



Oncology: mBC-CONNECT CCC RFP Program

Coordinated Oncology Navigation & Education for Comprehensive Treatment

Implementation of best practices from community oncology groups to improve current approaches for pretreatment education for patients with metastatic breast cancer (mBC) to enhance the patient experience and management of patient expectations.

Within a patient's cancer journey, a key point of complexity occurs after the decision to treat has been made, but before treatment begins and anticancer treatment-related information is shared with the patients.ⁱ This process has a significant impact on shaping patient expectations and conditions the subsequent patient experience of care during treatment (e.g., multiple visits to clinic for infusions, the experience of adverse events, etc.).

Given the complexity of cancer care, the burden associated with treatment can be significant.ⁱⁱ Patient treatment education is a key step in which the burden associated with therapy can be minimized, and in turn, a way of reducing the work patients' face while also increasing their capacity to self-manage their care.ⁱⁱⁱ

While this process is a standard part of care delivery, significant gaps exist with how best to deliver this type of education in real world settings, particularly in community settings where care teams may have access to fewer resources and infrastructure. For example, needs, preferences and modalities for information may differ between cohorts of patients, between individuals within a cohort, within individuals over time as their clinical conditions evolve, and between different phases of care.^{iv}

The importance of patient education in the delivery of cancer treatment is widely documented and accepted, however, gaps exist for approaches tailored by phase of cancer care and the relationship it has with the patient experience.^v

As treatment continues to increase in its own complexity, community practices need to continue to facilitate and evolve the development of mutual understanding and effective expectation setting related to the patient's subsequent therapeutic experiences.

Gilead is actively seeking to collaborate with community-based cancer centers that are currently conducting pretreatment education for patients with mBC to identify strengths, weaknesses and opportunities to facilitate adherence to treatment and management of patient expectations in the real-world setting. Community-based cancer centers include private oncology practices that are not a part of a hospital or academic/medical teaching institution or community cancer centers affiliated/partnered with an academic medical center.

This RFP will focus specifically on the provider perspectives as it relates to the educational processes and workflows conducted before and during delivery of anticancer therapy in patients with mBC. This may include, but is not limited to the manner in which pretreatment education is integrated into workflows, how time and resources are accounted for and how trade-offs are balanced, the evolving role of oncology navigators and different information modalities available to support navigation of the cancer knowledge landscape, and how clinical and non-clinical staff are used to facilitate adherence to treatment and effective expectation setting with patients with metastatic breast cancer.

OPPORTUNITY OVERVIEW

Element	Description
Funding Type	Externally sponsored collaborative project (non-grant program)
Total Project Budget	Up to \$500,000
Number of Awards	Two (2)
Project Period	Approximately one year (12 months)
Project Type	Implementation science research project (i.e., the scientific study of methods and strategies that facilitate the uptake of evidence-based practice and research into regular use) that is focused on implementation of evidence-based practices for facilitating anticancer therapy education with patients with metastatic breast cancer (mBC) after a decision to treat has been made and prior to administration of the selected agent to support adherence to treatment.
Application Criteria	<ul style="list-style-type: none"> • Community-based oncology practices that are currently conducting pretreatment education for patients with mBC • Project team members have sufficient experience and expertise with patient education and care delivery for patients with mBC • Project team members have sufficient experience and expertise with mixed methods research to successfully execute the project • Project can be interventional or observational in nature • Defined and clear timelines for start-up, enrollment and publications • Data collection evaluation methods are appropriate and well-defined • Described approach facilitates hypothesis generation and measurement generation related to mechanisms through which pretreatment education may be implemented to improve adherence to treatment and managing patient expectations • Proposed plan generates insights that can facilitate scale of subsequent interventions and deployment of tools in subsequent projects • Incorporation of a clear plan for educating a diverse patient population and methods for capturing the patient voice • Project can be completed within approximately 12 months, followed by rapid presentation of results • Study sites located in the United States • Multi-center proposals will be prioritized • Consideration of working with other investigators as part of the study team who are underrepresented in scientific research and medicine • Consideration of working with local advocacy groups to incorporate the patient voice in the study • Proposals or requests for Gilead products as part of the project will not be considered

Review Process	<ul style="list-style-type: none"> • Stage 1: Letter of intent (LOI) review • Stage 2: if selected, the applicant(s) will be invited to submit a full application for review (proposal and detailed budget)
Review Criteria	<p>The following are the review criteria for this RFP:</p> <ol style="list-style-type: none"> 1. Project design and methodology. 2. Impact of outcomes. 3. Applicability of results to inform implementation and process improvement interventions. 4. Project personnel. 5. Scalability and sustainability.
Contact Information	<i>OncologyCCCRFP@gilead.com</i>
KEY ELEMENTS	
Project Aims	<p>To implement and scale evidence-based practices that improve pretreatment education and treatment management by:</p> <ol style="list-style-type: none"> 1. Elucidating key facilitators and best practices that enhance pretreatment education from a community oncology practice's perspective. These include how pretreatment education is integrated into workflow, how time and resources are accounted for and how trade-offs are balanced, and facilitators of effective expectation setting with patients with mBC. 2. Elucidating key gaps, challenges, and barriers to the effective delivery of pretreatment education in the community oncology setting for patients with mBC. 3. Generating hypotheses as to how pretreatment education can be improved, including process improvement, approaches and deployment of support tools to support adherence to treatment, management of patient expectations and workforce capacity building. 4. Generating appropriate endpoints and outcomes to measure the impact of the implementation of evidence-based practices from the patient perspective, provider perspective, or both. 5. Facilitating sharing of best practices across institutions and subsequently with the community oncology field more broadly.
Population	Community-based oncology groups that provide care and conduct pretreatment education delivered by clinical or non-clinical navigators, nursing, social workers, medical assistants, or other team members involved in the care of patients with mBC.
Study Focus	Educational processes and workflows conducted before and during delivery of anticancer therapy in patients with mBC in the community setting and corresponding measures to assess impact of these processes and workflows on adherence to treatment and management of patient expectations.
Domains of Interest	<p>The application should address at least one core domain. Domains of possible interest include:</p> <ul style="list-style-type: none"> • Pretreatment education delivery

	<ul style="list-style-type: none"> • Adverse event education & management • Treatment schedule & adherence education • Patient reported outcomes
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Key Dates & Program Specifics

Review Process & Key Dates

- **October 1, 2024:** LOI submission window opens for submission via [G.Optics](#). All proposals should be discussed with your local Gilead Medical Affairs contact before submission into [G.Optics](#).
- **December 3, 2024 (23:59 PST):** LOI submission window closes.
- **December 18, 2024:** Notice of LOI outcome, with invitations for full application submission extended to successful applicants.
- **February 28, 2024 (23:59 PST):** Full proposals with detailed budget are due in [G.Optics](#).
- **March 31, 2025:** Notice of full application outcome.

Any questions about the 2024 GILEAD Oncology RFP Program or application process can be submitted to your local Gilead Medical Affairs contact (e.g. MSL or MVEL) or oncologyCCCRFP@gilead.com

Review Process

LOI will be rigorously reviewed by a Gilead internal committee. Each complete LOI that meets program requirements will be assigned to a reviewer. Each reviewer will assess and score the LOI according to the below criteria:

1. Project design and methodology
2. Impact of research results
3. Applicability of results to inform implementation and process improvement interventions
4. Project personnel
5. Scalability and sustainability

Budget Considerations

All Letters of Intent (LOIs) submitted in response to this RFP must adhere to a maximum budget of \$500,000 USD. Proposals exceeding this budget cap will not be considered for funding. Additionally, proposed budgets should reflect fair market value for a typical study of this nature.

No Guarantee of Funding

Gilead reserves the right to approve or decline any application at its sole discretion. Submission of an LOI or a full application does not guarantee funding. Applications are reviewed by an internal review committee.

No Inducement or Reward

Gilead approval of awards does not take into account the past, present, or future volume or value of any business or referrals between the parties. Awards are not being given, directly or indirectly, as an inducement or reward with respect to the past or potential future purchase, utilization, recommendation or formulary placement of any Gilead product. Further, the awardee is not required to purchase, order, recommend or prescribe to any patients any products manufactured by or available through Gilead.

About Gilead Sciences

Gilead Sciences, Inc. is a biopharmaceutical company that discovers, develops and commercializes innovative therapeutics in areas of unmet medical need. The company's mission is to advance the care of patients suffering from life-threatening diseases worldwide. Gilead has operations in more than 30 countries worldwide, with headquarters in Foster City, California.

ⁱ A Mistry, S Wilson, T Priestman, S Damery, and Ms Haque, How do the information needs of cancer patients differ at different stages of the cancer journey? A cross-sectional survey, *JRSM Short Reports* 2010 1:4, 1-10, <https://doi.org/10.1258/shorts.2010.010032>

ⁱⁱ Adam R, Nair R, Duncan LF, Yeoh E, Chan J, Vilenskaya V, et al. (2023) Treatment burden in individuals living with and beyond cancer: A systematic review of qualitative literature. *PLoS ONE* 18(5): e0286308.

ⁱⁱⁱ Cheng AC, Levy MA. Data Driven Approach to Burden of Treatment Measurement: A Study of Patients with Breast Cancer. *AMIA Annu Symp Proc.* 2017 Feb 10;2016:1756-1763. PMID: 28269934; PMCID: PMC5333259.

^{iv} Miriam Adams, Information and education across the phases of cancer care, *Seminars in Oncology Nursing*, Volume 7, Issue 2, 1991, Pages 105-111, ISSN 0749-2081

^v Karolina A. Kazimierczak, Zoë C. Skea, Mary Dixon-Woods, Vikki A. Entwistle, Deb Feldman-Stewart, James M.O. N'Dow, Sara J. MacLennan, Provision of cancer information as a "support for navigating the knowledge landscape": Findings from a critical interpretive literature synthesis, *European Journal of Oncology Nursing*, Volume 17, Issue 3, 2013, Pages 360-369, ISSN 1462-3889