

## Request for Proposals

January 2, 2025

The American Urological Association Education and Research, Inc. (AUAER) and

Pfizer | Pfizer-Astellas Alliance Joint Request for Proposals (RFP) – Quality Improvement Grants

### Improving the care process for patients with advanced prostate cancer

*Competitive grant program evaluated by an AUAER Expert Review Committee (ERC)*

The American Urological Association Education and Research, Inc. (AUAER) and Pfizer Medical Grants & Partnerships (GMGP) are collaborating to offer grant support to urology health institutions and organizations to identify gaps in patient care for individuals with advanced prostate cancer (APC) and develop solutions-based projects to address these gaps.

APC is a diverse and clinically heterogeneous disease state encompassing biochemical recurrence, metastatic hormone-sensitive prostate cancer (mHSPC), nonmetastatic castration-resistant prostate cancer (nmCRPC), and metastatic castration-resistant prostate cancer (mCRPC), requiring treatments tailored to the individual patient. Patient identification is paramount for evaluating appropriate treatment options. Furthermore, analysis of a patient's germline and somatic tumor genomic alterations can help inform prognosis and predict treatment effectiveness.

Over the past several decades treatment advances have yielded improvements in patient quality of life and survival, however, prostate cancer still accounts for 11% of all cancer-related deaths in men in the United States.<sup>1</sup> As the landscape for men with APC continues to evolve, therapy sequencing, treatment intensification and combinations, and the expansion of precision medicine are increasingly important factors to ensure successful outcomes.

AUAER is committed to being forward-thinking and innovative to align stakeholders of the urologic community to achieve better urologic health and urologic healthcare for all patients.

Pfizer's GMGP supports the global healthcare community's independent initiatives to improve patient outcomes in areas of unmet medical need that are aligned with Pfizer's medical and/or scientific strategies.

Pfizer and Astellas via the "Pfizer-Astellas Alliance" are collaborating to provide independent grant support in the area of prostate cancer. For all independent grants, the grant requester (and ultimately the grantee) is responsible for the design, implementation, and conduct of the independent initiative supported by the grant. The companies must not be involved in any aspect of project development, nor the conduct, of the independent education program.

This RFP is being issued by all three organizations. AUAER is the lead organization for review and evaluation of proposals. A review committee, led by AUAER, will make decisions on which proposals will receive funding. Grant funding and general oversight of the funded projects will be provided directly from Pfizer on behalf of the Pfizer-Astellas Alliance. Collectively, \$1.5 Million USD is available for award.

#### References:

1. Siegel RL, Miller KD, Fuchs HE, Jemal A. Cancer statistics, 2022. CA Cancer J Clin. 2022;72(1):7-33.

## RFP Intent

This RFP intends to encourage proposals to fund novel quality improvement projects that address barriers to optimal care for patients with APC, which include those with biochemical recurrence at high-risk for metastasis, nonmetastatic castration-resistant prostate cancer (nmCRPC), low- or high-volume metastatic hormone-sensitive prostate cancer (mHSPC), and metastatic castration-resistant prostate cancer (mCRPC), including those with germline and somatic genomic alterations.

Many factors contribute to the complexity of treating APC, including:

- Identifying patients who may be appropriate candidates for intensified or combination therapy.
- Coordinating care across multidisciplinary team members and locations of care.
- Integrating rapidly advancing treatment options, including access to biomarker and genetic testing, and next generation imaging.
- Effectively sequencing therapies to treat APC.
- Introducing appropriate treatment intensification for patients with APC.
- Appropriately managing toxicities of approved therapies.
- Navigating the discrepancies between national treatment guidelines.
- The complexity of ensuring an adequate health care workforce, which often results in patient access issues.

Proposed projects should measurably improve patient care by closing the gap between how patients with APC are currently being managed and how patients should be optimally treated and cared for.

## RFP Scope

AUAER and Pfizer are interested in funding projects that meet one or more of the following:

- Foster multidisciplinary team involvement, including advanced practice providers (APPs) and genetic counselors, to enhance shared decision-making with patients.
- Optimize referral processes from urology to medical oncology.
- Improve therapy management.
- Sequencing strategies in urology/oncology practices, including combination approaches and integration of new treatments (e.g., PARPi).
- Develop systematic approaches to conducting biomarker and genetic testing for patients.
- Improve access to treatment and diagnostics through improving adherence to AUA and NCCN Guidelines.
- Patient follow-up and close collaboration with Primary Care Physicians, who often monitor patients for PSA post- and during treatment.

If an education intervention is proposed as part of a quality improvement project, please consider the existing guidelines, resources, and education provided by the AUA. Education can be found on *AUAUniversity*, the *AUAUniversity* YouTube Channel and the *AUAUniversity* podcast.

If patient education materials are proposed, please consider using materials from the Urology Care Foundation which are free to all providers and patients.

Special consideration will be given to proposals that:

- Address disparities in APC care for those marginalized due to age, race, income, accessibility, or other factors.
- Propose a project team that is comprised of diverse perspectives and experiences.
- Provide sustainable and potentially transferable solutions that improve the quality of care.

This RFP will NOT support clinical research projects evaluating the efficacy of therapeutic or diagnostic agents.

## Disease Burden Overview

Prostate cancer is the most common solid organ malignancy among men in the U.S. and remains the second leading cause of cancer deaths for this population. In fact, approximately 288,300 new diagnoses of prostate cancer and 34,700 deaths are estimated in the U.S. in 2023.<sup>1</sup> The incidence of prostate cancer is 70% higher in Black men as compared to White men for reasons that remain unclear.<sup>1</sup> Importantly, the incidence of advanced stage disease including metastatic hormone-sensitive prostate cancer (mHSPC) has been increasing by about 5% per year in recent years.<sup>2</sup>

Per the NCCN guidelines, prostate cancer is often associated with somatic mutations that occur in the tumor but not in the germline. An estimated 89% of metastatic castration-resistant prostate cancer (CRPC) tumors contain a potentially actionable mutation, with only about 9% of these occurring in the germline.

While advances have been made, there are many unmet needs in APC management, including optimal strategies for node-positive disease and other APC disease states. Patients with APC often face challenges accessing medical care that is congruent with current medical guidelines, Black patients with advanced prostate cancer demonstrate worse outcomes, and personalized care with predictive markers for treatment selection based on tumor and host biology has not yet been achieved.

Additional unmet needs include high-level evidence directed at understanding the optimal sequencing of advanced prostate cancer therapies and additional studies and data to guide clinicians and patients in terms of treatment intensification and combinations of therapy. Improving access to care for those who are socioeconomically disadvantaged is also important.

Furthermore, there may be over-utilization of conventional imaging and under utilization of newer imaging modalities such as PSMA PET, genomic testing for APC, and novel evidence-based therapies or treatment regimens.

### References:

1. Cancer statistics, 2023. *CA Cancer J Clin.* 2022; 73:17.
2. Disparities and trends in genitourinary cancer incidence and mortality in the USA. *Eur Urol.* 2022:S0302.

## Geographic Scope

United States

## Applicant Eligibility Criteria

- Only organizations are eligible to receive grants, not individuals.
- Collaborations within institutions (e.g., between departments and/or inter-professional), as well as between different institutions, organizations, and associations, are encouraged. Please note all partners must have a relevant role and the requesting organization must have a key role in the project.
- The applicant must be the Project Lead or an authorized designee of such an individual (e.g., the Project Lead's grant/research coordinator).
- The Project Lead must be an employee or contractor of the requesting organization.
- 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 before applying. Grants awarded to organizations that are subsequently found to be unable to accept funding directly from Pfizer Inc. may be subject to rescission.
- For projects offering continuing education credit, the requesting organization must be accredited.

## Clinical Area

Advanced prostate cancer (APC)

## Other Requirements for this RFP

- Grantees are required to submit written status reports to Pfizer and participate in quarterly check-in calls in 2025 and 2026 with AUAER and ERC representatives, to discuss project progress.
- Grantees are required to participate in a grantee conference call at the approximate project mid-point in the spring of 2026, to discuss the gaps in practice that they are working to address, the methods in which they are addressing the gaps and what they have learned to date.
- Grantees are invited to present at the 2027 AUA Annual Meeting at a session as identified by AUAER.
- Grantees are required to submit their project outcomes to the medical community through presentation as an abstract to the AUA Annual Meeting and/or through publication to *JU Open Plus*, AUA's peer-reviewed, open-access publication.

## Who should apply?

Urology and urologic oncology health centers, institutions, and organizations are invited to submit grant applications for quality improvement projects that outline a planned process and methodology for improving APC care.

## Expected Monetary Range of Grant Applications

The total available budget related to this RFP is **\$1.5M**.

- Individual projects requesting up to **\$250,000** will be considered.
  - At the discretion of the AUAER ERC, additional funding may be awarded for exceptional proposals with detailed budget justifications.
- The amount of the grant awarded by Pfizer and AUAER for any project will depend upon the ERC's evaluation of the proposal and the costs involved and will be stated clearly in the grant agreement.
- Award amounts include direct costs, institutional overhead costs (capped at 28% per Pfizer policy), and indirect costs.
  - If an increase in staffing is proposed, please include a plan for the sustainability of the position beyond the life of the grant.
- Any additional sources of funding and the amounts must be disclosed.

## Project Length

2 years maximum: June 2025 – May 2027 (proposed start and end dates are approximate and may be adjusted)

## Key Dates

- RFP release date: January 2, 2025
- Proposal due date: March 11, 2025, 11:59 pm EST
- Review of submitted proposals by ERC: Week of April 14, 2025
- Anticipated notification date for selected proposals: Week of April 21, 2025
- Grants will be distributed following the completion of a fully executed agreement
- Anticipated project timeframes: June 2025 – May 2027

## How to Submit

- Please go to <https://www.cybergrants.com/pfizer/QI> 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.]*

### In the application:

- For the question “Are you replying to a Request for Proposal as part of the Competitive Grant Program?” select Yes
- Select the following Competitive Grant Program Name: 2025 ONC US AUA-QI Advanced Prostate
- Select the following Primary Area of Interest: Oncology - Genitourinary – QI – Prostate

### Requirements for submission:

- Complete all required sections of the online application and upload your project proposal in the Full Proposal Submission 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 by the committee.

## Questions

If you have questions regarding this RFP, please direct them in writing to the Grant Officer, Lori Carpenter ([lori.carpenter@pfizer.com](mailto:lori.carpenter@pfizer.com)) and Jody Donaldson ([jdonaldson@auanet.org](mailto:jdonaldson@auanet.org)) with the subject line “AUA Prostate QI Grant Inquiry”

## 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. The applicant is encouraged to share the core terms with counsel for approval before applying.

## Review and Approval Process

This Quality Improvement Grant RFP will be reviewed and scored by members of AUAER's Expert Review Committee (ERC), based on approved criteria.

## Mechanism Applicants will be Notified

- All applicants will be notified via email by week of April 21, 2025.
- Applicants may be asked for additional clarification during the review period.

## Appendix I. Full Proposal Instructions

Applications will be accepted via the online portal listed in the How to Submit section. Combined full proposal documents should be no longer than 10 pages in length (12-point font and 1-inch margins).

## Project Description and Significance

- State the goals and objectives of the quality improvement project and describe how they align with the goals of this RFP and the goals of the applicant organization(s).
- Clearly define the problem you are addressing and describe the intervention you will be implementing and measuring.
- Outline the anticipated project outcomes and indicators of success and how these outcomes will be measured.
- Describe how this project offers a unique, innovative, or valuable solution to a known problem.
- Describe how the proposed project would be practice-changing and integrated into the current workflow/workload.
- Describe how this project will reduce disparities or promote access for marginalized or underserved patient populations (e.g., racial and ethnic minorities, rural populations, and patients impacted by social determinants of health).

## Target Patient Population

- Describe the targeted patient population(s) for this project, the projected size of the population, and provide a demographic breakdown of this population (i.e., age, race, socioeconomic status).

## Methodology and Evaluation

- Outline the methods and evaluation plan for your proposed project.
- Describe how project partners will leverage data to identify gaps, monitor progress, and measure impact. If you have preliminary data, please include it as part of this RFP response.

## Sustainability and Feasibility

- Provide evidence of the staffing capacity to successfully implement the proposed project.
- Detail the commitment from institutional leadership, governing bodies, and/or practice leaders.
- Describe how the proposed project will be sustained following the completion of the grant period.

## Stakeholder Involvement

- Describe the urology health institutions, organizations, and practice leaders who will engage in the successful implementation of the proposed project.
- Outline the multidisciplinary team involvement, including relevant healthcare providers (e.g. physicians, APPs, nurses, etc.) and other specialists (e.g. genetic counselors, pharmacists, etc.).
- Describe how the project will meaningfully engage patients, caregivers, or community stakeholders.

**Please include at least one letter of support from organizational leadership and/or project partners.**

## Health Disparities

- If applicable, describe how this project will reduce disparities and promote access for marginalized and/or underserved populations (e.g., racial and ethnic minorities, rural populations, and patients impacted by social determinants of health).
- Outline how this project will account for the social and cultural needs of the targeted population(s)?

## Project Team

- Outline the individuals who will comprise the project team, their roles, and the percent of time allocated to this project.
- Specify the role that each organizational partner will play in program implementation.

**Please include a brief biosketch for each member of the project team.**

## Project Timeline

**Please include a timeline for your proposed project.**



## Project Budget

- Requested budget amounts must be in US dollars.
- While developing your project budget please consider the following:
  - General organizational running costs such as legal fees, insurance, heating, and lighting etc. should be included in an 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.
  - The inclusion of overhead costs cannot cause the amount requested to exceed the budget limit set forth in the RFP.
  - 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 GMGP 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 [click here](#) for details.

**Please include budget details** and a budget narrative **for your proposed project.**

## Dissemination Plan

Describe how you plan to disseminate the results of your proposed project.

## Additional Information

If IRB approval is required for QI projects by your institution, please briefly outline the process and timeline for that approval. Any disbursement of grant funding will be contingent on obtaining IRB approval.

If there is any additional information that you feel is relevant for review by the Expert Review Committee, please summarize it here.

## Appendix II: Guidance on What Constitutes a Quality Improvement Project

Quality improvement (QI) projects are systematic, data-guided, sustainable activities designed to bring about immediate, positive changes in the delivery of healthcare in particular settings<sup>1,2</sup>. Quality improvement seeks to standardize structure and processes to reduce variation, achieve predictable results, and improve outcomes for patients, healthcare systems, and organizations. Structure includes things like technology, culture, leadership, and physical capital. Process includes knowledge capital (e.g., standard operating procedures) or human capital (e.g., education and training)<sup>3</sup>.

QI projects systematically apply what is already known into the local practice, intended to quickly improve patient care within a specific setting. The goal of QI projects is to close a gap in performance at a specific health care system. The “performance” is a standard in health care that is not efficiently/appropriately/ consistently being done<sup>4</sup>. For these reasons, QI focuses on translating existing knowledge into programs or practices to immediately improve the quality of services to individuals and populations within a local institution or setting<sup>5</sup>. The risk of participation in QI is the same as the risk of receiving standard clinical care<sup>6</sup> since the standard of care remains the same for all patients.

In contrast, research projects use a systematic approach to discover something that is unknown. Research projects add new knowledge to what was previously unknown in literature through testing of a hypothesis or a scientific question<sup>4</sup>. Research aims to generate knowledge with broad applications, often through controlled studies. The subjects may or may not benefit directly from the knowledge gained. Research studies aim to evaluate an innovation, study something new, or analyze a process not yet rigorously studied<sup>6</sup>.

1) Baily MA, et al., *Hastings Cent Rep* 2006; 2) Lynn J, et al., *Ann Intern Med* 2007; 3) Centers for Medicare & Medicaid Services, *Page Last Modified: 09/10/2024*; 4) Jackson C, Research Quality Manager, Office of Research and Scholarship, University of Maryland, Baltimore School of Nursing; 5) COLUMBIA UNIVERSITY INSTITUTIONAL REVIEW BOARD GUIDANCE FOR THE CLASSIFICATION OF QUALITY IMPROVEMENT ACTIVITIES VERSUS RESEARCH WITH HUMAN SUBJECTS, Effective Date: December 1, 2023; 6) Newhouse, et al., *J Nurs Adm*, 2008.