Request for Expressions of Interest (REI): Advisory Group for Patient-Reported Outcome Implementation in Vulnerable and Underserved Populations (Due Date: February 24, 2023)

1. OVERVIEW

The PROTEUS Consortium (Patient-Reported Outcomes Tools: Engaging Users & Stakeholders) and Pfizer Global Medical Grants are collaborating to form an **Advisory Group for Patient-Reported Outcome Implementation in Vulnerable and Underserved Populations.** The Specific Aims of this collaborative agreement are:

1. To improve our understanding of the facilitators of and barriers to implementing routine PRO assessments in vulnerable and underserved populations *(see definition below)*.
2. To build capacity for PRO implementation to improve care for cancer patients who are vulnerable or underserved.

We are issuing this Request for Expressions of Interest to identify Advisory Group members from institutions in the United States who have expertise in addressing the needs of vulnerable and underserved populations and an interest in implementing PROs in routine oncology practice. Advisory Group members will attend a one-day meeting in the Baltimore/Washington, DC area on **Thursday, May 11, 2023** (travel expenses will be covered) and a 1-hour, pre-meeting planning call in April 2023. The Advisory Group will also include experts in PRO implementation for vulnerable and underserved populations (recruited through a separate mechanism).

The product of the Advisory Group meeting will be a strategy for promoting PRO implementation in institutions caring for vulnerable and underserved cancer populations. This information can then be used to inform a future Request for Proposals (RFP) or other projects and solutions.

Participation in the Advisory Group offers the opportunity to contribute meaningfully to advancing patient-centered cancer care for vulnerable and underserved populations. Advisory Group members will be recognized for their contributions on the PROTEUS website and on products that emerge from the discussions and in peer-reviewed publications (following authorship guidelines).

2. BACKGROUND

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] The Advisory Group focuses specifically on the use of individual cancer patient PROMs to inform their 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).

While evidence supports the potential effectiveness of PROMs in practice, a number of barriers to broad implementation are also evident – particularly for implementing PROMs to improve care for vulnerable and underserved populations.

For the purposes of the Advisory Group, we define Vulnerable and Underserved Populations as:*

Populations sharing a particular characteristic, as well as geographic communities, that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life, including:

- Black/African American populations and other persons of color
- American Indian / Alaskan Native and other Indigenous populations
- People whose first language is not English
- Older adults
- Members of religious minorities
- LGBTQ+ populations
- Individuals with disabilities
- People who live in rural areas
- Populations impacted by persistent poverty or inequality
- People with limited health literacy and/or numeracy
- Populations who may face barriers that make it difficult to get health coverage and basic health care services for other reasons

3. CONTENT FOR EXPRESSIONS OF INTEREST

Requests for Expressions of Interest (REIs) will be accepted via a brief, 6-item form available at https://osu.az1.qualtrics.com/jfe/form/SV_8AL9oKaRXL8GRfM, which asks the following **(limit of 100 words per question)**:

1. What is your institution's involvement in providing oncology care for vulnerable and underserved populations?
    - *NOTE: Anyone from an institution providing care for vulnerable and underserved populations is eligible; those from institutions with the most emphasis on care for vulnerable and underserved populations will have priority*
2. What is your personal involvement in researching and/or providing oncology care for vulnerable and underserved populations?
3. What is your and your institution's interest in and/or plans for using patient-reported outcomes (PROs) as part of routine oncology care?
4. Do you or your institution currently collect PROs as part of routine care? *(current PRO collection is not a requirement of Advisory Group participation)*
    - *Please briefly describe current PRO activities as part of routine oncology care, if applicable*
    - *Please briefly describe current PRO activities as part of routine care in other disease areas, if applicable*
5. How could participating on the Advisory Group help you or your institution implement PROs in vulnerable and underserved cancer populations?
6. Are you available to attend an all-day in-person meeting in the Washington, DC/Baltimore, area on Thursday, May 11 (travel expenses will be covered)?

4. PROCESS FOR EXPRESSIONS OF INTEREST

- **Submit Expression of Interest at:** https://osu.az1.qualtrics.com/jfe/form/SV_8AL9oKaRXL8GRfM
- **Focus Area:** Using individual-level PROs in clinical practice in oncology
- **Eligibility:** Applicants from institutions based in the United States

* Based on definitions from the U.S. Department of Health & Human Services and Centers for Medicare and Medicaid Services

- **Advisory Group Selection:** We anticipate inviting 20-25 applicants to join the Advisory Group. Advisory Group members will be invited based on their potential to contribute meaningfully to the discussions, as well as the potential for them to bring learnings from the Advisory Group back to their institutions to advance care for vulnerable and underserved cancer populations.
- **Questions:** Please direct questions in writing to Anne Schuster (Anne.Schuster@osumc.edu), with the subject line "2023 Onc US: REI."
- **Key Dates:**
    - Submissions of Expressions of Interest Due: **Friday, February 24, 2023**
    - Advisory Group Invitations Issued: **Friday, March 3, 2023**

5. ABOUT PROTEUS & PFIZER

5.1. 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 51 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. For more information, visit www.TheProteusConsortium.org.

5.2. 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.

6. REFERENCES

1. FDA 2020. Clinical Outcome Assessment (COA): Frequently Asked Questions. Available at: https://www.fda.gov/about-fda/clinical-outcome-assessment-coa-frequently-asked-questions#COADefinition. Last accessed: February 8, 2022.
2. Haywood KL, de Wit M, Staniszewska S, Morel T, Salek S. Chapter 9 (Part II) Developing Patient-Reported and Relevant Outcome Measures. In: Facey K, Hansen HP, Single ANV (eds). Patient Involvement in Health Technology Assessment. Adis. Springer Nature. 2017. DOI 10.1007/978-981-10-4068-9.
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.