Metastatic Breast Cancer (MBC)
Request for Proposals (RFP)

National Comprehensive Cancer Network (NCCN) and
Pfizer Independent Grants for Learning & Change (IGLC)

June 3, 2015

I. Background

Pfizer and the National Comprehensive Cancer Network (NCCN) are collaborating to offer a new grant opportunity focused on improving care for patients with metastatic breast cancer (MBC), where treatment goals focus on improving quality and length of life as there is, to date, no known cure. Multiple factors contribute to the complexity of treating the disease, including the rapidly changing options for personalizing treatment strategies, managing treatment and disease side effects, communicating with patients, caregivers and family members about quality of life and end-of-life decisions, as well as the many obstacles patients face when living with the disease.

Supporting health care professionals in their efforts to maintain and improve their knowledge, ability, and performance related to treating patients with MBC is critical to improving patient care. The quality of care that health care professionals provide takes place in complex systems that are often in need of analysis and modification to allow for more efficient and effective patient care. In addition, providing resources and education to patients, their caregivers, and family members is crucial to help ensure they are informed and can participate in the shared decision-making process.

The mission of Pfizer Independent Grants for Learning & Change (IGLC) is to accelerate the adoption of evidence-based innovations that align the mutual interests of patients, health care professionals, and Pfizer, through support of independent professional education activities. The term “independent” means the initiatives funded by Pfizer are the full responsibility of the recipient organization. Pfizer has no influence over any aspect of the initiatives, and only asks for reports about the results and impact of the initiatives, which it may share publicly.

NCCN, a not-for-profit alliance of twenty-six (26) of the world’s leading cancer centers, is dedicated to improving the quality and effectiveness of care provided to patients with cancer. 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. NCCN has access through its member institutions to the world’s leading thought leaders in all areas and aspects of oncology who are integral to the execution of this program.

This Request for Proposals (RFP) is being issued by both organizations. NCCN is the lead organization for review and evaluation of applications. A review committee, led by NCCN, will make decisions on which proposals will receive funding. Grant funding will be provided by Pfizer. Collectively, $2 million is available for award.

II. Purpose

The intent of the RFP is to encourage organizations to submit letters of intent (LOIs) describing concepts and ideas for design and implementation of programs that close clinical practice gaps and improve the

quality of care for patients with MBC through increased competence and performance of health care providers and health care systems.

Gaps in Clinical Practice

A gap in clinical practice is considered to be the difference between current practice and the optimal standard of care. Gaps are associated with a combination of:

- Clinician factors (e.g. knowledge, performance, preferences, reimbursement drivers);
- Patient factors (e.g. disease factors, comorbidities, preferences, Quality of Life (QOL), cost implications, work, family, etc.);
- Clinician and patient communication (e.g. end of life care, clinical trial recruitment, genetic counseling);
- Health system organization (e.g. care process, availability of all required aspects of care);
- Financial factors to the patient, provider, and the health system (e.g. formulary restrictions, economic factors impacting patients and family).

Gaps in clinical practice may relate to the ability or competencies of the health care professionals themselves, the abilities or competencies of the systems in which they work to promote or allow proper management, or other factors related to the external environment or patient population.

This RFP seeks to provide funding to projects that, ultimately, are aimed at helping health care professionals deliver the best treatment to each patient at the optimal time. Likewise, projects should describe educational interventions that provide ideal strategies for the learners to address the identified gap in practice at the proper time.

NCCN and Pfizer are committed to funding projects that:

(1) Further identify quality and performance gaps in the treatment of MBC with deeper analyses and understandings of the gaps and needs of those targeted and/or included in the intervention. These needs may include improved provider knowledge regarding pathology and mechanism of action and toxicities of treatment choices.
(2) Bring the heath care team together to understand gaps in practice and develop strategies to improve care.
(3) Facilitate health care systems and providers to engage patients, their caregivers and families in shared decision-making.
(4) Use evidence-based educational strategies that are aligned with the desired results of the intervention.

III. Needs Assessment

NCCN and Pfizer expect that funded projects will solve problems in practice for the learners that are included in the intervention. This means that needs assessment is critical to understanding “why” a gap exists. Existing data and information point to a variety of gaps in practice and learning needs, including how physicians/health care professionals:

1. Select the optimal treatment approach for patients with MBC as patients progress throughout the disease continuum. Specifically,
    a. Selecting optimal therapeutic strategies for patients with ER/PR positive MBC;
    b. Selecting optimal therapeutic strategies for patients with HER2 positive MBC who have progressed on previous therapy;

   c. Selecting optimal treatment for patients with newly diagnosed metastatic TNBC;
   d. Appropriately apply and understand genetic testing in metastatic breast cancer patients;
   e. Understanding the mechanism of action of approved or investigational therapies used for patients with MBC.
2. Personalize treatment strategies for patients with MBC based on individual patient and tumor characteristics;
3. Assess, quantify, and manage adverse effects in MBC patients;
4. Engage in effective communications with patients, their caregivers and family, especially in the context of difficult discussions such as hospice and palliative care;
5. Manage obstacles such as patient access and inadequate time as a resource;
6. Use tools for formal assessment and documentation of patient related information.

Successful proposals will build upon new and existing systems, processes and data regarding gaps and needs with detailed needs assessment of their own learners and analyses of their own processes and systems of care.

Issues and challenges related to Metastatic Breast Cancer:

In addition to the gaps in clinical care, patients face a multitude of barriers that impact both their quality of life and treatment. For example:

- Lack of or inadequate insurance may lead a patient to decline therapy;
- Limited financial resources may result in patients not adhering to recommended treatment plan. A patient's insurance plan may not cover the recommended treatment, so the patient may seek less efficacious treatments that are covered;
- Access challenges facing community patients (e.g. transportation, age, location, comorbidities);
- Awareness of possible supportive resources;
- Insurance pre-authorizations can lead to a delay in the initiation of recommended treatment.

Questions and issues to consider:

Shared Decision-Making:
Shared decision-making can play an important role in health care professionals' approach to communication with patients, their caregivers, and family members about treatment options for MBC. A 2012 Cochrane Collaborative review[1] of 115 studies involving 34,444 participants showed that when patients use decision aids they: a) were more informed and knowledgeable about treatment options, felt more informed and more clear about what mattered most to them c) had more accurate expectations of risks and d) participated more in decision-making. Decision aids also helped patients to reach decisions that were consistent with their values. Decision aids improve communication between patients and their health practitioner.

As there are many implications to each decision made to help achieve a patient's goals, it is important for patients to play a role in the decisions made about their care. The more patients can be involved in the decision, the more likely they are to maintain the recommended course of treatment. It is important

[1] Stacey D, Légaré F, Col NF et al. Decision aids to help people who are facing health treatment or screening decisions. Cochrane Database of Systematic Reviews 2014, Issue 1. Art. No.: CD001431. DOI: 10.1002/14651858.CD001431.pub4

that educational interventions for health care professionals consider the role of patient education, particularly how shared decision-making tools and strategies, can be used to help improve patient care.

End of Life Care Discussions:
There is no cure for MBC and health care professionals who treat patients with MBC inevitably face having difficult discussions regarding terminal care. Hospice and palliative care are under-utilized. Like barriers patients face, health care professionals face several challenges when confronted with the need for these difficult conversations. MBC is an unpredictable disease so end of life discussions may seem unnecessary but quickly become very relevant.

Health care professionals often struggle with questions related to hospice and palliative care, such as:

- Appropriate identification of MBC patients who would benefit;
- How to initiate the discussion regarding patient goals, expectations and end of life care without taking away hope;
- What health care professionals can do to help patients, their caregivers, and family to be more open to information about hospice and palliative care.

This RFP will also consider other issues not specified above.

IV. Letters of Intent/Proposals

This RFP model employs a 2-stage process: Stage 1 is the submission of the LOI. If an LOI is selected, the applicant will be invited to Stage 2 to submit a full program proposal into Pfizer's web-based system (see Section VI).

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.

Successful proposals will likely include a clinical education component for oncologists, a plan to assess and improve systems-of-care, plus a companion patient education strategy.

Successful proposals will include a detailed plan to generate quantitative evidence that the educational intervention has had an effect on health care professional behavior that is likely to be long-lasting and that this change in behavior is associated with changes in clinical outcomes.

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) and sustainability (e.g., plan for dissemination/applicability beyond the proposed institution).

Pfizer and NCCN are particularly vested in supporting programs that:

(1) Develop and implement interventions that are followed by rigorous assessment of the efficacy of the program;
(2) Examine outcomes that may include short- and long-term improvements in physician effectiveness and patient care;
(3) Involve partnering and collaboration between multiple departments or with other organizations.

Pfizer and NCCN are also vested in supporting programs that, because of their thoughtful, comprehensive, and evidenced-based design, will facilitate improvements beyond changes in clinical knowledge. To achieve changes in health care professionals' abilities, performance, and improvements in patient outcomes, implementation science frameworks that support effective adult learning practices, can be impactful tools. When presenting linkages between medical education and implementation science, Price, et al., (2015)[2] recommend that:

> *Medical educators need to understand and incorporate several different IS [Implementation Science] approaches in their educational design and delivery. This might mean working with others (quality improvement, clinical systems leadership) to identify and prioritize gaps in practice based on local contexts, anticipating or identifying barriers to implementation of learning (7) and proactively addressing them as part of educational activities, and providing IS-based tools to facilitate learner practice change.*

Frameworks and references to tools provided in the article may be of interest and relevant to organizations submitting proposals.

The NCCN Peer Review of Proposals Committee (PRPC) has been formed to oversee this process and will utilize a formalized review procedure to accept LOI's and subsequently select the proposals of highest scientific merit. The NCCN PRPC has overseen the development of the RFP and will perform the peer review of applications.

All proposals will be considered, including those incorporating independent education of health care professionals and not limited to those offering CME credit.

Researchers seeking funding for studies evaluating the efficacy of therapeutic interventions will not be considered under this RFP.

The members of the NCCN PRPC are as follows:

Mary Ellen Beliveau, MEd, Knowledge to Practice
Kathleen Doherty Smith, RN, MS, Stanford Cancer Institute
William Gradishar, MD, Robert H. Lurie Comprehensive Cancer Center of Northwestern University -Chair
Cheryl F. Jones, MD, Georgia Cancer Care
Thaer Khoury, MD, FCAP, Roswell Park Cancer Institute
P. Kelly Marcom, MD, Duke Cancer Institute
Mary Martin Lowe, PhD, Learning Advisors, LLC
Julia J. Perkins, MD, Pfizer
Elizabeth Reed, MD, Fred & Pamela Buffett Cancer Center
Kathryn Tumelty, MSN, AOCNP, Fox Chase Cancer Center

V. RFP key information

Total awards	$2.0M is available to fund grants for this RFP. It is expected that approximately 6-8 proposals will ultimately be funded, depending on the size and scope of the projects. Individual projects can be funded for up to a maximum of 24-months'

[2] Medical Education Online 2015, **20**: 27003 - http://dx.doi.org/10.3402/meo.v20.27003

	duration.
Specific area of interest	Advanced or Metastatic Breast Cancer, including (1) Addressing clinical gaps regarding treatment sequencing; (2) Appropriately assessing and managing side effects; (3) Improving health care professionals knowledge and ability to refer patients to clinical trials; (4) Timely and effective communication with patients, their caregivers and families regarding hospice and palliative care; (5) Supporting health care professionals in their efforts to address and help patients overcome barriers to recommended treatment; (6) Improving patients' knowledge of and engagement in their care by using patient-focused tools and strategies that help support shared decision-making.
Geographic scope	United States only
Target audience	Oncologists, pathologists, hospitalists and other members of the health care team, including nurses, social workers, etc.
Recommended format	Educational research or implementation science type protocol. IRB approval will be needed before implementation, if appropriate. This RFP is NOT seeking basic or clinical research proposals. Interventions should be educational, or systems-based in nature.
Eligible applicants	Academic medical centers, health care institutions, professional associations and other non-for-profit entities with a mission related to health care improvement.
Selection criteria	Applicant organizations will be evaluated on the basis of • Knowledge of and experience with the area; • Capability of carrying out the work; • Collaboration if appropriate; • Potential effect and expected outcomes of the project; • Dissemination strategies.
Key dates/deadlines	**June 3, 2015**—RFP released **July 15, 2015**—Letters of Intent due **September 8, 2015**—Applicants notified via email; invited to submit full proposal **October 20, 2015**—Full proposals due date **December 10, 2015**—Notification of decisions **January 2016**—Funded projects start

VI. How to Submit:

Please go to the website at www.pfizer.com/independentgrants and click on the button "Go to the Grant System".

If this is your first time visiting this site in 2015 you will be prompted to take the *Eligibility Quiz* to determine the type of support you are seeking. Please ensure you identify yourself as a first-time user. Select the following Area of Interest: 2015 RFP Metastatic Breast Cancer.

Complete all required sections of the online application and upload the completed LOI template.

The LOI is a brief concept document that describes the proposed project at a high level. The Proposal Review Committee will select letters of intent that are best aligned with the purpose of the RFP. All applicants will be notified with either an acceptance or a declination. Successful applicants will be asked to submit a full grant proposal for funding consideration.

VII. Letter of Intent Submission Guidance

Submission requirements

1. The letter of intent should be no more than three (3) pages, single spaced, using Calibri 12-point font and 1-inch margins. It should contain the following information about the proposed project:
    a. Project title;
    b. Organization(s) involved;
    c. Principal investigator;
    d. High-level project description, including;
        i. Primary goal(s);
        ii. Description of how the proposal builds on existing work, projects, or programs;
        iii. Anticipated challenges and solutions;
        iv. Expected outcome and how the impact of the project will be evaluated;
    e. Deliverables and dissemination strategies;
2. A letter of intent longer than three pages will be **RETURNED UNREVIEWED;**
3. Submit the letter of intent online via the Pfizer IGLC website;
    a. Please go to the website at www.pfizer.com/independentgrants and click on the button "Go to the Grant System";
    b. If this is your first time visiting this site in 2015 you will be prompted to take the *Eligibility Quiz* to determine the type of support you are seeking. Please ensure you identify yourself as a first-time user;
    c. Submit your letter of intent in the 2015 RFP Metastatic Breast Cancer;
4. Complete all required sections of the online application and upload the completed letter of intent template.

VIII. Full proposals

A limited number of applicants will be invited to submit for consideration a full proposal of no more than 10 pages, accompanied by a line-item budget. The full proposal format will be shared with the invitation to submit.

IX. Questions

If you have questions regarding this RFP, please direct them in writing to the Grant Officer for this clinical area, Jacqueline Waldrop at Jacqueline.waldrop@pfizer.com with the subject line, "2015 RFP Metastatic Breast Cancer."

X. Terms and conditions

1. This RFP does not commit Pfizer or its 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. Pfizer reserves the right to accept or reject any or all applications received as a result of this request, or to cancel this RFP in part or in its entirety, if it determines it is in the best interest of Pfizer to do so.

3. For compliance reasons and in fairness to all applicants, all communications about the RFP must come exclusively to Pfizer IGLC. Applicants should not contact other departments within Pfizer regarding this RFP. Failure to comply will disqualify applicants.

4. Consistent with its commitment to openness and transparency, Pfizer reports education grants provided to medical, scientific, and patient organizations in the United States. Pfizer reserves the right to announce the details of successful grant application(s) by whatever means insures transparency, such as on the Pfizer website, in presentations, and/or in other public media. In the case of this RFP, a list of all LOIs selected to move forward may be publicly disclosed. In addition, all approved full proposals, as well as all resulting materials (e.g., status updates, outcomes reports, etc.) may be posted on the IGLC website and/or any other Pfizer document or site.

5. Pfizer reserves the right to share with organizations that may be interested in contacting you for further information (e.g., possible collaborations) the title of your proposed project and the name, address, telephone number, and e-mail address of the applicant from the requesting organization.

6. To comply with 42 U.S.C. § 1320a-7h and 42 C.F.R. §§ 403.900-.914 (the Sunshine Act), Provider (sponsor) must provide to Pfizer specific information for the U.S. -licensed physicians and U.S. teaching hospitals ("Covered Recipients," as defined by applicable law) to whom the Provider (sponsor) furnished payments or other transfers of value from the original independent grant awarded by Pfizer. Those payments or transfers-of-value include compensation, reimbursement for expenses, and meals provided to faculty (planners, speakers, investigators, project leads, etc.) and "items of value" (items that possess a discernible value on the open market, such as textbooks) provided to faculty and participants, if those faculty and/or participants meet the definition of Covered Recipient. Provider (sponsor) must submit the required information during the reconciliation process or earlier, upon Pfizer's request, so Pfizer can meet Sunshine Act reporting commitments. Be advised Pfizer will not make any payments to any individuals; grant funding shall be paid directly to Provider (sponsor).

7. No portion of a Pfizer independent grant may be used for food and/or beverages for learners and/or participants in any capacity. Provider (sponsor) will be required to certify during the

reconciliation process and/or the periodic collection of Sunshine reporting that funds were not used for food and/or beverages for learners and/or participants.

8. In the performance of all activities related to an independent grant, the Provider (sponsor) and all participants must comply with all applicable Global Trade Control Laws. "Global Trade Control Laws" include, but are not limited to, U.S. Export Administration Regulations; the International Traffic in Arms Regulations; EU export controls on dual-use goods and technology; Financial Sanctions Laws and Restrictive Measures imposed within the framework of the CFSP-Treaty on European Union; and the economic sanctions rules and regulations administered by the U.S. Treasury Department's Office of Foreign Assets Control.

9. For all research projects the institution(s) must agree to assume all responsibilities as sponsor of the study as outlined in the proposal, which includes:
   - Obtaining institutional review board (IRB)/independent ethics committee (IEC) approval for studies involving human subjects or human tissue and obtaining a subsequent renewal of this approval as required by local regulations (e.g., yearly, biannually, etc.). In addition, obtaining any IRB/IEC approval for amendments to protocol as they pertain to the research;
   - Obtaining all required personal data privacy or informed consent documentation (as appropriate);
   - Obtaining all required regulatory approval(s) per local regulations;
   - Assuming all reporting obligations to local regulatory authorities;
   - A statement that the research will be conducted in compliance with relevant provisions of the International Conference on Harmonisation to the extent they are consistent with FDA GCPs, Good Clinical Practice as adopted by the Food and Drug Administration ("FDA"), or Good Pharmacoepidemiology Practice guidelines and all applicable local legal and regulatory Requirements.

XI. Transparency

Consistent with our commitment to openness and transparency, Pfizer publicly reports its medical educational grants and support for medical and patient organizations in the United States. A list of all letters of intent selected to move forward may be publicly disclosed, and whatever emanates from this RFP is in the public domain. In addition, all approved full proposals, as well as all resulting materials (e.g., status updates, outcomes reports, etc.) may be posted on the website. Grantees will be required to submit semi-annual reports and/or updates.