Pfizer Quality Improvement Request for Proposals *Optimizing Care for patients with locally advanced or metastatic Urothelial Carcinoma (la/mUC)*

Competitive Grant Program – using an Expert Review Panel

Overview

This competitive grant offering seeks to optimize the care of patients with locally advanced or metastatic Urothelial Carcinoma (la/mUC).

Geographic Scope/Location of Project

Canada

Project Types and Area of Interest

This RFP seeks solutions for the optimization of care of patients with locally advanced or metastatic Urothelial Carcinoma (la/mUC). Ideally, these projects will have short-term impact, aiming at closing significant care gaps in 1L la/mUC, have the ability to benefit community clinical practices, and/or involve multi-institution collaborations. This may include, but is not limited to:

- Solutions for improving the early identification and/or management of Adverse Events (AEs) in 1L la/mUC (with priority given to neuropathy and skin reactions)
- Solutions for improving 1L la/mUC treatment in hard-to-treat populations
- Solutions for optimizing the delivery of 1L la/mUC treatment
- Solutions for managing patients who have an excellent response to 1L la/mUC treatment

Key Milestones

- Application submission deadline: March 20, 2025
- Anticipated decision notification date: May 8, 2025
- Anticipated project start date: September 2025

Funding Range

\$

The total available budget related to this RFP is \$200,000 (CAD).

Individual projects requesting up to a maximum of \$100,000 (CAD) will be considered.



I. Eligibility

Geographic Scope/Location of Project:

• Canada

Applicant Eligibility Criteria

- The following may apply: medical, dental, nursing, allied health, and/or pharmacy professional schools; healthcare institutions (both large and small); professional organizations; government agencies; and other entities with a mission related to healthcare improvement.
- Only organizations are eligible to receive grants, not individuals or medical practice groups (i.e., a medical practice group includes any group of individual physicians who are not affiliated with a hospital, academic institution, or professional society).
- Collaborations within institutions (e.g., between departments and/or inter-professional), as well as between different institutions / organizations / 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/Principal Investigator (PI) or an authorized designee of such individual (e.g., Project Lead/PI's grant/research coordinator).
- The Project Lead/PI must be an employee or contractor of the requesting organization.
- Requesting organization must be legally able to receive award funding directly from Pfizer International, LLC. 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 International, LLC be subject to rescission.

II. Requirements

Date RFP Issued

• 7 January 2025

Clinical Area

• Oncology - Genitourinary - Bladder

Specific Area of Interest for this RFP:

- It is our intent to support projects that focus on quality improvement and not research. For more information, please refer to "About Pfizer Quality Improvement Grants" below.
- Multi-disciplinary collaborations, are encouraged when appropriate, but all partners must have a relevant role.
- There is a considerable amount of interest in receiving responses from projects that utilize system-based changes. Although educational efforts for health care professionals and patients may be entirely appropriate components in responses to this RFP, projects that include an overt description of system changes will be given high priority.

It is not our intent to support clinical research projects. Projects evaluating the efficacy of therapeutic or diagnostic agents will not be considered.

Target Audience

• Medical oncologists, urologists, nurses, dermatologists, neurologists, other specialists, and all healthcare professionals involved in the care of patients with bladder cancer.



Disease Burden Overview

Bladder cancer ranks as the fifth most common cancer in Canada. It is estimated that in 2024, 12,300 Canadians will be diagnosed with bladder cancer and 2,600 Canadians will die from bladder cancer (Canadian Cancer Society. Canadian Cancer Statistics 2024). At diagnosis, 70% of patients will have non-muscle invasive disease (NMIBC), 25% muscle-invasive disease (MIBC), and 5% will have locally advanced or metastatic Urothelial Carcinoma (la/mUC). Treatment outcomes for UC remain suboptimal. (Stecca CE, Chowdhury D, Blais N, et al. Can Urol Assoc J 2024;18(12):379-90).

A Canadian retrospective real-world study of patients with de novo unresectable la/mUC in Alberta reported that many patients were not referred to a medical oncologist, and the large majority of patients (65.0%) did not receive any first-line systemic therapy, and among those that did, less than half received subsequent second-line therapy (Alimohamed et al. Curr. Oncol. 2022, 29, 7587–7597). The treatment of la/mUC is associated with many other challenges and represents an important area for care improvement.

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 \$200,000.
- 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 proposal and costs involved and will be stated clearly in the grant agreement.

Key Dates:

- RFP Release Date: January 7, 2025
- Full Proposal Due Date: March 20, 2025
 - Please note the deadline is 23:59 Eastern Standard Time (e.g., New York, GMT -5).
- Review of Full Proposals by ERP: April 2025
- Anticipated Full Proposal Notification Date: May 8, 2025
- 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 <u>www.cybergrants.com/pfizer/QI</u> 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 Quality Improvement Application" button.
- In the application:
 - For the question "Competitive Grant?" select Yes
 - Select the following Competitive Grant Program Name: 2025 ONC CAN QI Bladder
 - Select the following Primary Area of Interest: Oncology Genitourinary QI
- Requirements for submission:

Complete all required sections of the online application and upload your project proposal (see Appendix) 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.



Questions:

• If you have questions regarding this RFP, please direct them in writing to the Grant Officer, Lori Carpenter, (<u>lori.carpenter@pfizer.com</u>), with the subject line "2025 ONC CAN QI Bladder".

Grant Agreements:

- If your grant is approved, your institution will be required to enter into a written grant agreement with Pfizer. Please click <u>here</u> 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.
- This RFP is supported by Pfizer International, LLC.

Review and Approval Process

- A specific grant program RFP uses 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

- Canadian Cancer Society. Canadian Cancer Statistics 2024. https://cancer.ca/en/research/cancer-statistics
- Stecca CE, Chowdhury D, Blais N, et al. 2024 CUA-GUMOC Expert Report: Management of unresectable locally advanced and metastatic urothelial carcinoma. Can Urol Assoc J 2024;18(12):379-90
- Alimohamed, N.; Grewal, S.; Wirtz, H.S.; Hepp, Z.; Sauvageau, S.; Boyne, D.J.; Brenner, D.R.; Cheung, W.Y.; Jarada, T.N. Understanding Treatment Patterns and Outcomes among Patients with De Novo Unresectable Locally Advanced or Metastatic Urothelial Cancer: A Population-Level Retrospective Analysis from Alberta, Canada. Curr. Oncol. 2022, 29, 7587–7597

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 Request for Proposal (RFP) that provides detail regarding a specific 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 specific gaps in practice as outlined in the specific RFP.

For all quality improvement grants, the grant requester (and ultimately the grantee) is responsible for the design, implementation, and conduct of the independent initiative supported by the grant. Pfizer must not be involved in any aspect of project development, nor the conduct or monitoring of the quality improvement program.

About Pfizer Quality Improvement Projects

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^{1,2}. 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)³.

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 done⁴. 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 setting⁵. The risk of participation in QI is the same as the risk of receiving standard clinical care⁶ 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 question⁴. 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 studied⁶.

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. 2006.



Appendix

Specific RFP Submission Requirements

Applications will be accepted via the online portal listed in the How to Submit section. Project Proposals/Protocols should be single-spaced using Calibri 12-point font and 1-inch margins. Note there is a 15-page limit exclusive of references. When uploading your Full Proposal please ensure it addresses the following sections:

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 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.

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.

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.
- If your methods include educational activities, please describe succinctly the topic(s) and format of those activities.

Innovation

- Explain what measures you have taken to assure that this project idea is original and does not duplicate other projects or materials already developed.
- 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

- 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.

Budget Detail

- The budget amount requested must be in CAD dollars (\$ CAD).
- While estimating your budget please keep the following items in mind:
 - 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 GMG 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 <u>click here</u> for details.

