



Enhancing Academic-Community-Patient Partnerships in Metastatic Breast Cancer Care Request for Proposals (RFP)

I. Introduction

National Comprehensive Cancer Network® (NCCN) and Pfizer Global Medical Grants (Pfizer) are collaborating to offer a new grant opportunity for improving care for patients with metastatic breast cancer (MBC). Management goals in this situation focus on improving quality and length of life as there is, to date, no known cure.

The intent of this RFP is to encourage investigators at NCCN Member Institutions to submit proposals describing concepts for developing best practices and collaborative oncology care models between academic centers and referring community providers. The overarching goal is to leverage the expertise and resources of NCCN-designated cancer centers to improve quality and outcomes across the continuum of care for all MBC patients.

The majority of cancer patients in the United States are cared for in community settings. Community oncologists have considerable experience and can provide patients who have a non-curable (life-threatening) illness with the convenience and quality of life benefit of potentially having care closer to home with a skilled provider. Oncologists in academic cancer centers may provide a deeper level of disease-specific expertise and access to a wider selection of clinical trials than their community clinic colleagues. The current model in the U.S. generally results in three groups of patients:

- those cared for exclusively in community-based practices,
- those cared for exclusively in academic practices, and
- those who are cared for in the community with ad hoc consultations in academic cancer cancers.

Only a small proportion of patients in the U.S. are cared for primarily within academic breast centers; this has limited and slowed the diffusion of disease-specific expertise. Furthermore, though clinical trials in general may be discussed, most patients in the community are not offered participation in a specific clinical trial, due in part to gaps in trial awareness on the part of both community-based physicians and MBC patients. Most early-phase and many later-phase clinical trials are limited to selected study sites, often academic sites. Combined, these factors adversely affect clinical trial accrual and clinical-translational research. Structural barriers exist in the interactions between academic and community-based providers, and this may hamper efforts to deliver collaborative care. There is frequently a lack of well-developed infrastructure to support collaboration between these two settings—leading patients to feel they must choose to be seen exclusively in either the community or

academic setting. From a clinical trial perspective, patients are also frequently not seen at optimal times to support potential trial eligibility.

In addition, ad hoc consultations in academic practices are of variable utility because robust tracking and communication systems typically do not exist to maximize the value of academic-community partnerships. Moreover, as academic cancer centers target the growth and expansion in the community through network and satellite development, the need for enhanced educational support and communication across these settings becomes more apparent. Harnessing the combined strengths of these two settings, together with patient empowerment through enhanced educational opportunities and supportive care resources, has the potential to transform the delivery of care to patients with metastatic breast cancer, and if successful, be translated to other cancer types.

NCCN is a not-for-profit alliance of 28 leading cancer centers devoted to patient care, research, and education. NCCN is dedicated to improving and facilitating quality, effective, efficient, and accessible 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.

The mission of Pfizer Global Medical Grants is to accelerate the translation of science into quality patient care through independent grants, partnerships, and collaborations. Pfizer Global Medical Grants 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 Request for Proposals (RFP) is issued by NCCN. The NCCN Peer Review of Proposals Committee (PRPC) has been formed to oversee this process and will utilize a formalized review procedure to select the proposals of highest scientific merit. Funding will be provided to successful applicants by NCCN through a grant provided by Pfizer. Funding is available only to applicants from NCCN Member Institutions.

II. Background

In 2015, the EMBRACE (Ending Metastatic Breast Cancer for Everyone) program at the Dana-Farber Cancer Institute's Susan F. Smith Women's Cancer Center, was funded by a Pfizer grant through a partner-RFP with the NCCN. The program was designed to implement a comprehensive program that combines clinical care, clinical research, physician engagement and patient education to optimize the care of MBC patients. More specifically, the aims of the program are as follows:

- enhance longitudinal care of MBC patients through support of the health care providers;
- develop a robust, seamless, collaborative care model between the referring provider and our academic center; and
- enhance the quality of life and satisfaction with care and to facilitate shared decision making among patients with MBC, with a combination of personalized follow-up, educational programs and supportive care programs.

The EMBRACE program developed a consistent intake process and follow-up approach for MBC patients who were seen at least once in the clinic. A key component of the approach is the EMBRACE coordinator who meets with each MBC patient at the first clinic visit to review the clinical program, to introduce available educational and supportive resources, and to assist and support the medical oncologist in identifying, approaching, and consenting patients for potential clinical trials and/or research studies. A coordinator then supports the cancer center's medical oncologist and follows a discrete patient panel longitudinally for whom they are responsible for the following tasks:

- facilitating referrals for supportive care resources,
- identifying potential candidates for trial prescreening,
- coordinating tissue requests for molecular testing
- tracking availability of results from molecular testing for clinical trial matching,
- facilitating communication between the cancer center's medical oncologist and referring provider post-consultation and when tumor testing results are available,
- identifying potential clinical trials that a patient may be eligible at time of progression based on subtype, presence of genomic mutations and other biomarkers, and previous lines of therapy, and
- organizing re-consultation visits when clinically appropriate.

To support the EMBRACE coordinator, the program successfully established a robust tracking system and standard templates to allow for consistent updates on return of results to the medical oncologist and referring provider and to support accurate clinical trial matching at a patient's time of progression.

In addition, several patient-facing components have been incorporated, including: bi-annual print newsletters, quarterly webcasts, quarterly electronic newsletters, and an annual educational forum for patients and their caregivers.

Since its inception in 2016, this multi-pronged effort from provider, patient, and system perspective has become fully integrated in today's clinic and the program has made a tangible improvement in the care of patients with metastatic breast cancer. Over 2,000 patients are currently participating in the program, and are followed by a total of 4 EMBRACE coordinators. The current program is the result of many iterations and incremental improvements that are uniquely tailored to the characteristics and culture of a specific cancer center. While the program has solely been based in one cancer center, it is believed that components of the EMBRACE program have the potential for impact beyond the current institution where it is implemented and ultimately can serve as a model for enhanced academic-community patient partnership.

Additional information regarding the EMBRACE can be found on Dana Farber's website at <https://www.dana-farber.org/metastatic-breast-cancer-program/support-and-education/> or on NCCN's site at www.nccn.org/clinical_trials/clinicians.aspx.

It is important to note that the purpose of this RFP is not necessarily to duplicate, but to build upon the components of such a program like EMBRACE. Each institution and region has unique strengths and challenges. The intention is for the RFP to build a network of participating institutions that share similar goals to improve the model for enhanced academic-community-patient partnerships in the context of metastatic breast cancer care where the network can share best practices on a common platform.

III. Scope

The overall aim of this RFP is to develop programs to improve the model for enhanced academic-community-patient partnerships in the context of metastatic breast cancer care. Results from projects funded should be quickly disseminated to other practices and settings to rapidly improve delivery of cancer care.

Successful applicants will be able to describe the specific clinical practice gaps that exist for their own providers, health care system, or patient community and describe what they will do to close these gaps or problems. Site-specific obstacles to success should be identified and coupled with strategies to overcome the obstacles.

Programs must describe how the intervention, when implemented, will directly affect patient care and provide evidence of scalability (e.g., integration with an electronic medical record system), sustainability (e.g., plan for dissemination/applicability beyond the proposed institution), and can be completed within the timeframe specified.

This RFP is open to investigators from NCCN Member Institutions. Collaboration between NCCN Member Institutions is strongly encouraged in order to foster the interactive sharing of knowledge and expertise, and to utilize the combined strengths of members. Although the submitting applicant must be from an NCCN Member Institution, additional participating institutions do not need to be NCCN Member Institutions.

Only projects specific to the care of metastatic breast cancer patients will be considered for funding.

The areas of emphasis identified for this RFP include the following:

Concepts can focus on gaps in clinical practice related to:

- **Provider factors examples:** level of knowledge of the most recent advances and standard of care in metastatic breast cancer treatment; level of knowledge regarding clinical trial opportunities; barriers to molecular testing and screening and understanding return of results of patients for marker-specific clinical trials; access to symptom/pain management/palliative care at the optimal time. Proposals that focus on provider factors must include both academic and community-based providers.
- **Patient factors examples:** level of knowledge of metastatic breast cancer and its treatment options; potential clinical trial options; access and use of genetic counseling and supportive oncology at the optimal time, and caregiver knowledge, education, and support.
- **System factors examples:** coordination between academic and community-based providers, including but not limited to: expedited consultations, appropriate timing of re-consultations, enhanced longitudinal communication, clinical trial screening and matching, and enhanced infrastructure for collaborative care (e.g. tracking systems, coordinator/navigator, information technology, telemedicine, remote tumor boards) to support optimal communication, collaboration, and sharing of knowledge on standard treatment and trial options between NCCN center and referring providers.

Successful proposals will target a gap or combination of gaps in clinical practice that simultaneously address a combination of provider, patient and/or system factors.

Areas of particular interest include:

- Leveraging the expertise of NCCN Member institutions to improve care in the surrounding region
- Enhancing clinical trial awareness, including clinical trial matching to patients seen in the community setting
- Identifying potential candidates for trial prescreening (for example, PDL1 testing as part of a clinical trial consent, which could occur ahead of tumor progression),
- Tracking and understanding the availability of results from molecular testing for clinical trial matching,
- Facilitating communication between the cancer center's medical oncologist and referring provider post-consultation and when tumor testing results are available,
- Identifying potential clinical trials that a patient may be eligible at time of progression based on subtype, presence of genomic mutations or other alterations, and previous lines of therapy, and
- Organizing re-consultation visits when clinically appropriate, and
- Facilitating referrals to supportive care resources and providing updates on educational events for patients and referring providers.

Efforts to address these areas of particular interest through improvement in infrastructure and systems/processes to support communication and team work between academic oncologists and referring providers (including not limited to those within the cancer center's network of providers and satellites) as well as the patient is key to this RFP. "Infrastructure" and systems/processes could include the following concepts (including and not limited to):

- development of standard materials (using various media and technology) for understanding what trials are available with target audience of MBC patients and referring providers.
- development of technology-enabled solutions (including software solutions) to track patients, communicate with referring physicians, and enable individualized care.
- understanding the importance of early molecular testing and screening; returning results for marker-specific clinical trials; role of symptom/pain management/palliative care at optimal time.
- development of a coordinator role to support these areas within the cancer center;
- initiation of tumor board (or other mechanisms) between academic center and referring providers to discuss potential clinical trial opportunities for shared patients;
- mechanism to encourage appropriate institution of hospice care/supportive/symptom management for early engagement for shared patients.
- development of educational and supportive care materials for patients to understand better metastatic breast cancer and its treatment options; role of clinical trials in their care; how genetic counseling and supportive oncology can be beneficial early on in their

MBC care continuum; and what types of financial counseling and family counseling are available.

These materials, media, and other infrastructure developed under this RFP might contribute to a collection of centralized materials from each institution that in turn can be shared on a common platform with the network of participating institutions.

All funded proposals must:

1. Promote evidence-based care
2. Be sustainable after the award funding is complete
3. Collect data and report outcomes
4. Have a goal to enhance clinical outcomes, patient satisfaction, or provider satisfaction
5. Be flexible enough to address patient variability
6. Promote administrative and system efficiency

In addition, proposals that are scalable, reproducible, and quickly implementable, with tangible outcomes, are preferred. Ideally, proposed projects will offer a roadmap with a short runway to launch and demonstrate the ability to stick to timelines for deliverables.

Specific exclusions from this RFP include:

1. Funding for therapeutic clinical trials
2. Funding for correlative studies from clinical trials
3. Funding for Basic science projects
4. Costs of care delivery, treatments, medications, or other direct care services
5. Travel and logistical costs, food and beverage
6. Capital equipment

V. Requirements

Date RFP Issued:	June 19, 2019
Clinical Area:	Metastatic Breast Cancer
Target Audience:	<ul style="list-style-type: none"> • Members of the health care team and administrators involved in the care of metastatic breast cancer patients at NCCN Member Institutions • Referring providers (including and not limited to the community affiliates and providers under the cancer center’s network). • Patients with metastatic breast cancer
Applicant Eligibility Criteria:	NCCN Member Institution
Expected Approximate Monetary Range of Grant Applications:	A total of \$1.4 million in funding is available; it is anticipated that 3 to 6 projects will be funded.

<p>Estimated Key Dates: update based on RFP release date</p>	<p>Proposal Deadline*: August 28, 2019 Please note the deadline is 11:59pm Eastern Time.</p> <p>Anticipated Notification Date:</p> <p>Period of Performance: Three years</p> <p>Reporting: Interim reports every three months; final report within six months of project completion</p> <p>Dissemination of Results: Within nine months of project completion</p>
<p>How to Submit to NCCN:</p>	<p>Please email proposal submission to NCCNEMBRACE@nccn.org <i>Please note that proposals are submitted directly to NCCN and no online submission is required for this RFP.</i></p> <p>IMPORTANT: Be advised proposals submitted to the wrong email address or after the due date will not be reviewed by the committee.</p>
<p>Selection Criteria:</p>	<p>Applications will be evaluated on the basis of:</p> <ul style="list-style-type: none"> • Knowledge of and experience with the area; • Comprehensive needs assessment and description of target population; • Capability of carrying out the work; • Feasibility; • Collaboration if appropriate; • Scalability and sustainability; • Potential effect and expected outcomes of the project; • Dissemination strategies and overall impact.
<p>Questions:</p>	<p>If you have questions regarding this RFP, please direct them in writing to Donna Scharff at scharff@nccn.org with the subject line “2019 Pfizer MBC Project”</p>
<p>Mechanism by which Applicants will be Notified:</p>	<p>All applicants will be notified via email by the anticipated date noted above.</p> <p>Applicants may be asked for additional clarification if needed by the PRPC.</p>

VII. Proposal Submission Guidance

Proposals must be single-spaced, using Calibri 12-point font and 1-inch margins. Note that the main section (section C, below) of the proposal has a 15-page limit and the organization detail (section E, below) has a 3-page limit. There is no reason to submit the organization detail (section E) as a separate document from the main section (section C) of the proposal. **All proposals must follow the outline detailed below.**

Proposal requirements will include the following sections:

A. Cover Page (do not exceed 1 page):

1. **Title:** Please include the project title, Grant ID number and main collaborators.

2. **Organization(s)**
3. **Principal Investigator**
4. **Abstract:** Please include an abstract summary of your proposal including the overall goal, target population, methods and assessment. Please limit this to 250 words.

B. Table of Contents (no page limit)

C. Main Section of the proposal (not to exceed 15 pages):

1. **Overall Goal & Objectives:** Describe the overall goal for this project. Describe how this goal aligns with the focus of the RFP, the goals of the applicant organizations and the proposed project. List the **key** objectives and how they are intended to address the established need for this project.
2. **Current Assessment of need in target area**
 - a. Describe the need for this project in your target area. Only include information that impacts your specific project, linking regional or local needs to those identified on the national basis if appropriate. Describe the need for your project in terms of “what is” versus “what should be”.
 - b. Please include quantitative baseline data summary, initial metrics (e.g., quality measures), or project starting point (please cite data on gap analyses or relevant patient-level data that describes the problem) 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.
3. **Target Audience:** Describe the primary audience(s) targeted for this project.
 - a. Describe the level of commitment from the potential participants including your plan for recruitment as necessary.
 - b. Demonstrate the scope of your target audience has a potential to impact the goal established in this proposal.
 - c. Describe who will directly benefit from the project outcomes. Include in this description whom, beyond the primary target, would potentially benefit from the project in terms of this being a model for others to replicate or expand.
4. **Project Design and Methods:** Describe your project design and methods.
 - a. Include a description of the overall strategy, methodology and analysis linking them to the goal of the project.
 - b. Describe the way the project planned addresses the established need and produces the desired results.
 - c. Indicate how you will determine if the target audience was fully engaged in the project.
 - d. Include a description of the measures you have taken to assure that this project idea is original and does not duplicate other projects or materials already developed.
 - e. If appropriate, show how this project builds upon existing work, pilot projects, or ongoing projects developed either by your institution or other institutions related to this project.
 - f. If your project includes the development of tools note if they would be available publically at no cost.

5. Evaluation Design

- a. In terms of the metrics used to assess the need for this project, describe how you will determine if the practice gap was addressed for the target group.
 - Identify the sources of data that you anticipate using to make the determination.
 - Describe how you expect to collect and analyze the data.
 - Describe how you will determine if the results evaluated are directly related to the intervention described in this proposal
 - b. Quantify the amount of change expected from this project in terms of your target audience (e.g., a 10% increase over baseline or a decrease in utilization from baseline between 20-40%)
 - c. Describe how you plan for the project outcomes to be broadly disseminated.
6. **Detailed Work Plan and Deliverables Schedule:** Include a narrative (which counts toward the 15-page limit) describing the work plan and outlining how the project will be implemented over the 2-year period. Using a table format (no page limit), list the deliverables and a schedule for completion of each deliverable.

D. References (no page limit)

E. Organizational Detail (not to exceed 3 pages)

1. **Organizational Capability:** Describe the attributes of the institution(s)/organization(s)/association(s) that will support and facilitate the execution of the project.
2. **Leadership and Staff Capacity:** Include the name of the person(s) responsible for this project (PI/ project lead (PL) and/or project manager). The project manager, whether a current staff member or someone to be hired, is essential to the work outlined in your proposal. Demonstrate the PI/PL and project manager's availability, commitment, and capability to plan, implement, and evaluate the proposed project; describe how the project manager will oversee the project activities, including ensuring that tasks are accomplished as planned.
 - a. List other key staff members proposed on the project (e.g., healthcare provider champion, medical advisor, statisticians, IT lead, etc.), if relevant, including their roles and expertise. Please list out key staff for each institution/organization/association the specific role that they will undertake to meet the goals of this project.
 - b. When listing staff, please include staff first name, last name, professional credentials, and Country of Residence.

F. Detailed Budget (Refer to/Complete **Budget Template**; no page limit for the Excel file or the narrative):

1. Upload a detailed budget, using the Excel template provided. Applicants are expected to customize the budget for their proposal, adding additional details and deliverables as appropriate.
2. Provide a **written narrative** that contains a detailed explanation of each cost element proposed. Budget narratives should include a justification for all personnel, indicating the percentage of time allocated to the project. The budget should demonstrate appropriate and reasonable costs for project expenses.

3. Institutional overhead and indirect costs may be included within the grant request.
 - a. The inclusion of these costs cannot cause the amount requested to exceed the budget limit set forth in the RFP.
 - b. NCCN and its Member Institutions have an agreement to include a maximum of 25% indirect costs for projects funded by NCCN.

G. Staff Biosketches (no page limit):

Applicants must provide brief biosketches of all individuals listed in section E in an appendix. NIH Biosketches are an acceptable format, but not required.

H. Letter(s) of Commitment (no page limit):

Letter(s) must be provided from all organizations listed in section E documenting their support and commitment to the project. Letters should be issued from an institutional authority or authorities and collaborators acknowledging need for proposed project, guaranteeing access, resources and personnel (as the case may be) for proposed project.

Submission: Proposals should be submitted via email to NCCNEMBRACE@nccn.org. All submissions are due by **August 28, 2019, at 11:59pm Eastern Time.**

Please adhere to the page limits listed for each section. Tables and Figures should be included in the main section of your proposal and do count to the page count. Only sample forms or other full page documents can be included as an appendix.

All required sections (aside from the budget) should be combined in one document (MS Word or Adobe PDF). There is no need to submit the organization detail or references in a document separate from the main section of the full proposal. Budgets should be submitted in a separate excel file.

VIII. Terms and Conditions

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.