Gilead Request for Proposals Announcement:

mBC-CHOICE: Putting Patients at the Center of Cancer Care Decisions – U.S. RFP Program

Implementing Innovative Approaches to Patient-Centered Decision-Making (PCDM) in Metastatic Breast Cancer Care Delivery

Announcement Date: June 1, 2024

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Background

Despite its recognized broad benefits, research on the implementation of patient-centered decision-making (PCDM) in metastatic breast cancer (mBC) care delivery has been limited. Specifically, PCDM accounts for both the patient and the provider's knowledge, experience, values, and preferences when making treatment decisions. Further, by recognizing that care evolves with the patient over time (i.e., patient's care continuum), identifying and understanding what matters most to patients offers an opportunity to facilitate better decision-making that aligns with patient values and preferences at various time points throughout the patient's care continuum. Incorporating PCDM as a standard approach in clinical practice may contribute to improved patient-provider partnerships, care that encompasses the whole person, including outcomes that are meaningful to people living with mBC, and reduced healthcare delivery disparities among underrepresented/underserved populations. However, there remains a substantial gap in understanding how oncology health care professionals can optimally employ PCDM across the patient's care continuum, and in understanding effective measures to assess and document its use in routine clinical practice.

Opportunity Description

Gilead is actively seeking to further the science of PCDM in mBC care delivery by funding projects designed to facilitate the implementation of an innovative PCDM intervention, across the patient's care continuum. This opportunity includes identifying and funding implementation science research projects that establish and incorporate PCDM as a core component of mBC care delivery and includes partnerships with patients and community organization (breast cancer advocacy organizations, community-based oncology cancer centers, and other organizations serving people with breast cancer), from planning through final dissemination of study findings. 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 is an opportunity to explore the development and implementation of a preference-aligned decision-making model of mBC care delivery that fosters an ongoing collaborative patient-provider relationship.

The goal of this RFP is to inform the knowledge around implementation of PCDM during mBC care delivery in the community practice settings and throughout the patient's care continuum.

Opportunity Overview

Element	Description
Funding Type	Externally sponsored capacity-building collaborative project (non-grant program)
Total Project Budget	Up to $500,000
Number of Awards	Three (3)
Project Period	Approximately two years (24 months) (e.g., interim deliverables in 2025; project completion/ final deliverables in 2026)
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 the implementation of an innovative intervention to facilitate the delivery of PCDM among people with mBC in the community-based oncology practice setting. *Note: piloting the intervention, proof of concept also accepted*
Application Criteria	• Project team members/personnel have sufficient expertise and interventions experience in the mBC care delivery. • Applicants (research/clinical entities) will partner (existing partnership or developing partnership) with a community organization, defined as breast cancer advocacy organizations, community clinics, and other organizations serving people with breast cancer. • Data collection and evaluation methods are appropriate and well-defined • data describes the influence of a PCDM intervention on mBC care delivery, including data collected directly from patients (e.g., use of patient-reported outcomes measures) • Intervention is scalable and sustainable after funding completion (as applicable) • Project can be completed within approximately 24 months, followed by rapid presentation of results. • Study sites and community partner located in the United States
Review Process	**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) *For more detail, please see the Full Application Review Process section*

Review Criteria	The following are the review criteria for this RFP: 1. Importance of research results 2. Readiness for implementation 3. Project design and evaluation 4. Project personnel 5. Patient-centeredness 6. Stakeholder engagement *For more detail on each criterion, please see the Full Application Review Process section*
Contact Information	mBC-CHOICE@gilead.com
Key Elements	
Project Aim	An innovative intervention designed to facilitate PCDM and capture/measure data on patient-centered outcomes in mBC care delivery. Of particular interest are projects that 1) include patients from an underrepresented/underserved population(s), 2) engage patients and community organizations throughout the project, and 3) clearly describe presentation/publication plans that inform and promote sharing of knowledge and sustainability *For more detail, please see the following sub-sections included in the Required Proposal Elements section: Health Equity, Stakeholder Engagement, Dissemination and Sustainability*
Population	Adults living with metastatic breast cancer The project is encouraged to include a sub-group population(s) of interest that is aligned with the FDA guidance on health equity category/target(s) that encourage the inclusion of populations underrepresented in research defined by demographics (e.g., age, gender identity, race, ethnicity, socioeconomic status, disability, pregnancy status, lactation status, and comorbidity)
Context/Setting	Community-based oncology practice setting (i.e., 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) To include community and patient involvement, applicants will partner with a community organization (breast cancer advocacy organizations, community-based centers, and other organizations serving people with breast cancer)
Intervention Focus	Intervention that is focused on the implementation of PCDM during treatment decision-making, with particular interest in a multi-level intervention

Intervention Targets	People living with mBC, including underrepresented/underserved sub-populations, providers, health systems, and/or caregivers within community-based oncology practice settings

Required Proposal Elements

Research Questions

The applicants should answer the following questions in their proposal:

- What is the problem you are addressing (e.g., patient access to health information; patient participation in treatment choice)?
- Who does the problem impact?
- What are the current solutions to this problem and why are they limited?
- Why is PCDM important for solving this problem and how does this proposal address this problem among this specific population?
- How is your intervention innovative?
- How will the intervention be implemented within a community healthcare system, including what outcomes will be measured and how these outcomes relate to the intervention?

Domains of Interest

The application should address at least one core domain. Domains of possible interest include:

- Quality of communication
- Relationship-centered care (trust)
- Health equity
- Patient engagement/activation

Implementation and Stakeholder Approaches

The inclusion of multiple components that reflect a comprehensive view of the barriers and facilitators to using PCDM in the proposed implementation approach and intervention is strongly suggested to ensure a proposed project's success. We also encourage the consideration of different strategies to facilitate involvement of various stakeholders (e.g., patients, including those from underrepresented/underserved sub-populations, providers, caregivers, advocacy organizations, community members, etc.) at several points along the care continuum.

Outcomes and Outcome Measures

Selected short-term, intermediate, and long-term outcomes should be relevant and meaningful to patients, providers, and/or caregivers, and systems. Outcomes may include a mix of the following:

- PCDM process outcomes
- Patient-centered outcomes (examples include but not limited to)
    - Improved quality of communication (i.e., the patient was heard and understood)
    - Reduction in decisional conflict
    - Improved knowledge about condition/options
    - Care plan alignment with patients' goals/values/preferences
- Practice-level outcomes (examples include but are not limited to)
    - Length of appointment times
    - Time from diagnosis to treatment initiation, including time to referral
    - Receipt of the standard of care, preference-aligned care, or neither

The application should demonstrate that the selected outcome measures are fit-for-purpose and are appropriate/relevant based on the concept being measured. Applicants will have an opportunity to provide their view on the measure(s) that are impacted by PCDM and how the outcomes might change over time.

Use of Proprietary Decision Aids or Similar Tools

Applicants may propose to use proprietary decision aid(s) as part of their PCDM strategy. Note that the use of such proprietary aides would not be an endorsement of such aids. Gilead recognizes that commercially available products may offer advantages in terms of assured maintenance and sustainability. Applicants proposing to use proprietary decision aids must provide clear rationale for their choice of the specific proposed decision aid(s). Applicants should specify how costs associated with the proprietary tools will be covered during the project, for example, by sites or through licensing agreements between the applicant and the decision aid developer or vendor. Applicants must also disclose in their proposals that they retain (or will retain) the appropriate rights, permissions and/or licenses to use such aid(s) in their proposed project, along with potential conflicts of interest related to use of the decision aid during the proposed project. Gilead may require applicants being considered for funding to provide documentation that all relevant conflicts of interest have been appropriately disclosed and managed by the applicant's relevant institutional official.

Health Equity

Healthy People 2030 defines health equity as "*the attainment of the highest level of health for all people. Achieving health equity requires valuing everyone equally with a focused and ongoing societal efforts to address avoidable inequalities, historical and contemporary injustices, and the elimination of health and health care disparities*".[1] Achieving health equity will take a concerted effort from all sectors to address the systemic barriers in health care delivery that prevent individuals from receiving

information about their health and that can be used to inform their decisions and preferences.

Applications are encouraged to adhere to health equity targets by including a description of sub-population(s) and health equity categories and/or targets of interest (cap targets) in accordance with US Food and Drug Administration (FDA) guidance documents that describe ways to address underrepresented populations in research.[2-4] Specifically, applications should address how the proposed PCDM intervention may help address health care disparities and promote health equity by accounting for the needs of underrepresented populations, including demographic characteristics of study populations (e.g., sex, gender identity, race, ethnicity, age, socioeconomic status, location of residency) and non-demographic characteristics of populations (e.g., patients with organ dysfunction, comorbid conditions, disabilities, those at the extremes of the weight range, and populations with diseases or conditions with low prevalence). For example, the study sample would require X% of the study population to comprise members of an underrepresented group that represents the proportion of the population in the community.

Stakeholder Engagement

Applicants will include a plan for meaningful patient engagement and a plan for working with a community organization partner, defined as breast cancer advocacy organizations, community-based cancer centers, and other organizations serving people with breast cancer. These plans will describe how the applicant will engage patients and community organizations throughout the project, including during planning, implementation, and dissemination phases.

At the time of full application submission, applicants are required to demonstrate that a collaborative partnership with a community organization(s) has been established. As part of the full application, the applicant will provide a letter of intent from the community-based organization partner agreeing to work with the applicant. The community organization will be viewed as external to the research endeavor and will contribute to the project as meaningful team members, partners, or advisors.

For the purposes of this RFP, Gilead welcomes diverse, well-considered multi-stakeholder approaches to implementation of PCDM in the metastatic breast cancer care setting.

Dissemination and Sustainability

Applicants will include a presentation/publication plan (e.g., conference presentation; journal publication]) and a sustainability plan (e.g., uptake of PCDM intervention in a community-based practice setting), even if such sustainability will not be realized during the project period.

Application Process

Applying for funding is a two-stage process:

- Stage 1: develop and submit a Letter of Intent (LOI). Including a letter of intent from the community-based partner agreeing to work with the applicant is preferred at this stage.

  If needed, Gilead will provide support with connecting research/clinical entities with a community-based organization partner at the LOI stage. This partnership must be finalized by full submission.

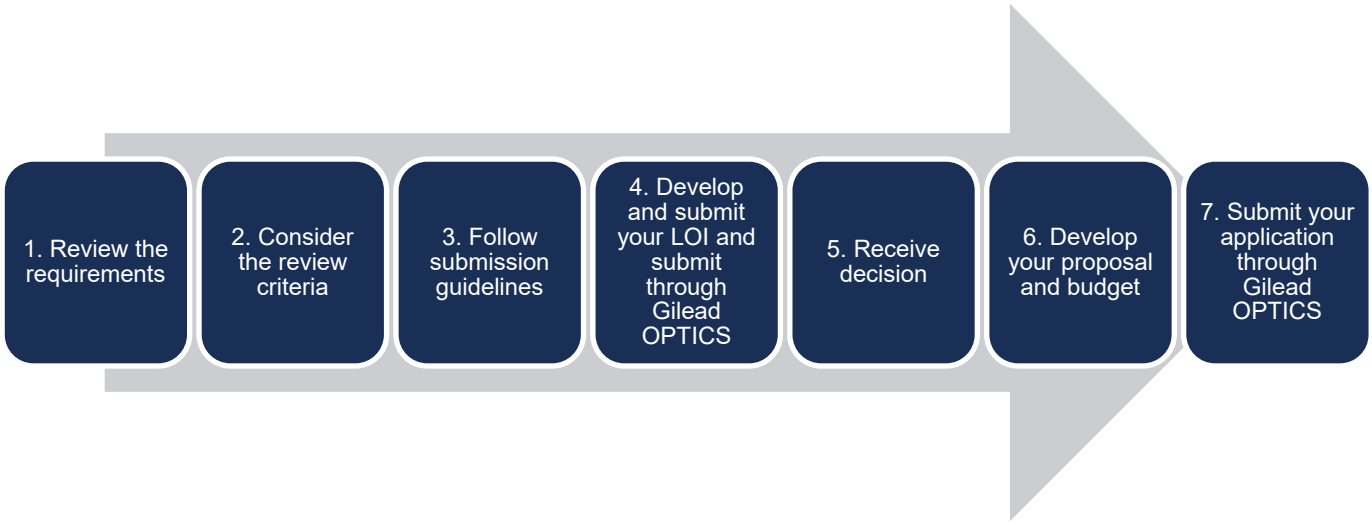
- Stage 2: applicant invited to develop and submit a full application (proposal and detailed budget). At this stage, a letter of intent from the community partner agreeing to work with the applicant is required.

Please refer to the Summary of Key Dates for due dates and the Submission Guidelines, below, for information on how to submit an LOI and full application online Gilead OPTICS Portal.

Summary of Key Dates

Activity	Timeline	Date
Request for Proposal Announcement	June 1, 2024, 8am PST	June 1, 2024, 8am PST
Question Period Deadline	21 days	June 22, 2024, 8am PST
Response to Questions	30 days post announcement date	July 1, 2024, 8am PST
Stage 1: Letter of Intent (LOI) Submission		
LOI Submission Window Opens	30 days post announcement date	July 1, 2024, 8am PST
LOI Submission Window Closes	60 days post announcement date	July 31, 2024, 8am PST
Stage 2: Full Application Submission		
Invited to Submit Full Application (Proposal/Detailed Budget)	75 days post announcement date	August 15, 2024, 8am PST
Full Application Deadline	120 days post announcement date	September 29, 2024, 8am PST
Notice of Full Application Outcome	75 days post application deadline	December 13, 2024, 8am PST
Project Start Date	6–9-month estimate	June – September 2025

How to Apply



1. **Review the requirements**

   Examine all sections of the RFP.

2. **Consider the review criteria**

   Consider the organization eligibility requirements and Gilead's specific requirements to see whether your organization, your interests, and your capabilities fit the requirements listed in this RFP. Check the Gilead website for any modifications or amendments up to the submission deadline.

3. **Follow submission guidelines**

   All applications must be completed in Gilead OPTICS

4. **Develop and submit your LOI**

   Develop your letter of intent to be submitted to Gilead.

5. **Receive decision**

   Gilead will contact your team with a decision regarding your LOI. All those who have submitted an LOI will be informed of the outcome of the LOI review by August 15, 2024, 8am PST.

6. **Develop your proposal and detailed budget**

   Certain applicants will be invited to submit a full application, including a detailed budget. Develop your proposal and budget to meet the RPF requirements.

7. **Submit your application through Gilead OPTICS**

   August 15, 2024, 8am PST: Notice of LOI outcome, with invitations for full application submission

   September 29, 2024, 8am PST: Deadline for receipt of full application

   December 13, 2024, 8am PST: Notice of full application outcome

Review Process

Applying for funding from Gilead is a two-stage process. An LOI must be submitted, and an applicant must be invited to submit a full application (proposal and detailed budget).

Stage 1: Letter of Intent

Responsive applicants must thoroughly address all LOI fields according to the instructions in the Gilead LOI Template. Gilead will screen all LOIs for responsiveness and to ensure compliance with the Gilead Submission Instructions. A minimum of two Gilead staff will review the LOIs (primary and secondary reviewers), which are not scored during review. Gilead will invite only applicants whose LOIs are most responsive to this limited RFP to submit a full application. LOIs deemed to be nonresponsive, including those submitted using an incorrect LOI Template and those not adhering to the Submission Guidelines, will not be invited to submit a full application.

In developing the LOI and proposal, please consider the following criteria:

- The sponsoring institution is in the United States
- Proposals are treatment/drug agnostic
- Scientific objectives and endpoints are clear and based on scientific hypotheses
- Data collection and evaluation methods are appropriate, defined and specific
- Community and/or patient involvement, including a letter of intent from the community-based partner agreeing to work with the applicant (preferred)
- The proposed intervention is scalable and sustainable after funding completion (as applicable)
- The project is to be completed within approximately 24 months after contract execution, followed by rapid dissemination of results
- Awards shall be for research purposes only; routine medical care or other costs associated with routine medical care will not be considered for funding

Stage 2: Full Application

Gilead will invite select LOIs to submit a full application and additional instructions will be provided to the applicant. Gilead's review process is designed to support the following goals:

- Identify applications that have the strongest potential to facilitate implementation of a novel PCDM intervention in a community-based clinical setting and, ultimately, lead to improved health care and health outcomes.

- Ensure a transparent, fair, objective, and consistent process to identify these applications.
- Gilead's review is a two-stage process that includes an initial review of full applications by internal review panel members and a subsequent blinded review by an external multidisciplinary panel of experts.

Applications will be evaluated based on the following review criteria:

- **Criterion 1. Importance of research results**
    - Does the application propose to implement a PCDM intervention during metastatic breast cancer care and best practice for achieving PCDM during cancer treatment in a community-based practice setting?
    - Does the application clearly describe the evidence supporting the effectiveness of the proposed PCDM intervention (or initial evidence from pilot/proof of concept intervention) and strategies that facilitate PCDM uptake, as well as scalability and sustainability?
    - Does the application clearly describe how the study results relate to PCDM, including the effectiveness of the PCDM intervention in terms of impact on outcomes that are meaningful to patients?
- **Criterion 2. Readiness for implementation**
    - Have the proposed implementation site(s) been identified? If so, has the applicant demonstrated the preparedness of the implementation sites, including the identification of site champions and key decision makers?
        - If not, has the applicant provided a rationale for why this is not possible, along with acceptable assurances that all implementation sites can be activated within the initial project phase?
    - Does the application sufficiently describe the target group for the proposed PCDM intervention? Does it describe the setting of the project? Are the results generalizable to these stakeholders and settings?
    - Are the stakeholders and settings representative of additional audiences who stand to benefit beyond this proposed implementation project?
    - Does the application describe how understanding and broader use of these results, beginning with the proposed project, will lead to a meaningful change in practice and improved health care and health outcomes?
        - How do these results add to the total evidence related to the choice among treatment or other healthcare options summarized and presented within the proposed PCDM intervention?
    - If applicable, please describe IT/clinical data infrastructure and research capabilities:
        - IT infrastructure:
            - Integrated EHR.

        - Integrated Practice Management system.
        - Oral pharmacy system/oral pharmacy data (for patients for whom scripts are filled in house).
        - Data infrastructure.
    - Clinical data infrastructure and research capabilities:
        - Data is organized/stored in a fashion that can be accessed.
        - Has personnel with expertise on how to work with data for the purposes of analysis.
        - Capabilities to share data.
        - Capabilities to extract data for chart review.
        - Sufficient data size for research purposes.

- **Criterion 3. Project design and evaluation**
    - Does the application provide an appropriate multicomponent strategy for implementing the proposed PCDM intervention into real-world clinical practice? Are all components of this approach well described?
    - Are the chosen implementation strategies appropriate for this effort? Consider the extent to which they are tested, evidence based, and consistent with principles and findings from implementation science.
    - Are the proposed project activities clearly described, and are these activities likely to result in successful uptake of the evidence and to lead to meaningful changes in practice and improvements in health care and health outcomes?
    - Does the application propose an appropriate evaluation strategy that includes plans for the following?
        - Evaluating the effectiveness of the proposed implementation approach as well as the continued effectiveness of the PCDM intervention as appropriate
        - Measuring fidelity of the PCDM intervention as delivered, as well as its impact on relevant decisional, clinical, and healthcare utilization outcomes as appropriate
        - Measuring the impact of these activities on stakeholders in the immediate and over the longer term (i.e., changes in knowledge, satisfaction, behavior change, healthcare utilization, and health outcomes)
    - Does the application describe a theory of change or logic pathway that shows how the proposed implementation approach is likely to lead to meaningful changes in knowledge, behavior, and practice?
    - Do the proposed strategies consider factors that may help or hinder PCDM uptake in the proposed project, including specific barriers to implementation and how to mitigate them?
    - Are the proposed timeline and specific project milestones realistic?

- **Criterion 4. Project personnel**
    - This criterion should assess the appropriateness (e.g., qualifications and experience) of the project personnel/team to support the proposed project.
        - How well qualified is the project team (e.g., PIs, collaborators, other stakeholders) to conduct the proposed project activities?
        - Does the application describe the project team's expertise relevant to PCDM and moving evidence into practice?
        - Does the investigator (or co-investigator) have demonstrated experience conducting projects of a similar size, scope, and complexity?
        - Does the leadership plan adequately describe and justify roles and areas of responsibility of the investigators? Specifically, do the investigators have complementary and integrated expertise? Further, are the leadership, governance, and organizational structures appropriate for the project?
        - Is the level of effort for each team member appropriate for successful conduct of the proposed work?
- **Criterion 5. Patient-centeredness**
    - Does the application describe how the proposed PCDM intervention has the potential to help people make more informed healthcare decisions or to improve healthcare delivery and/or health outcomes?
    - Does the proposed evaluation capture patient-centered outcomes as appropriate?
- **Criterion 6. Stakeholder engagement**
    - Does the application demonstrate that relevant stakeholder perspectives—including those of patients and providers—have informed the development of the proposal, and does it describe how these stakeholders will be meaningfully engaged throughout the project?
    - Does the application demonstrate that decision makers at the proposed site(s) for implementation are sufficiently committed to the proposed implementation project and to sustaining successful PCDM approaches beyond the funded project?
        - Does the application describe how these decision makers will be meaningfully engaged throughout the project?
        - Did the applicant provided a letter of intent from the community-based partner agreeing to work with the applicant (required)
    - Does the application demonstrate that personnel (e.g., the frontline staff delivering the PCDM intervention or directly supporting the implementation activities) at the proposed implementation sites are clearly interested in the

proposed implementation project and are committed to participating as active partners in the project?

- Have these staff provided input on, or endorsed, the activities they will undertake during the project?

Additional Considerations

In developing the research budget, please consider the following:

- Gilead plans to award a total of approximately $500,000 in funds for research proposals under the Gilead Patient Focused Implementation Science 2024 RFP Program, dependent upon availability of funds and receipt of meritorious applications. Any proposal greater than $500,000 will not be considered for this application.
- The budget should include overhead costs and applicable taxes
- Proposed overhead costs should not exceed 30% of the total budget
- There must be no more than one sponsor for contract negotiations and/or Institutional Review Board (IRB) review.
- 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.
- Gilead approval of award(s) will depend on the availability of funds and receipt of meritorious and complete proposals. Awards shall be granted solely on the merit of the research and alignment with the criteria of this program.
- Gilead approval of awards does not consider 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.
- As the study sponsor, the principal investigator will be responsible for compliance with all laws and regulations applicable to research sponsors, including satisfying local requirements and obtaining all necessary regulatory approvals prior to beginning the study.

References

1. Office of Disease Prevention and Health Promotion. Health Equity in Healthy People 2030. https://health.gov/healthypeople/priority-areas/health-equity-healthy-people-2030
2. Food and Drug Administration. *Patient-Focused Drug Development: Collecting Comprehensive and Representative Input: Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholder*. 2020. https://www.fda.gov/drugs/development-approval-process-drugs/fda-patient-focused-drug-development-guidance-series-enhancing-incorporation-patients-voice-medical
3. Food and Drug Administration. *Enhancing the Diversity of Clinical Trial Populations: Eligibility Criteria, Enrollment Practices, and Trial Designs, Guidance for Industry*. 2020. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enhancing-diversity-clinical-trial-populations-eligibility-criteria-enrollment-practices-and-trial
4. Food and Drug Administration. *Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials Guidance for Industry: Draft Guidance*. 2022. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/diversity-plans-improve-enrollment-participants-underrepresented-racial-and-ethnic-populations