Quality Improvement Project: Improving the Care of Patients with Metastatic Breast Cancer (mBC) Through Innovative Strategies

Request for Proposals (RFP)

Date Issued: April 21, 2025

1.0 Purpose

The National Comprehensive Cancer Network® and Pfizer Global Medical Grants & Partnerships (Pfizer) are collaborating to offer a new grant opportunity seeking proposals for quality improvement initiatives and implementation to improve the care of patients with metastatic Breast Cancer (mBC). Pfizer (hereafter, "Grantor") is providing $1.5 Million in funding to support quality improvement projects to advance healthcare quality, the delivery of quality care, and sustainably improve healthcare provider performance in the care of patients with mBC. The Grantor will serve as the funding organization. Grants are only available to healthcare providers from institutions within the United States. ***All community and academic-based programs, regardless of NCCN affiliation, are eligible and encouraged to apply.***

2.0 Organization Information

National Comprehensive Cancer Network

The National Comprehensive Cancer Network® (NCCN®) is a not-for-profit alliance of 33 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 & Partnerships

Pfizer Global Medical Grants & Partnerships (GMGP) 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.

This RFP is being issued by both organizations. NCCN is the lead organization for the review and evaluation of proposals. An External Review Committee (ERC), 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.**

For all grants, the grant requester (and ultimately the grantee) is responsible for the design, implementation, sponsorship and conduct of the independent initiative supported by the grant, including compliance with any regulatory requirements. NCCN and Pfizer

must not be involved in any aspect of project development, nor the conduct or monitoring of the project.

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. Processes include 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 done[4]. 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[5]. The risk of participation in QI is the same as the risk of receiving standard clinical care[6] 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[4]. 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[6].

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 INSTIUTIONAL 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.

3.0 Background

In the United States, 6-10% of women who are diagnosed with breast cancer present with de novo metastatic disease; nearly 30% of those diagnosed with early-stage breast cancer will later go on to develop metastatic disease.[1] Progression-free and overall survival have steadily improved due to therapeutic advances, including chemotherapy, immunotherapy, targeted therapy, and antibody-drug conjugates. However, survival from mBC continues to vary greatly depending on factors like tumor biology, treatment response, and access to high-quality, guideline-concordant care.

The overall aim of this RFP is to develop innovative, impactful, scalable, and sustainable quality improvement projects to advance the delivery of quality care to people with mBC. This will allow:

1. Better understanding of the impact of treatments and treatment decision making, including clinical trials;
2. Enhanced healthcare provider performance including guideline concordance;

3. Expanded accessibility and availability of supportive resources as it relates to both physical and emotional functioning; and
4. Mitigation of the impact of non-medical factors (i.e., health-related social needs [HRSN] or social determinants of health [SDOH]) on the delivery of quality care to cancer patients with mBC.

Proposals submitted in response to this RFP should guide the development of processes that will improve the delivery of comprehensive quality care and/or the patient experience for those with mBC. Priority will be given to projects that address quality gaps in the delivery of healthcare for patients with mBC that have not been sufficiently addressed. Projects that include a plan for broad applicability to all patient populations (e.g., under-represented, underserved, remote, or rural) and sustainability beyond the funding period will be given higher priority.

4.0 Aims and Eligibility

Aim:	To advance the delivery of quality care and/or healthcare provider performance that will lead to the improvement in the overall care of all patients with mBC.
Geographic Scope:	United States
Eligibility Criteria: *Investigators from the following organizations may apply*	• US community and academic institutions (including NCCN and non-NCCN Member Institutions). • Health care professional organizations and other organizations related to health care improvement. • Collaborations should foster the collaborative or multidirectional sharing of knowledge and expertise as well as utilize the combined clinical strengths of members. • This can also include cross-institutional collaboration for the conduct of quality improvement initiatives. • Health care delivery organizations must serve as the lead applicant, if partnered with health technology companies.
Additional Eligibility Information:	• Collaboration among academic health care centers and/or community health centers and community organizations is strongly encouraged to foster interactive sharing of knowledge and expertise, and to utilize the combined strengths of the collaborating organizations. • Junior faculty (i.e., Assistant Professors and below) are encouraged to apply. • Trainees may participate as a sub-investigator under appropriate mentorship from a PI.

5.0 Letters of Intent (LOI)

This RFP model employs a 2-stage process: Stage 1 is the submission of a LOI (see Section 8). If a LOI is selected, the applicant will be invited to Stage 2 and will submit a full program proposal into Pfizer's web-based system (additional information for full proposal submission will be provided at the time of notification).

6.0 Requirements

Clinical Area:	Metastatic Breast Cancer (mBC)
Target Audience:	Key stakeholders in mBC care (including, but not limited to, medical oncologists, radiation oncologists, supportive oncology providers [PCPs, psychologists, palliative care, etc.], and allied health care providers [APPs, social workers, nurse navigators, etc.]).
Funding Considerations:	• A total of $1.5 Million is available to fund all projects. • There is a funding cap of $250,000 per project. • Exceptional proposals with multiple significant collaborating organizations and the potential for wide expansion beyond a single health system may request additional funding above the $250,000 cap. • Smaller, lower-cost projects are encouraged. • All budgets must include line-item information and a robust justification. • Overhead (indirect cost) rates of up to 28% of the total proposed project budget are allowed and *must be included in the total requested amount.* • Costs associated with publication of a manuscript and/or travel to present the results of the project at a national meeting will be given consideration for support. • Applicants are required to disclose additional sources of funding for the proposed project and demonstrate that funding does not overlap. • Funding decisions are deferred to the members of the external review committee as chosen by NCCN and are independent of Grantor.
Areas of interest/emphasis:	Areas of interest include but are not limited to: • Facilitation of NCCN guideline concordant care for all patients with mBC; • Optimization of treatment toxicity management; • Optimization of treatment adherence; • Increasing access to appropriate testing (biomarker / genetic/genomic) and relevant targeted treatment options; • Improving participation in clinical trials (e.g., increasing community enrollment, access to clinical trials, referral process); • Improving access to community support services to decrease the negative impact of social determinants of health (SDOH); • Integration of ancillary services including palliative care, primary care and supportive oncology or multi-disciplinary teams including subspecialists to co-manage the unique needs of patients with mBC;

	• Addressing (patient-clinician) cultural barriers to improve adoption of treatment recommendations; • Increasing health literacy of mBC patients to self-manage and engage in shared clinical decision making; and • Integration of the patient experience and/or the voice of patient advocates/advisory board into delivery of quality care for patients with mBC.
Areas excluded or considered out of scope:	Specific areas considered out-of-scope or excluded include: • Clinical research projects (i.e., those evaluating the efficacy of therapeutic, screening, or diagnostic agents); • Projects that focused on development of new biomarker technology/techniques; • Projects involving opioids; and • Medical Education Companies cannot be the primary applicant (can be a collaborator). **LOIs/Proposals duplicative of completed, ongoing, or planned projects will not be considered.**

Timeframes for Approved Projects:	• Commencement: no later than 3 months after notice of project approval.
	• Period of Performance: 2 years
	• Reporting/dissemination of results preferably in manuscript form: no later than 9 months after project endpoint achieved.
	  • Other acceptable forms of dissemination include, but are not limited to, an oral presentation or poster at a national conference or publication in a peer reviewed journal.
	  • Those selected for full proposal submission will be required to describe the dissemination plan in detail.
	All projects will require documentation of the feasibility of completion; projects may be multi-institutional.

Selection Criteria:	LOIs must include background information, needs assessment, objectives, target audience, project design and methods, evaluation and outcomes, sustainability plan, organizational details and requested funding amount. Proposals will be judged based on the following criteria: • Strategic Alignment to RFP • Innovation/Uniqueness • Methodology • Organizational Capability • Approach/Feasibility • Sustainability The GRANTOR can reject any project with safety or compliance issues.

Key Dates:	• RFP release date: April 21, 2025 • **LOI submission deadline**: June 9, 2025 • LOI notification date: July 21, 2025 • **Proposal submission deadline**: September 2, 2025 • Anticipated grant award notification date: End of October 2025 (**Please note that the submission deadline is 5:00 PM Eastern**)
Questions:	If you have questions regarding this RFP, please direct them in writing to Nicole Zion, Senior Clinical Research Manager, at zion@nccn.org and Lori Carpenter, Grant Officer, Pfizer lori.carpenter@pfizer.com with the subject **"NCCN Pfizer mBC RFP"**.

How to Submit:	• Please go to www.cybergrants.com/pfizer/loi and sign in. First-time users should click "REGISTER NOW".
	• Select the following Competitive Grant Program Name: **2025 ONC US NCCN QI mBC RFP**
	• Select the following Area of Interest: **Oncology - Breast - LOI**
	• Requirements for submission:
	  • 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.

Review and Approval Process:	An NCCN Request for Proposals Development Team (RFPDT) was formed to oversee this process and will utilize a formalized review procedure to select the proposals of highest clinical relevance and chance of success at improving quality healthcare. 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 Grantor.
Mechanism by which Applicants will be Notified:	• All applicants will be notified via email by the date noted above. • Applicants may be asked for additional clarification during the review period.

7.0 Terms and Conditions

1. This RFP does not commit Pfizer, 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. 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®) or the NCCN Biomarkers Compendium 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 or Biomarkers Compendium.

8.0 LOI Submission Requirements

The 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. 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 and Preliminary Data	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. 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 for patients with mBC. 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. Describe how the project could be sustained beyond the grant end date.
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 **(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 will be required at the Full Proposal stage only and should not be included with the LOI.
Budget Detail	The 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: • 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

Budget Detail (continued)	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 therapeutic agents (prescription or non-prescription). Pfizer maintains a company-wide, maximum allowed overhead rate of 28% for independent projects.

9.0 References

1. Wang R, Zhu Y, Liu X, Liao X, He J, Niu L. The Clinicopathological features and survival outcomes of patients with different metastatic sites in stage IV breast cancer. BMC Cancer. 2019 Nov 12;19(1):1091.

2. Mertz S, Benjamin C, Girvalaki C, Cardone A, Gono P, May SG, Comerford E, Than KS, Birch K, Roach M, Myers S, Sasane M, Lavi L, Cameron A, Cardoso F. Progression-free survival and quality of life in metastatic breast cancer: The patient perspective. Breast. 2022 Oct;65:84-90.

3. Jacobsen PB, Davis K, Cella D. Assessing quality of life in research and clinical practice. Oncology (Williston Park). 2002 Sep;16(9 Suppl 10):133-9.