

**Request for Proposals (RFP)
Clinical Pathways in Breast Cancer**

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

I. Introduction

Pfizer Inc. and the National Comprehensive Cancer Network® (NCCN®) are collaborating to offer a new grant opportunity seeking proposals that use clinical care pathways to address a quality improvement initiative along the continuum of care for breast cancer patients. In the context of this RFP, a clinical pathway is defined as an evidence-based and systems-based standardization of a clinical process in order to support decision-making and improve the quality of breast cancer patient care.

Pfizer and NCCN recognize the emerging role of cancer care pathways as point of care informational tools used by health care providers with the potential to improve quality care based on the most current medical evidence and NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Supporting health care professionals in their use of clinical pathways is critical to improving patient care as clinicians face a variety of constraints on how they treat patients while payers and health care systems seek opportunities to improve cost effectiveness.

The mission of Pfizer Independent Grants for Learning & Change (IGLC) is to partner with the global health care community to improve patient outcomes in areas of mutual interest through support of measurable learning and change strategies. “Independent” means that the projects funded by Pfizer are the full responsibility of the recipient organization. Pfizer has no influence over any aspect of the projects and only asks for reports about the results and the impact of the projects in order to share them publicly.

NCCN, a not-for-profit alliance of twenty-seven (27) leading cancer centers, is dedicated to improving the quality, effectiveness and efficiency 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. World renowned experts from NCCN Member Institutions, who diagnose and treat patients with a broad spectrum of cancers and are recognized for dealing with complex, aggressive, or rare cancers, 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 Inc. Collectively, \$2 million is available to fund several proposals.

II. Background

The intent of the RFP is to encourage organizations to submit letters of intent (LOIs) describing concepts and ideas for developing, implementing and evaluating guideline-based clinical pathways in breast cancer.

Guidelines & Pathways

Clinical practice guidelines, such as the NCCN Guidelines[®], generally offer a broad array of therapeutic options and are agnostic to cost and side effects. The inclusion of a therapeutic strategy or treatment on a guideline is predicated on FDA approval and/or long-standing assurance of safety and efficacy by the clinical community. Guidelines have been demonstrated to decrease unnecessary variation in care. Variation in therapeutic interventions, diagnostic testing, and the adoption of appropriate palliative care all create excessive variation in cost, which often decreases the value of care. However, unnecessarily complex and potentially redundant reporting of quality measures including choice of therapy in addition to patient experience and outcome measures are often expensive to collect and report and, therefore, may reduce the value of care received.

In contrast, clinical pathways offer a narrower group of recommendations than those provided in guidelines. Pathway decisions are based on efficacy, safety, and cost. They are typically limited to systemic treatment and its management, but have recently expanded into radiation therapy, surgery, and imaging. They also offer an ability to assess metrics of appropriate use. However, as straightforward as the concept of “pathways” seems, many questions remain regarding their use.

Pathway programs generally include four main components:

1. Pathway development and maintenance: Pathways are developed and continuously updated through an evaluation of national guidelines and evidence to determine which interventions are most effective, least toxic, and have the best benefit-risk profile for a particular diagnosis and/or patient condition for a particular clinical scenario.
2. Compliance rate: Target provider compliance rates are typically set between 65-80%.
3. Implementation and reporting infrastructure: A mechanism for evaluation of pathway implementation must be in place.
4. Incentive realignment: The goal is to decouple provider payment from treatment choice.

ASCO recently published *American Society of Clinical Oncology Policy Statement on Clinical Pathways in Oncology*, defining high-quality pathways¹. Prior to this there were no agreed-upon standards which has led to wide variations and inconsistencies among the many different pathway systems already developed across the United States². ASCO’s criteria for high quality clinical pathways in oncology supports the need for pilot projects to understand pathway impact on care and outcomes. The measurement of adherence to clinical guidelines and pathways must be accomplished while maintaining and promoting practice efficiency, patient engagement, autonomy, empowerment, and overall patient experience.

Pathway Application in Breast Cancer Care

In breast cancer care, there is not only a growing number of therapeutic options, but also a growing number of tools that will be integrated into care. In the early breast cancer setting, numerous adjuvant chemotherapy and endocrine approaches are appropriate. With the introduction of molecular assays, several tools are now available (and more anticipated) that potentially can define which patients will or will not require chemotherapy. Additionally, these tools also potentially define patients who have such a low risk of recurrence following 5 years of adjuvant endocrine therapy that they do not require extended adjuvant therapy. Molecular assays now have a potential role in both the early and late stage disease setting, but add an additional layer of cost and uncertainty. Utilizing pathways that distill a more

concise approach to patient care from broader guidelines can achieve equivalent patient outcome, more consistency in care delivered and better quality measures.

Pathway Application in Community Cancer Care

The majority of cancer patients receive care in communities where they reside. However, for many community cancer programs, numerous barriers to implementation of national clinical practice guidelines exist. These include fragmented multispecialty care and disciplines; limited access to specialized services (i.e., fertility, genetics, geriatrics, palliative care); absent/ limited navigation services and ancillary services (i.e., counseling, PT/OT, speech therapy, nutrition, cardio-oncology); limited infrastructure and financial resources to support and measure quality metrics; as well as limited access and staffing to support clinical trial activity and enrollment. Cancer patients, survivors, and their family members deserve to have access in their geographic community to efficiently enter, navigate, and receive a full range of essential multidisciplinary services to achieve best outcomes.

Therefore, the intent of the RFP is to encourage organizations to submit LOIs describing concepts and ideas for design and implementation of clinical care pathways in breast cancer that allow adherence to and reporting of adherence to clinical guidelines in a fashion which contributes to the improvement in the quality of care in any and all treatment delivery environments.

III. Scope

NCCN and Pfizer encourage proposals using clinical pathways as decision support in order to improve clinical processes and improve the quality of breast cancer patient care. Proposals should focus on quality improvement in all stages of breast cancer. They may be pilot projects or build on already existing pilot projects. Proposals that address the needs of underserved communities across the United States are especially encouraged.

Clinical pathways require evidentiary and operational processes, as well as measurement and reporting capabilities and/or strategies. They should be derived from a focus on high quality, cost-effective regimens, thereby limiting choices, but optimizing outcome for patients.

Proposals can address issues of appropriate and timely therapeutic interventions (i.e. medical, surgical, radiation oncology, and imaging), appropriate and timely diagnostic, molecular and pathologic evaluation, as well as appropriate and timely evaluation by integral specialties such as genetic counseling, fertility and reconstruction specialists. Additionally, proposals can address issues of compliance, adherence, toxicities, and survivorship.

All proposals funded must:

- Be based on guidelines (NCCN or other)
- Promote evidence-based care
- Be sustainable after the award funding is complete
- Collect data and report outcomes
- Have a goal to enhance clinical outcomes, patient satisfaction, or provider satisfaction
- Be flexible enough to address patient variability
- Promote administrative and system efficiency

Successful proposals will consider the overall efficiency of measurement and ways to incorporate measurement into care without increasing cost. Although proposals may include third party systems or

other internal resources to promote guideline adherence, their overall cost to the system must be considered and reported.

Specific Areas of Interest:

1. Clinical Care Pathways Development
 - A. Develop and implement programs that improve efficiency and reduce costs to improve the quality of breast cancer patient care, including one or more of the following:
 - a. May be technology-based, but it is not necessary
 - b. Support multidisciplinary collaboration
 - c. Include partnerships to improve access to multidisciplinary and specialized care
 - d. Improve patient adherence to medications and improve patient safety
 - e. Address patient emotional needs, psychosocial support and advocacy issues
 - f. May incorporate virtual tumor boards, telemedicine, support services, etc.
 - g. May reduce payer administrative burden for authorization or payment of breast cancer patient care for providers
2. Clinical Care Pathways Implementation or Education
 - A. Demonstration of care or process improvement in centers through the utilization of pathway programs
 - B. Integration into electronic health records
 - C. Implementation throughout healthcare system/affiliates
 - D. Strategies for provider training and education

NCCN and Pfizer strongly encourage proposals that address the use of clinical pathways in community centers, low-resource centers, and centers that focus on the treatment of underserved patients. Community networks with academic collaborations (i.e. NCCN Affiliates) are also encouraged.

IV. Letters of Intent/Proposals

This RFP model employs a 2-stage process: Stage 1 is the submission of the 3-page 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 VII).

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.

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

The NCCN Peer Review of Proposals Committee (PRPC) has been formed to oversee this process and will utilize a formalized review procedure to accept LOIs 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.

The members of the NCCN PRPC are as follows:

William Gradishar, MD, Robert H. Lurie Comprehensive Cancer Center of Northwestern University
 Kathleen Doherty Smith, RN, MS, Stanford Cancer Institute
 Karen Fields, MD, Moffitt Cancer Center
 Cheryl F. Jones, MD, Georgia Cancer Specialists
 Joan McClure, MS, NCCN
 Lynn McRoy, MD, Pfizer Inc.
 Michael N. Neuss, MD, Vanderbilt-Ingram Cancer Center
 Michael Rabin, MBA, MPA, City of Hope Comprehensive Cancer Center
 Kathryn Tumelty, MSN, AOCNP, Fox Chase Cancer Center

V. Requirements

Date RFP Issued:	May 15, 2017
Clinical Area:	Breast Cancer
Target Audience:	Members of the health care team and administrators involved in the care of breast cancer patients. Proposals addressing under-represented populations as well as those from community settings are encouraged.
Applicant Eligibility Criteria:	Health care institutions, large and small, health care professional organizations and other organizations with a mission related to health care improvement. More information on organizations eligible to apply directly for a grant can be found at http://www.pfizer.com/files/IGLC_OrganizationEligibility_effJuly2015.pdf .
Expected Approximate Monetary Range of Grant Applications:	Individual projects requesting up to \$250,000 will be considered; smaller, lower-cost projects are strongly encouraged.
Estimated Key Dates:	LOI Deadline: June 26, 2017 Please note the deadline is 11:59pm Eastern Time (New York, GMT -5). Anticipated LOI Notification Date: August 14, 2017 Full Proposal Deadline: *September 25, 2017 *Only accepted LOIs will be invited to submit full proposals. Please note the deadline is 11:59pm Eastern Time (New York, GMT -5). Anticipated Full Proposal Notification Date: November 13, 2017 Grants distributed following execution of fully signed Letter of Agreement Period of Performance: January 2018 to January 2020

<p>How to Submit:</p>	<p>Please go to www.cybergrants.com/pfizer/loi and sign in. First-time users should click “REGISTER NOW”.</p> <p>Select the following Area of Interest: 2017 Clinical Pathways in Breast Cancer</p> <p>Requirements for submission: Complete all required sections of the online application and upload the completed LOI template (see Appendix).</p> <p>If you encounter any technical difficulties with the website, please click the “Need Support?” link at the bottom of the page.</p> <p>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>
<p>Questions:</p>	<p>If you have questions regarding this RFP, please direct them in writing to the Grant Officer, Jacqueline Waldrop (Jacqueline.Waldrop@pfizer.com), with the subject line “2017 Clinical Pathways in Breast Cancer”</p>
<p>Mechanism by which Applicants will be Notified:</p>	<p>All applicants will be notified via email by the anticipated dates noted above.</p> <p>Applicants may be asked for additional clarification or to make a summary presentation during the review period.</p>

VI. 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 at the email address IGLC@Pfizer.com. Applicants should not contact other departments within Pfizer regarding this RFP. Failure to comply will disqualify applicants.
4. Complete Pfizer RFP Terms and Conditions are available for your review at www.pfizer.com/files/PfizerIGLC_RFP_TermsandConditions_2017Apr.pdf

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.

VII. Appendix: Letter of Intent Submission Guidance

LOIs should be single-spaced using Calibri 12-point font and 1-inch margins. There is a 3-page limit for the main section and a 1-page limit for organizational detail. If extensive, references may be included on 1 additional page. Final submissions should not exceed 5 pages in total (3 pages for the main section, 1 page for organizational detail, and 1 page for references). LOIs not meeting these standards will not be reviewed. It is helpful to include a header on each page listing the requesting organization.

All required sections 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 LOI.

Please note the formatting and page limit for the LOI. The LOI is inclusive of additional information of any kind. A submission exceeding the page limit WILL BE REJECTED and RETURNED UNREVIEWED.

LOIs should include the following sections:

Main Section (not to exceed 3 pages):

A. Title

B. Project Classification

1. There are multiple project types that are eligible for funding through this RFP. Please indicate which of the following best represents your project. More information on these classifications can be found in the [Decision Matrix](#) posted on the [Tips & Templates](#) tab on the IGLC website.
 - Dissemination and Implementation (D&I) Research
 - Quality Improvement
 - Education or Educational research
2. Background Information
 - It is expected that D&I research projects follow generally accepted principals. For all research projects the institution(s) must agree to assume all responsibilities as sponsor of the study as outlined in the proposal. These are listed in the **RFP Terms and Conditions (#9)**.
 - At the time of approval of a full proposal, applicants will be required to sign a research contract, submit IRB approval and a research protocol.
 - Quality improvement projects should be described in terms of generally accepted principles of improvement science such as those described by the IHI model for improvement or LEAN.
 - At the time of approval of a full proposal, applicants will be required to sign a letter of agreement.
 - Educational projects should be planned using generally accepted principals of adult learning. More information on principals of learning and behavior change for health professionals can be found at www.pfizer.com/files/HealthProfessionalsLearningandBehaviorChange_AFewPrinciples.pdf.
 - At the time of approval of a full proposal, applicants will be required to sign a letter of agreement.

- C. Goal and Objectives
1. 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).
 2. 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.
- D. Assessment of Need for the Project
1. 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. Only include information that impacts your specific project, linking regional or local needs to those identified on the national basis, if appropriate.
- E. Target Audience
1. 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
- F. Project Design and Methods
1. Describe the planned project and the way it addresses the established need.
 2. If your methods include educational activities, please describe succinctly the topic(s) and format of those activities.
- G. Innovation
1. Explain what measures you have taken to assure that this project idea is original and does not duplicate other projects or materials already developed.
 2. 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.
- H. Evaluation and Outcomes
1. 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.
 2. Quantify the amount of change expected from this project in terms of your target audience.
 3. Describe how the project outcomes will be broadly disseminated.
- I. Anticipated Project Timeline-Projects must complete in two years
- J. Requested Budget
1. A 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.
 2. The budget amount requested must be in U.S. dollars (USD).
 3. While estimating your budget please keep the following items in mind:

- 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.
- Pfizer does not provide funding for capital equipment.
- May not underwrite the entire cost of an electronic health record.
- May not include costs of buying already developed software or clinical care pathways.
- The inclusion of these costs cannot cause the amount requested to exceed the budget limit set forth in the RFP.
- It should be noted that grants awarded through IGLC cannot be used to purchase therapeutic agents (prescription or non-prescription).
- Pfizer maintains a company-wide, maximum allowed overhead rate of 28% for independent studies and projects.

K. Additional Information

1. If there is any additional information you feel Pfizer should be aware of concerning the importance of this project, please summarize it in within the page limitations.

Organizational Detail (not to exceed 1 page)

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.

Please note that any project partners listed in this section should also be listed within the online system. Tax-IDs of partner organizations will be requested when entering this information. If a partnership is only proposed, please indicate the nature of the relationship in the Organizational Detail section of your LOI.

References

1. Zon RT, Frame JN, Neuss MN, Page RD, Wollins DS, Stranne S, Bosserman LD. American Society of Clinical Oncology Policy Statement on Clinical Pathways in Oncology. *Journal of Oncology Practice* 2016;12(3):261-266.
2. Schroeder, Amy. Clinical Pathways: A Current Snapshot, and the Journey Ahead. *Journal of Clinical Pathways* 2017;3(2):33-40.