Applying Patient-Reported Outcomes in Oncology Patient Care Using Quality Improvement and Implementation Science Strategies

1. 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 the use of patient-reported outcome measures (PROMs) in clinical practice to improve the monitoring and management of patients with cancer. Funding can be used to implement new, or improve existing, PROM initiatives. Grantees will participate with one another, and PROTEUS Consortium members, in a Learning Health Network.

Grants will support applying quality improvement and/or implementation science strategies targeting the use of patient-reported outcomes (PROs) in oncology clinical practice, goals aligned with the objectives of the PROTEUS Consortium and the Pfizer Global Medical Grants program. This grant opportunity focuses specifically on the use of individual cancer patient PROMs to inform their monitoring and management. Use of aggregated PROM data for quality evaluations or pay-for-performance are outside the scope of this opportunity. Researchers seeking funding for clinical research projects will also not be considered under this request for proposals (RFP).

2. BACKGROUND

2.1. RFP SETTING

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 to monitor how patients are doing and inform their care.[5-9]

Research suggests that this use of PROMs in cancer care can provide benefits, including promoting patient-clinician communication, assisting with problem detection, influencing management, and improving outcomes such as symptom control, health-related quality of life, and functioning.[10-15] Recent studies have shown a survival benefit associated with use of PROMs in clinical practice for patients with advanced cancer.[16,17]

While evidence supports the potential effectiveness of PROMs in practice, a number of barriers to broad implementation are also evident. These barriers include operational challenges (e.g., data collection strategies, integration with workflow, incorporation into the health record), difficulties interpreting the meaning of PROM scores, questions regarding how to act on the PROM results, and the culture changes required in the clinical practice for successful PROM use.

2.2. RFP INTENT

The intent of this RFP is to support proposals to use PROMs in routine oncology clinical practice to inform individual patient monitoring and management. Proposals should apply quality improvement or implementation science strategies, or both. Successful proposals will promote the implementation and/or the quality of PROMs used in oncology clinical practice with a focus on individual-patient care. While we expect that most applicants will use electronic PRO (ePRO) interventions, interventions that use non-electronic (e.g., paper) PRO assessments will be considered if there is an appropriate justification. Grantees will participate in a Learning Health Network, along with PROTEUS Consortium members. This Learning Health Network will provide a forum for grantees and other PROTEUS Consortium members to share experiences and lessons learned regarding PROM clinical practice initiatives. The Network will meet virtually each month, and there will be an in-person meeting of the Network and Consortium in 2024.

The RFP is intended to support quality improvement and implementation science projects, not primary research proposals. Further, the focus is on individual patient monitoring and management and not on other uses of PROs in the clinical setting (such as use of PROMs at the aggregate level for quality evaluations or pay-for-performance initiatives).

2.3. RFP SCOPE

This RFP encourages proposals to initiate or improve the use of PROMs in cancer clinical practice at the individual-patient level, as described above. The overall goal of this funding is to improve individual patient care using PROMs. Examples of relevant topics include (but are not limited to) the following, and proposals may address multiple topics:

- Designing and/or executing a PROM collection strategy; such strategies may include “top-down” (generated from management and implemented by staff) and/or “bottom-up” (initiated by staff and then coordinated with management) approaches
- Improving and optimizing the efficiency of and resource utilization associated with PROM collection and use
- Selecting appropriate and actionable PROMs to improve efficiency and patient-centeredness while balancing pragmatism with psychometric rigor
- Engaging and training patients, physicians, nurses, pharmacists, administrators, and other clinic staff to promote the collection and application of PROM data. These activities might include, for example:
    - Demonstrating the value of PROMs in clinical practice to clinicians, patients, administrators, and others
    - Ensuring effective patient-clinician communication regarding PROM results
    - Demonstrating how use of PROM data in clinical care incentivizes patients to complete PROMs
    - Empowering patients to advocate for use of their PROM data in their clinical care

- Ensuring inclusivity of diverse patient groups in PROM interventions (i.e., aiming to decrease – not increase – disparities)
- Creating and/or improving processes to support the collection and use of PROM data in the clinical workflow. These activities may include:
  - Promoting clinical culture changes that encourage PROM use in clinicians' work routines and practices
  - Improving modalities for data collection
  - Incorporating PROM results in electronic medical records
  - Integrating remote monitoring using PROMs between visits
- Presenting results in a way to promote understanding and use among *all* patients, including low literacy, non-native speakers, and other hard-to-reach populations
- Promoting methods to aid PROM data interpretation and facilitate action based on PROM results (e.g., clinical pathways, consensus guidelines, decision support)
- Designing and forming governance structures to oversee the collection and application of PROM data, including evaluating whether PROMs are used clinically as designed
- Exploring and addressing ethical and legal issues related to PROM collection and use (e.g., ensuring PROM alerts are addressed)

In all cases, projects must demonstrate how the intervention addresses the use of PROMs for individual patient management.

2.4. ABOUT THE PROTEUS CONSORTIUM

The PROTEUS Consortium has been formed with the objective of ensuring that patients, clinicians, and other decision-makers have PRO data from research studies (PROTEUS-Trials) and in clinical care (PROTEUS-Practice) to make the best decisions they can about treatment options. To accomplish this objective, the PROTEUS Consortium is partnering with 37 key patient, clinician, research, health system, funding, and regulatory groups from the U.S. and internationally to promote the systematic use of methodologic tools developed to optimize the assessment and reporting of PROs. These tools include: the International Society for Quality of Life Research User's Guide for Implementing PRO Assessment in Clinical Practice,[18] which describes options and considerations involved in implementing PROs in routine care; the User's Guide for Integrating Patient-Reported Outcomes in Electronic Health Records,[19] which describes options and considerations for integrating PROs in electronic health records; Stakeholder-Driven, Evidence-Based Standards for Presenting PROs in Clinical Practice,[20] which recommends best practices for displaying PRO data to promote understanding and use; "A PRO-cision Medicine Methods Toolkit" supplement to the journal Medical Care,[7] which provides a range of approaches for interpreting and acting on PRO data in clinical practice; and the ePROs in Clinical Care website,[21] which helps health systems with PRO intervention design and implementation.

2.5. ABOUT PFIZER GLOBAL MEDICAL GRANTS

The mission of Pfizer Global Medical Grants (GMG) is to accelerate the translation of science into quality patient care through independent grants, partnerships, and collaborations. Pfizer GMG supports the global health care communities' 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. For all grants, the grant requester and grantee are responsible for the design, implementation, sponsorship, and conduct of the independent initiative supported by the grant including compliance with any regulatory requirements.

3. ELIGIBILITY

Geographic Scope

Open to applicants 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 affiliated with the applicant institution.
- Only organizations are eligible to receive grants, not individuals or small physician-owned practice groups.
- The applicant institution must be involved in patient care and may include Academic Cancer Centers, Healthcare Delivery Networks, and Community Cancer Centers or Hospitals; partnership with non-healthcare delivery organizations is acceptable.
- The applicant PI must have a medical or postdoctoral degree (MD, PhD, or equivalent), an advanced nursing degree (BSN with a MS/PhD), a degree in Psychology, Pharmacy, Physiotherapy, or Social Work, or be in a health administration position with a key role in the implementation of PROMs in clinical practice.
- A multidisciplinary team with expertise aligned with the proposal objectives, including involvement of patient partners, is encouraged.
- Only one Letter of Intent (LOI) per PI will be accepted.
- Typically, an institution or organization will be limited to one full proposal; institutions are encouraged to coordinate internally prior to LOI submission.

4. REQUIREMENTS

Date RFP Issued

March 1, 2022

Clinical Area

Using individual-level PROs in clinical practice in oncology

Specific Area of Interest for this RFP

The intent of this RFP is to support the use of PROs in routine oncology clinical practice to inform individual patient monitoring and management. Proposals should apply quality improvement or implementation science strategies, or both, as described in section 2.3 above. LOIs addressing relevant topics will be considered. A plan for long-term sustainability should be included within the submission. While we expect that most applicants will use electronic PRO (ePRO) interventions, interventions that use non-electronic (e.g., paper) PRO assessments will be considered if there is an

appropriate justification. Grantees will participate in a Learning Health Network, along with other PROTEUS Consortium members.

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 2 steps. First, 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 likelihood of impact of the project in implementing or improving the quality of PROM use in oncology practice; both projects that implement proven methods and those that explore innovative approaches will be considered
- Design and feasibility of the intervention, including pilot data or relevant background
- Use of quality improvement and/or implementation science frameworks to inform the project's methods
- Rigor of the evaluation strategy
- Expertise, experience, and accomplishments of the investigators and project team, including influence in the organization
- Involvement of relevant perspectives through a multidisciplinary team and partnership with patients; team must be ready-to-go on March 1, 2023
- Environment and resources consistent with the needs of the study
- Sustainability

Target Audience

- Researchers, members of the health care team, and administrators involved in the design, implementation, and evaluation of PROM use in cancer clinical practice
- Projects addressing pediatric and/or adult oncology patients with any stage of cancer will be considered eligible
- Treatment, survivorship, and end-of-life care patient populations are all considered eligible

Expected Approximate Monetary Range of Grant Applications

- Individual projects requesting up to $150,000 to be spent over 2 years will be considered. The total available budget related to this RFP is $1.5 million USD.
- The amount of the grant Pfizer will be prepared to fund for any project will depend upon the external review panel's evaluation of the proposal and costs involved, and will be stated clearly in the approval notification.

Key Dates

- RFP release date: March 1, 2022
- LOI due date: April 28, 2022
  - Please note the deadline is 23:59 Eastern Time (New York, GMT -5).
- Review of LOIs by External Review Panel: May 2022
- Anticipated LOI Notification Date: June 15, 2022
- Full Proposal Deadline: August 31, 2022*

  *Only accepted LOIs will be invited to submit full proposals
  - Please note the deadline is 23:59 Eastern Time (New York, GMT -5).
- Review of Full Proposals by External Review Panel: September-October, 2022
- Anticipated Full Proposal Notification Date: November 1, 2022
- Grants distributed following execution of fully signed Letter of Agreement, due by December 31, 2022
- Anticipated Project Start and End Dates: March 1, 2023 to February 28, 2025

How to Submit

- Please go to http://www.cybergrants.com/pfizer/loi and sign in. First-time users should click "REGISTER NOW". *[Note: there are individual portals for each grant application type (e.g., knowledge, LOI, research full proposal, and QI full proposal). Please be sure to use the URL above.]*
- Click the "Start a New LOI"
- For the question "Competitive Grant?" select Yes
- Select the following Competitive Grant Program Name:
  2022 Onc US: PROMs in Practice
- Requirements for submission:

  Complete all required sections of the online application (see Appendix).
- If you encounter any technical difficulties with the website, please click the "Technical Questions" link at the bottom of the page.
- If you are invited to submit a full proposal based on your LOI, a full proposal will be due on August 31, 2022. The requirements for the full proposal will be communicated at the time that the LOI is accepted.

IMPORTANT: Be advised applications submitted through the wrong application type and/or submitted after the due date will not be reviewed by the committee.

- 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 "2022 Onc US: PROMs in Practice."

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.
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.

5. REFERENCES

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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.
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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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16. 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.
17. Denis F, Lethrosne C, Pourel N et al. Randomized Trial Comparing a Web-Mediated Follow-up With Routine Surveillance in Lung Cancer Patients. Journal of the National Cancer Institute 2017; 109(9).
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APPENDIX A

LETTER OF INTENT 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

Briefly state the overall goal of the project. Also describe how this goal aligns with the focus of the RFP and the goals of the applicant organization(s).

List the *overall* objectives you plan to meet with your project both in terms of implementation and expected outcomes. Objectives should describe the target population as well as the outcomes you expect to achieve as a result of conducting the project.

Assessment of Need for the Project

Please include a quantitative baseline data summary, initial metrics (e.g., quality measures), or a project starting point (please cite data on gap analyses or relevant patient-level data that informs the stated objectives) in *your* target area. Describe the source and method used to collect the data. Describe how the data was analyzed to determine that a gap existed. If a full analysis has not yet been conducted, please include a description of your plan to obtain this information. The fundamental benefits of measuring PROs in practice as described in the background of the RFP need not be reiterated in the LOI.

Target Audience

Describe the primary audience(s) targeted for this project. 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 the planned project and the way it addresses the established need.

Address how quality improvement and/or implementation science methods will be applied.

Innovation

Both projects that implement proven methods and those that explore innovative approaches will be considered. As applicable:

- 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.
- Describe how this project is innovative, with a rationale for why the innovation is likely to be successful and contribute to the use of PROMs in routine oncology clinical practice.

Evaluation and Outcomes

In terms of the metrics used for the needs assessment, describe how you will determine if the practice gap was addressed for the target group. Describe how you expect to collect and analyze the data.

Quantify the amount of change expected from this project in terms of your target audience.

Describe how the project outcomes will be broadly disseminated.

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 Pfizer should be aware of concerning the importance of this project, please summarize here.

Organization Detail

Describe the attributes of the institutions / organizations / associations that will support and facilitate the execution of the project and the leadership of the proposed project. Articulate the specific role of each partner in the proposed project. Letters of support should not be included with the LOI.

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:

- Institutional overhead and indirect costs may be included within the grant request. Examples include human resources department costs, payroll processing and accounting costs, janitorial services, utilities, property taxes, property and liability insurance, and building maintenance as well as additional project expenses such as costs for publication, IRB / IEC review fees, software license fees, and travel. Please note: Pfizer does not provide funding for capital equipment.
- 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 therapeutic agents (prescription or non-prescription).

Pfizer maintains a company-wide, maximum allowed overhead rate of 28% for independent studies and projects.