2023
- Full Proposal Due Date: 6/21/2023
 - Please note the deadline is 23:59 Eastern Standard Time (e.g., New York, GMT -5).
- Review of Full Proposals by ERP: 8/1/2023
- Anticipated Full Proposal Notification Date: 9/1/2023
- 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:
 - Project Type: Select General Research: Health Services Research
 - Grant Request Type: Select Funding
 - Primary Area of Interest: Support for Health Outcomes
 - For the question "Competitive Grant?" select Yes
 - Select the following Competitive Grant Program Name: 2023 GMG G Patient Preferences for Drug Delivery
- 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), with the subject line "Patient Preferences for Drug Delivery: Literature Review."
- 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.
- 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 10-15-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 <u>click here</u> for details.

