Request For Proposals

Investigating the Value of Using Patient-Reported Outcomes in Oncology Patient Care

Overview

The PROTEUS Consortium (Patient-Reported Outcomes Tools: Engaging Users & Stakeholders) and Pfizer Global Medical Grants are collaborating to offer a grant funding opportunity to support studies investigating the value of using patient-reported outcome measures (PROMs) in oncology clinical practice for individual patient care. Value in health care is the measured benefits from the patient, institutional, or societal perspective relative to the cost of achieving those benefits.

Geographic Scope

Open to applicants in the United States

Project Types and Area of Interest

Proposed projects should examine both the resources required and monetary and non-monetary returns on the investment in PROMs programs. While a formal cost-benefit or cost-effectiveness analysis is not required, proposals should specify the costs and benefits being considered and how they will be summarized to characterize the value of using PROMs in practice. The results of these analyses should be of interest to decision-makers in institutions with a PROM program, or considering implementation of a PROM program.

Funding can be used to conduct studies involving primary data collection, secondary data analysis, cost-benefit/effectiveness analysis, and/or modelling. Quantitative, qualitative, and mixed-methods approaches are appropriate.

Projects should investigate the use of PROMs in adult cancer patients. Proposals must include patients with breast cancer and/or prostate cancer and/or hematologic malignancies; however, applications do not have to focus solely on those disease areas. For example, proposals that include breast cancer along with other solid tumors are considered within scope.

Key Milestones

- Letter of intent (LOI) submission deadline: **Thursday, April 25, 2024**
- Full proposal submission deadline: **Thursday, August 15, 2024**
- Anticipated decision notification date: **Friday, November 1, 2024**
- Anticipated project start date: **Monday, February 3, 2025**

Funding Range and Project Length

Grants of up to $100,000 for 12-month projects are planned.

I. Eligibility

Geographic Scope

Open to applicants in the United States. Projects must address the value of using PROMs in the United States.

Applicant Eligibility Criteria

- The applicant institution and principal investigator (PI) must be based in the United States.
- The PI must be an employee or contractor of the applicant institution.
- Only organizations are eligible to receive grants, not individuals or medical practice groups (i.e., an independent group of physicians not affiliated with a hospital, academic institution, or professional society).
- If the project involves multiple departments within an institution and/or between different institutions / organizations / associations, all institutions must have a relevant role and the requesting organization must have a key role in the project.
- The applicant must have the expertise and data access necessary to conduct the proposed project successfully. In general, the applicant PI will be expected to have a medical or postdoctoral degree (MD, PhD, or equivalent). Applicants with a Masters degree in a relevant field and sufficient experience will be considered.
- A multidisciplinary team is encouraged, and should include both clinical and methodologic expertise aligned with the proposal objectives, as well as patient partners.
- Only one Letter of Intent (LOI) per PI will be accepted.
- The 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.

I. Requirements

Date RFP Issued

Tuesday, February 13, 2024

Clinical Area

The use of patient-reported outcome measures (PROMs) in oncology clinical practice. Projects should investigate the use of PROMs in adult cancer patients in the United States. Proposals must include patients with breast cancer and/or prostate cancer and/or hematologic malignancies; however, applications do not have to focus solely on those disease areas. For example, proposals that include breast cancer along with other solid tumors are considered within scope.

Background

Patient-reported outcomes (PROs) capture how patients feel, function, live their lives, and survive.[1,2] They include outcomes such as symptoms, functional status, well-being, and health-related quality of life reported directly by the patient without interpretation by a clinician or anyone else.[3,4] Standardized and validated PRO measures (PROMs) are used to assess PROs. Increasingly, PROMs are being collected systematically to assess individual patients' status, screen for conditions, monitor how patients are doing, and inform patient care.[5-9] For more information, see *The PROTEUS Guide to Implementing Patient-Reported Outcomes in Clinical* Practice,[10] which presents a framework of 16 considerations involved in using PROs in clinical care.

Research suggests that this use of PROMs in cancer care can provide benefits, including enhancing patient understanding, promoting patient-clinician communication, assisting with problem detection, informing management, and improving outcomes such as symptom control, health-related quality of life, and functioning.[11-19] Studies have shown a survival benefit associated with use of PROMs in clinical practice for patients with advanced cancer.[17,18] While research supports the potential effectiveness of PROMs in practice, evidence regarding the value of using PROMs in practice is needed.

The importance of evidence to demonstrate the value of using PROMs as part of routine care was emphasized in the "Advisory Group for Patient-Reported Outcome Implementation in Vulnerable and Underserved Populations."[20] The issue of establishing the value and cost of implementing PROs as part of routine care is important for all cancer providers, but may be particularly important to cancer providers who are under-resourced and/or serve disadvantaged communities. Data to support the monetary and non-monetary benefits of PROM programs, as well as the associated costs, was highlighted by the Advisory Group as necessary to address one of the key barriers to PROM implementation.

Specific Area of Interest for this RFP

The intent of this Request for Proposals (RFP) is to support studies investigating the value of using PROMs in oncology clinical practice for adult patients in the United States. Projects should focus on the use of PROMs data for individual patient management (screening for conditions, monitoring progress, informing management). While PROM data can also be used at an aggregated level for quality assessment and pay-for-performance initiatives, those applications are not the focus of this RFP.

Funding can be used to conduct studies involving primary data collection, secondary data analysis, cost-benefit/effectiveness analysis, and/or modelling. Quantitative, qualitative, and mixed-methods approaches are appropriate.

Applicants are encouraged to identify and address value in health care. Based on Porter and Teisberg,[21] for the purposes of the RFP, value is defined as the measured benefits from the patient, institutional, or societal perspective relative to the cost of achieving those benefits. Proposed projects should examine both the resources required and monetary (e.g., improved efficiency) and non-monetary (e.g., patient satisfaction) returns on that investment. While a formal cost-benefit or cost-effectiveness analysis is not required, proposals should specify the costs and benefits being considered and how they will be summarized to characterize the value of using PROMs in practice. The results of these analyses should be of interest to decision-makers in institutions with a PROM program, or considering implementation of a PROM program.

Example topics include but are not limited to:

- Estimates of the cost of implementing PROMs programs and/or the costs of ongoing PROMs program maintenance, along with the estimated benefits of the program
- Secondary analyses or modelling studies of value based on prior single institution or multi-institutional studies evaluating PROM programs
- An institutional budget impact analysis and/or business case for PROMs programs that explicitly considers both costs and benefits
- The impact of different reimbursement models (e.g., capitation vs. fee-for-service) on the value of implementing PROMs in practice
- The value of different approaches to implementing PROMs in routine oncology care (e.g., for screening only vs. ongoing patient monitoring, or in-clinic only vs. both in-clinic and remote collection)
- Qualitative studies that identify the costs and benefits of PROM programs from multiple perspectives (e.g., patient, clinician, institutional administration)

Expected Approximate Monetary Range of Grant Applications

- Individual projects requesting up to $100,000 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.
- 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 proposed proposal and costs involved, and will be stated clearly in the grant agreement.

Evaluation Criteria

PROTEUS and Pfizer have developed this RFP with a formalized review procedure to accept proposals and select the projects of highest merit and perceived potential impact. A Review Committee has been convened that includes subject matter experts and a patient advocate who will perform an independent and confidential peer review of applications.

The review procedure will comprise two steps. First, letters of intent (LOIs) will be invited to assess eligibility and potential merit of the proposal. Full proposals will be invited based on review of the LOIs. The following factors will be taken into consideration when evaluating proposals:

- Significance and generalizability of the project (i.e., the usefulness of the data to institutional decision-makers regarding PROM program value)
- Feasibility of conducting the study, including
    - Access to or ability to collect the data necessary to conduct the proposed value analysis and
    - A scope of work consistent with the funding and timeline
- Involvement of relevant expertise and experience through a multidisciplinary team and partnership with patients
- Expertise, experience, and accomplishments of the investigators and project team
- Rigor and quality of the methods and approach
- Extent to which patients with breast cancer and/or prostate cancer and/or hematologic malignancies are included. (NOTE: Applications do not have to focus solely on those disease areas. For example, proposals that include breast cancer along with other solid tumors are considered within scope.)

Key Dates

- RFP Release Date: **Tuesday, February 13, 2024**
- LOI Due Date: **Thursday, April 25, 2024**
    - Please note the deadline is 23:59 Eastern Standard Time (e.g., New York, GMT -5).
- Review of LOIs by External Review Panel: **May-June 2024**
- Anticipated LOI Notification Date: **Monday, June 17, 2024**
- Full Proposal Due Date: **Thursday, August 15, 2024**
    - 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 External Review Panel: **September-October 2024**
- Anticipated Full Proposal Notification Date: **Friday, November 1, 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: **2024 Onc US PROMs Value RES**
- Complete all required sections of the online application. See Appendix for additional guidance.
- 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, Jacqueline Waldrop (Jacqueline.Waldrop@pfizer.com) and Jennifer O’Donnell (jennifer.odonnell@kingstonhsc.ca), with the subject line “2024 Onc US PROMs Value RES.”

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.

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.

References

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3. FDA. Guidance for Industry. Patient-Reported Outcomes Measures: Use in Medical Product Development to Support Labeling Claims. 2009: 65132-65133.
4. Acquadro C, Berzon R, Dubois D, et al. Incorporating the Patient's Perspective into Drug Development and Communication: An Ad Hoc Task Force Report of the Patient-Reported Outcomes (PRO) Harmonization Group Meeting at the Food and Drug Administration, February 16, 2001. Value in Health 2003; 6 (5): 522-531.
5. Greenhalgh J. The Applications of PROs in Clinical Practice: What Are They, Do They Work, and Why? Quality of Life Research 2009; 18 (1): 115-123.
6. Snyder CF, Aaronson NK, Choucair AK, et al. Implementing Patient-Reported Outcomes Assessment in Clinical Practice: A Review of the Options and Considerations. Quality of Life Research 2012; 21 (8): 1305-1314.
7. Snyder CF, Brundage MD, Rivera YM, et al. A PRO-cision Medicine Methods Toolkit to Address the Challenges of Personalizing Cancer Care Using Patient-Reported Outcomes: Introduction to the Supplement. Medical Care 2019; 57: S2-S7.
8. Stover AM, Tompkins SC, Hammelef K, et al. Using Stakeholder Engagement to Overcome Barriers to Implementing Patient-Reported Outcomes (PROs) in Cancer Care Delivery. Medical Care 2019; 57 (S92): S99.
9. Lavallee DC, Chenok KE, Love RM, et al. Incorporating Patient-Reported Outcomes Into Health Care To Engage Patients And Enhance Care. Health Affairs 2016; 35 (4): 575-582.
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12. Gibbons C, Porter I, Gonçalves-Bradley DC, et al. Routine Provision of Feedback from Patient-Reported Outcome Measurements to Healthcare Providers and Patients in Clinical Practice. Cochrane Database of Systematic Reviews. 2021 (10).
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14. Velikova G, Booth L, Smith AB, et al. Measuring Quality of Life in Routine Oncology Practice Improves Communication and Patient Well-Being: A Randomized Controlled Trial. Journal of Clinical Oncology 2004; 22 (4): 714-724.
15. Basch E, Deal AM, Kris MG, et al. Symptom Monitoring With Patient-Reported Outcomes During Routine Cancer Treatment: A Randomized Controlled Trial. Journal of Clinical Oncology 2016; 34: 557-65.
16. Cleeland CS, Wang XS, Shi Q, et al. Automated Symptom Alerts Reduce Postoperative Symptom Severity After Cancer Surgery: A Randomized Controlled Trial. Journal of Clinical Oncology 2011; 29: 994-1000.
17. Basch E, Deal AM, Dueck AC, et al. Overall Survival Results of a Trial Assessing Patient-Reported Outcomes for Symptom Monitoring During Routine Cancer Treatment. JAMA 2017; 318 (2): 197-198.
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About the PROTEUS Consortium

The PROTEUS Consortium helps navigate the use of PROs in clinical trials and clinical practice. The goal is for patients, clinicians, and other decision-makers to have PRO data from research studies and in clinical care to make the best decisions they can about treatment options. To accomplish this objective, PROTEUS partners with over 50 patient, clinician, research, health system, funding, and regulatory groups from the U.S. and internationally to promote the systematic use of methodologic tools to optimize the capture and communication of PRO data.

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 - Letter of Intent Specifications

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). Describe how it will investigate the value of using PROMs in oncology clinical practice and how the results will be useful to institutional decision-makers regarding PROMs programs.

Assessment of Need for the Project

- Provide a rationale for your study goals and describe how the study results will contribute to our understanding of the value of using PROMs in practice.

Target Audience

- Describe the study population that will be included in your project.
    - Projects should investigate the use of PROMs in adult cancer patients.
    - Specify which cancer types will be included. Provide the estimated percentage of the population with breast cancer, with prostate cancer, and with hematologic malignancies.
    - Describe the age, gender, and other demographic information of the study population.
- Summarize how PROMs were or will be used in clinical practice for this population.
- Indicate the populations to whom you believe the study results will be generalizable.

Project Design and Methods

- Describe concisely the research design and methods for achieving the stated goals.
- Specify how the project will assess both costs/resource use and benefits. While a formal cost-benefit or cost-effectiveness analysis is not required, proposals should specify the costs and benefits being considered and how they will be summarized to characterize the value of using PROMs in practice. Indicate the perspective of the analysis. The results of these projects should be of interest to institutional decision-makers regarding PROMs programs.
- Provide a brief overview of the PROM intervention included in the evaluation and how the project will investigate its value.
- Include an overview of the analytic methods.

Innovation

- Explain what measures you have taken to assure that this project idea is original and does not duplicate other projects – or – 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 the primary and secondary outcomes, indicating how costs/resource use and benefits will be described to provide an indication of value.
- 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.

Additional Information

- If there is any additional information you feel the reviewers should be aware of concerning the importance of this project, please summarize here.

Organization Detail

- This information is used to assess the capability of the organizational resources available to perform the effort proposed. Identify the available facilities and access to the relevant data. If appropriate, indicate resource 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.
- 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, insurances, heating, and lighting should be included in 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.
    - 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 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.