

Quality of Care Initiative to Improve the Treatment of Locally Advanced or Metastatic (Stage IV) Bladder Cancer Patients Request for Proposals (RFP)

1. Introduction

The National Comprehensive Cancer Network® (NCCN), Pfizer, and EMD Serono are pleased to collaborate to offer a second grant opportunity to support Quality Improvement (QI) projects that will advance the quality of care, including guideline concordant care¹, and best practices around treatment for patients with Locally Advanced or Metastatic Disease (Stage IV; according to the AJCC TNM staging system) Bladder Cancers. For the purposes of this project, locally advanced or metastatic bladder cancer is defined as stage IV unresectable disease that has progressed beyond the bladder to the surrounding tissue or lymph nodes, or with overt metastases.

The original RFP, issued on April 14, 2022, called for LOIs describing the potential design and performance of quality improvement projects focused on improving care for patients with advanced bladder cancer. It was well received and a number of LOIs were invited to submit full proposals. Given the collective interest to optimize the residual funding, the funders and NCCN have agreed to re-release the RFP, with adjusted scope and funding amounts.

This RFP is being re-released to continue our commitment to improve the quality of patient care and offer organizations another opportunity to seek support for QI projects. This RFP is open to all eligible applicants, prior involvement in the original RFP is not required. This RFP will follow a single step process, eliminating the Letter of Intent (LOI) first step. All applications will be required to submit a full detailed proposal by the date outlined below.

The intent of this QI RFP is to support programs that will improve the quality of patient care with metastatic or locally-advanced (Stage IV) bladder cancer. QI considers aspects of quality such as clinical competence, outcomes and process assessment, program evaluation, quality indicators and quality assurance. QI grants help improve patient outcomes in areas of unmet medical needs. They should not be confused with general research grants which are focused on the development or refinement of specific and defined medical knowledge. Research projects answer questions about best practice, whereas Quality Improvement projects implement best practices. Research projects (e.g., clinical trials) will not be considered under this RFP.

National Comprehensive Cancer Network

The National Comprehensive Cancer Network® (NCCN®) is a not-for-profit [alliance of 32 leading cancer centers](#) devoted to patient care, research, and education. NCCN is dedicated to improving and facilitating quality, effective, efficient, and equitable cancer care so patients can live better lives. Through the leadership and expertise of clinical professionals at [NCCN Member Institutions](#), NCCN develops resources that present valuable information to the numerous stakeholders in the health care delivery system. By defining and advancing high-quality cancer care, NCCN promotes the importance of continuous quality improvement and recognizes the significance of creating clinical practice guidelines appropriate for use by patients, clinicians, and other health care decision-makers around the world.

Pfizer Global Medical Grants and EMD Serono US Medical Education

Pfizer Global Medical Grants and EMD Serono (the biopharmaceutical business of Merck KGaA, Darmstadt, Germany in the United States and Canada) US Medical Education are collaborating to provide grant support in the area of immuno-oncology and in particular urothelial carcinoma. 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. Our 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. NCCN is the lead organization for review and evaluation of proposals. A review committee, led by NCCN, 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 both Pfizer and EMD Serono.** Collectively, at least \$300,000 USD is available for award.

2. Background

The intent of the RFP is to encourage NCCN Member Institutions and non-NCCN Member Institutions to submit proposals describing concepts and ideas around how to improve the quality of care, including guideline concordant care, and best practices around treatment for patients with Locally Advanced or Metastatic (Stage IV; according to the AJCC TNM staging system) Bladder Cancers.

A successful project will incorporate quality improvement methods to overcome identified barriers to improve care. These barriers include, but are not limited to, identifying clinical and treatment related factors, patient-related psychosocial factors and healthcare system or technological related barriers.

Surgically unresectable metastatic bladder cancer remains largely incurable, with few patients surviving more than two years. Real-world studies suggest that 40%-65% of bladder cancer patients are not receiving front-line therapy and, many that do, are not offered second-line or subsequent therapies despite the benefits of survival with these treatments. Less than 40% of patients receive platinum-containing chemotherapy although they meet the eligibility criteria for this therapy.²

Despite the development of maintenance therapy, agents with improved toxicity profiles, and the approval of frontline immunotherapy, many patients are still unable to access these treatments. One reason is that the patient population is predominantly geriatric with co-morbid conditions who are unable to tolerate the toxicity of, or are ineligible for, currently available standard treatments. In addition, the implementation of technology for accessing medical care through devices may be challenging for this population. Other reasons include socioeconomic factors, including minorities, and those in zip codes which are health care deserts who may find access to standard treatments and clinical trials challenging.^{3,4} Education of clinical teams, patients, caregivers, and healthcare systems is needed to improve the implementation of available, and recommended treatment options, in order to support guideline concordant care.⁴ Furthermore, best practices to improve the quality of care may include the use of pathways, navigation, expert care review, real-time guidance, shared-decision making, care planning workflows, and patient reported outcomes (PROs).

3. Eligibility

Geographic Scope:	United States
Eligibility Criteria:	<ul style="list-style-type: none">• Academic and Community Centers (Principal Investigators from Academic Centers are encouraged to include a co-investigator from the community)• Patient Advocacy Groups• Open to any type of care delivery system with the exception of small, physician-owned group practices• Health care professional organizations and other organizations with a mission related to health care improvement
Eligibility Criteria: (Continued)	<ul style="list-style-type: none">• Health technology companies must partner with a health care delivery organization and the health care delivery organization must be the lead applicant

4. Proposals

This RFP model employs a single step process in which all applicants submit a full detailed proposal. This model will not require a letter of intent.

Researchers seeking funding for therapeutic clinical trials projects will not be considered under this RFP.

The NCCN Request for Proposals Development Team (RFPDT) has been formed to oversee this process and will utilize a formalized review procedure to accept applications and subsequently select the proposals of highest scientific merit. The NCCN RFPDT has overseen the development of the RFP and will perform the peer review of applications.

5. Requirements

Date RFP Issued:	July 13, 2022
Clinical Area:	Locally Advanced or Metastatic Bladder Cancer (stage IV) as defined previously above.
Areas of Interest for this RFP:	The intent of this Request for Proposal (RFP) is to support Quality Improvement initiatives that will advance the quality of patient care, including NCCN Guideline concordance care, and best practices around treatment related Metastatic (Stage IV) or Locally Advanced Bladder Cancers.

Areas of Interest for this RFP:

Proposals in the following topic areas are strongly encouraged:

- Optimizing how selection of first-line therapy is determined, including assessment of platinum eligibility and fitness for front-line systemic therapies.
- Addressing barriers to initiating systemic therapy, including reasons for patients to be recommended hospice as initial therapy choice and not receiving later lines of therapy.
- Addressing barriers, challenges, and opportunities in establishing and delivering guideline-concordant care, including differences in resources between academic and community practice settings and considerations of disease-specific guidelines and supportive care guidelines.
- Equity and access to care, including disparities arising from practice setting (i.e. academic versus community, rural versus urban) and demographics (i.e. race, age, gender, etc.).
- Patient-facing navigational support tools to improve access to care and to empower patients in care planning and decision making, including available patient resources, education, and support tools, as well as, mechanisms for dissemination of information to patients and caregivers.
- The role of interdisciplinary care in optimizing care coordination and guideline-concordant care, including the role of advanced practice providers and allied health professionals in care.
- Supportive care and educational needs related to improving treatment decision making and receipt of guideline-concordant care.
- Ways practice setting and care team characteristics influence patient decision making.
- Ways to increase enrollment and retention in Clinical Trials with a particular focus on under-represented populations.
- Innovative approaches to promote effective communication between members across the care continuum (e.g., decision-making, care planning, and/or patient monitoring). This includes community health workers, social needs navigators, or other means, that connect patients to community-based organizations and resources (especially in practices serving low-income and/or socially vulnerable patient populations).
- Novel technology solutions to improve the care of bladder cancer patients.

<p>Areas NOT of Interest for this RFP:</p>	<p>Proposals in the following topic areas will be considered out-of-scope for this RFP:</p> <ul style="list-style-type: none"> • Proposals addressing only earlier stage bladder cancer, non-muscle invasive bladder cancer (NMIBC) and/or muscle invasive bladder cancer (MIBC) will not be considered. • Clinical trials investigation new drug entities. • Clinical trials comparing drug entities. • Proposals outside of the United States.
<p>Target Audience for the QI initiatives:</p>	<ul style="list-style-type: none"> • Practicing HCPs and researchers in the United States. • Patients with Advanced or Metastatic Bladder Cancer and their caregivers.
<p>Expected Approximate Monetary Range of Grant Applications:</p>	<ul style="list-style-type: none"> • There is at least \$300,000 available for funding of all projects. • The intent is to fund individual projects capped at \$150,000 (direct and indirect costs) although smaller, lower-costs projects are encouraged. Funding greater than \$150,000 will be considered for exceptional proposals with detailed budget justification. • The maximum indirect (overhead) rate is 28% and must be included in the total grant request amount. • Applicants are required to disclose additional sources of funding for this project and demonstrate that funding does not overlap. • The decision relative to funding is deferred to the members of the Scientific Review Committee (SRC) as chosen by NCCN and independent of Pfizer and EMD Serono.
<p>Key Dates:</p>	<ul style="list-style-type: none"> • RFP release date: July 13, 2022 • Full Proposal Submission Deadline: August 18, 2022 • Anticipated Grant Award Notification Date: September 29, 2022 • Grants will be distributed in-full following execution of a Letter of Agreement and documentation of an IRB approval or waiver. • Period of Performance: January 2023 to December 2025 (projects may be shorter; 2-year project maximum)
<p>Questions:</p>	<ul style="list-style-type: none"> • If you have questions regarding this RFP, please direct them in writing to Nicole Zion, NCCN Clinical Research Manager, at Zion@nccn.org or Pfizer’s Grant Officer, Amanda Kaczerski at Amanda.Kaczerski@pfizer.com with the subject line “July NCCN Pfizer EMD Serono Bladder Cancer Quality Initiative”.

<p>How to Submit:</p>	<ul style="list-style-type: none"> • Please go to https://www.cybergrants.com/pfizer/QI and sign in. First-time users should click “REGISTER NOW”. • Select the following Competitive Grant Program Name: 2022 Onc US – NCCN Pfizer EMD Serono July Metastatic Bladder Quality Initiative • Select the following Area of Interest: Oncology – Genitourinary • Requirements for submission: <ul style="list-style-type: none"> • Complete all required sections of the online application referring to the guide included in the Appendix. • If you encounter any technical difficulties with the website, please click the “Need Support?” link at the bottom of the page. • IMPORTANT: Be advised applications submitted through the wrong application type and/or submitted after the due date will not be reviewed by the committee.
<p>Review and Approval Process:</p>	<ul style="list-style-type: none"> • An NCCN Request for Proposals Development Team (RFPDT) has been formed to oversee this process and will utilize a formalized review procedure to select the proposals of highest scientific merit. The NCCN RFPDT oversaw the development of this RFP and will perform the peer review of applications. All reviews, evaluations and award decisions are independent of Pfizer and EMD Serono.
<p>Mechanism by which Applicants will be Notified:</p>	<ul style="list-style-type: none"> • All applicants will be notified via email by the dates noted above. • Applicants may be asked for additional clarification during the review period.

6. Terms and Conditions

1. This RFP does not commit Pfizer, EMD Serono or their partners to award a grant or a grant of any particular size if one is awarded, nor to pay any costs incurred in the preparation of a response to this request.
2. If your grant is approved, your institution will be required to enter into a written grant agreement with Pfizer and EMD Serono. Please [click here](#) to view the core terms of the agreement. These terms have been drafted 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.
3. This RFP does not provide permission and license for the use (including the creation of derivative products) of the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for commercial use. Grant recipients will need to maintain a separate end-user or other license agreement directly with NCCN for use of the NCCN Guidelines.

7. Submission Requirements

Applications will be accepted via the online portal. Full Proposal documents should be no longer than 10-15 pages in length (12-point font and 1-inch margins) excluding Organization Detail and References.

When uploading your Full Proposal please ensure it addresses the following*:

Goals and Objectives	<p>Briefly state the overall goal of the project. Describe how this goal aligns with the focus of the RFP and the goals of the applicant organization(s).</p> <p>List the <i>overall</i> objectives you plan to meet with your project both in terms of learning 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.</p>
Assessment of Need for the Project and Preliminary Data	<p>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 <i>your</i> 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.</p>
Target Audience	<p>Describe the primary audience(s) targeted for this project. 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.</p>
Project Design and Methods	<p>Describe the planned project and the way it addresses the established need.</p> <p>If your methods include educational activities, please describe succinctly the topic(s) and format of those activities.</p>
Innovation	<p>Explain what measures you have taken to assure that this project idea is original and does not duplicate other projects or materials already developed.</p> <p>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.</p>
Evaluation and Outcomes	<p>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.</p> <p>Quantify the amount of change expected from this project in terms of your target audience.</p> <p>Describe how the project outcomes will be broadly disseminated.</p>

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 (Environment and Mentors)	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 from partner organizations are required to be submitted with the full proposal.
Budget Detail	<p>The budget amount requested must be in U.S. dollars (USD).</p> <p>While estimating your budget please keep the following items in mind:</p> <p style="padding-left: 40px;">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.</p> <p style="padding-left: 40px;">The inclusion of these costs cannot cause the amount requested to exceed the budget limit set forth in the RFP.</p> <p style="padding-left: 40px;">It should be noted that grants awarded through GMG cannot be used to purchase therapeutic agents (prescription or non-prescription).</p> <p>Pfizer maintains a company-wide, maximum allowed overhead rate of 28% for independent studies and projects.</p>

8. References

1. NCCN Guidelines Version 2.2022 Bladder Cancer 5/20/22 © 2022 National Comprehensive Cancer Network® (NCCN®)
2. D. Geynisman, E. Broughton, Yi Hao, et al. Real-world treatment patterns and clinical outcomes among patients with advanced urothelial carcinoma in the United States. *Urologic Oncology: Seminars and Original Investigations*, 2021, ISSN 1078-1439.
<https://doi.org/10.1016/j.urolonc.2021.11.014>
3. I. Iyer, S. Zhang, H. Born. Evaluating therapeutic bladder cancer trial disparities in race/ethnicity. *Journal of Clinical Oncology* 2022 40:6_suppl, 446-446
4. J. Vehawn, M. Choudry, T. Hunt, et al.; Urban families ameliorate rural genitourinary cancer disparities; *Journal of Clinical Oncology* 2022 40:6_suppl, 25-25
5. M. Bierbaum, F. Rapport, G. Arnolda, et al. Clinicians' attitudes and perceived barriers and facilitators to cancer treatment clinical practice guideline adherence: a systematic review of qualitative and quantitative literature. *Implementation Sci* 15, 39 (2020).
<https://doi.org/10.1186/s13012-020-00991-3>