NCCN Request for Proposals (RFP): Patient-Centered Quality Improvement Across the Breast Cancer Care Continuum

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1.0 Purpose

The National Comprehensive Cancer Network® (NCCN) and Novartis Pharmaceuticals Corporation are collaborating to offer a new funding opportunity seeking proposals for quality improvement initiatives in Breast Cancer. NCCN has received support from Novartis (hereafter, "Funder") to support NCCN Member Institution faculty for the performance of quality improvement initiatives in the management of breast cancer. NCCN will serve as the funding organization. Funds are available only to investigators from NCCN Member Institutions.

2.0 Organization Information

National Comprehensive Cancer Network

The National Comprehensive Cancer Network® (NCCN®) is a not-for-profit alliance of 33 leading cancer centers devoted to patient care, research, and education. NCCN is dedicated to improving and facilitating quality, effective, efficient, and equitable cancer care so patients can live better lives. Through the leadership and expertise of clinical professionals at NCCN Member Institutions, NCCN develops resources that present valuable information to the numerous stakeholders in the health care delivery system. By defining and advancing high-quality cancer care, NCCN promotes the importance of continuous quality improvement and recognizes the significance of creating clinical practice guidelines appropriate for use by patients, clinicians, and other health care decision-makers around the world.

Funder

Novartis is an innovative medicines company. Every day, we work to reimagine medicine to improve and extend people's lives so that patients, healthcare professionals and societies are empowered in the face of serious disease. Our medicines reach more than 250 million people worldwide. Our purpose is to reimagine medicine to improve and extend people's lives. At Novartis, we use science-based innovation to address some of society's most challenging healthcare issues. We discover and develop breakthrough treatments and find new ways to deliver them to as many people as possible. As a global company, we have a great responsibility and an even greater opportunity to lead the world in creating a positive social change, embracing societal impact as a core business objective.

3.0 Background

Breast cancer is the most frequently diagnosed and second leading cause of death in females in the United States [1]. An estimated 316,950 new cases of female and 2,800 new cases of male breast cancer will be diagnosed in 2025 [1]. Additionally, 42,170 women and 510 men will die from breast cancer within the same year [1]. Breast cancer is treated according to stage and molecular subtype. The 5-year relative survival rate varies greatly by stage at diagnosis, reaching above 90% for stage I but less than 30% for stage IV [1]. Moreover, breast cancer is largely under-screened and diagnosed in men. Racial and socioeconomic disparities in access to care, treatment, and outcomes continue to exist and new cases of breast cancer continue to be diagnosed every day. Efforts to increase screening, genetic testing, and early diagnosis of breast cancer must be optimized [2-8].

There is a need for increasing efforts such as access to screening mammography and decreasing delay of diagnosis. At present, gaps exist as current screening guidelines are inconsistent in terms of recommended age to begin and stop screening, the best screening modality, and genetic assessment recommendations [2, 3, 5-7, 9]. Creative solutions are needed to tailor educational initiatives for minority communities and community clinicians on barriers to breast cancer screening and completion of recommended follow up.

Treatment has evolved over the last decade due to the implementation and routine utilization of novel innovative therapies [10, 11]. Patients are now living longer due to these novel therapeutics and attention should be given to the breast cancer patients' treatment experience [12-14]. In addition, there is a need for greater awareness of, access to, and retention within clinical trials. Current gaps exist in clinical care in the subpopulations of AYA, geriatrics, and minorities in the assessment and interventions on barriers to care [9, 12-16]. Opportunities exist to enhance educational and supportive resources for the patient, care giver, and health care provider to provide optimal psychosocial support, side effect management, and communication techniques to patients to support their treatment goals, and clinical trial participation [9, 12-16].

Thus, this RFP aims to develop innovative quality improvement projects along the breast cancer continuum including, but not limited to, screening, diagnosis, treatment, and survivorship.

4.0 Aims and Eligibility

Aim	Develop innovative quality improvement projects to optimize the care and outcomes across the breast cancer continuum including, but not limited to, screening, diagnosis, treatment, and survivorship. It is hoped that proposals submitted in response to this RFP will be scalable and sustainable after funding completion, with potential for widespread dissemination and implementation.
Geographic Scope:	United States
Eligibility Criteria: Investigators from the following organizations may apply	• NCCN Member Institutions • Collaboration between NCCN Member Institutions is strongly encouraged in order to foster interactive sharing of knowledge and expertise, and to utilize the combined clinical strengths of Member Institutions. • Although the submitting investigator must be from a Member Institution, all participating institutions do not need to be an NCCN Member Institution. • Proposal submissions from junior faculty are encouraged. • Trainees may participate as a sub-investigator under appropriate mentorship from a PI at a Member Institution.

5.0 Requirements

Clinical Area:	Breast Cancer
Target Audience:	The intent of this Request for Proposal (RFP) is to support proposals that seek to improve the quality of care across the Breast Cancer continuum.

Funding Considerations:	• There is $1 Million available for funding of all projects. • *Please see Section 7.0 for details on maximum per project funding amounts.* • The intent is to fund individual projects capped at $250,000 (direct and indirect costs) although smaller, lower-cost projects are encouraged. Funding greater than $250,000 will be considered for exceptional proposals with detailed budget justification. • Maximum indirect (overhead) rate is 25% and *must* be included in total funding request amount. • Direct funding will include all costs. For example, $80,000 direct costs and $20,000 indirect costs for a total budget of $100,000. Any funds in excess of the limits stipulated in this section for direct funding will require detailed justification and review. • No travel or publications costs will be covered. • Applicants are required to disclose additional sources of funding for this project and demonstrate that funding does not overlap. • The decision relative to funding is deferred to the members of the Scientific Review Committee (SRC) as chosen by NCCN and independent of Funder.
Areas of Interest/Emphasis:	The intent of this RFP is to support data generation proposals to improve patient care and patient-centered outcomes across the Breast Cancer continuum that lead to publication(s). **Proposals in the following topic areas are strongly encouraged:** **1. Diagnosis and risk assessment** • Improve access by identifying and removing barriers to breast cancer screening and genetic testing (including interventions for younger, geriatric, and minority populations). • Develop patient education programs on the importance of completing breast cancer screening, recommended follow up, and dispel misinformation. Tailor educational approaches to community specific needs. • Develop clinician education programs (primary care providers, gynecologists, radiologists, etc.) for patient risk assessment, genetic testing, and alleviating patient barriers to screening and follow up. • Developing interventions to address patient barriers to breast cancer screening and follow up of abnormal or incomplete results. • Optimize workflows for the screening and diagnosis of Breast Cancer for the Primary Care Provider, Advanced Care Practitioner, Gynecologist, and Radiologist. • Develop shared decision-making aids to assist in the screening and genetic testing of breast cancer.

Areas of Interest/Emphasis (continued):	• Enhance and optimize patient financial and logistic access to additional diagnostic tests. **2. Personalization of the breast cancer treatment experience** • Optimize workflows for the role of telehealth and remote lab work in clinical care to decrease barriers to adherence. • Optimize workflows for standard of care geriatric/functional assessment and reduction of polypharmacy. • Assess and develop innovative interventions to promote patient support resources to optimize mental health of patients living with all stages of breast cancer. • Develop patient educational programs on breast cancer side effects, therapeutic management, and support services. • Create health care provider educational programs on communication strategies to facilitate shared decision-making conversations to define patient goals and continuing reassessment throughout the patient's treatment journey. • Utilize technology modalities of electronic medical records, artificial intelligence, social media, telehealth, and/or text messaging to optimize workflows and develop mitigation strategies for populations with limited access to technology. **3. Innovative ways to enhance access to clinical trials.** • Optimize workflows/infrastructure to ensure all patients are approached and, if interested, screened for participation in a clinical trial. • Increase the patient's voice in clinical trial design and execution. • Develop interventions to overcome patient barriers to clinical trial enrollment and continued participation, ensuring diversity in clinical trials. • Develop patient education programs on clinical trials basics, screening, phases, and outcomes. • Create health care provider educational programs on bias, bidirectional trust, barriers to participation, and diversity in clinical trials. • Create well-functioning academic and community collaborations in standard of care management and clinical trial participation of Breast Cancer patients.
Areas Excluded or Considered Out of Scope:	**Proposals in the following topic areas will be considered out-of-scope for this RFP:** • Proposals not relevant to the Breast Cancer care continuum. • Clinical therapeutic interventional trials and specific drug/drug-

	based interventions. • Translational, correlative, or basic science studies. • Medical technology device studies. • *Proposals duplicative of completed, ongoing, or planned studies will not be considered.*
Study Timeframes for Approved Studies:	• Commencement (defined as activation at the institution): Within 6 months, unless IRB approval is required. If IRB approval is required by Institution, activation must commence no later than 9 months after Institution is provided with notice of funding approval by NCCN. • Period of Performance: Two years • Reporting and Dissemination of Results in manuscript form: Within 9 months of study completion. *Please note that manuscript must be submitted to NCCN and Funder for review prior to submission for publication consideration. • Studies will be funded as described in Section 7.0 and should be designed with subject numbers commensurate with study time frames and funding. • Studies that do not meet the timeframe requirements for completion may have funds rescinded and will be required to return any and all unused funds previously disbursed
Selection Criteria:	Applications will be evaluated on the basis of: • Knowledge of and experience with the area; • Capability of carrying out the work; • Collaboration if appropriate; • Scalability and sustainability; • Potential effect and expected outcomes of the project; and • Dissemination strategies. *The FUNDER has the ability to reject any study with safety issues or if it is an already studied concept.*
Key Dates:	• RFP release date: **May 20, 2025** • Proposal Submission Deadline: **July 15, 2025.** Please note the deadline is 5:00 pm Eastern Time • Anticipated Fund Award Notification Date: **August 21, 2025**

Questions:	• If you have questions regarding this RFP, please direct them in writing to Nicole Zion, Senior Clinical Research Manager, at Zion@nccn.org with the subject **"NCCN Novartis Breast QI RFP"**.

6.0 Review and Approval Process

The NCCN Request for Proposals Development Team (RFPDT) has developed a Request for Proposals (RFP) with a formalized review procedure to accept applications and select the proposals of highest scientific merit. The NCCN RFPDT has overseen the development of the RFP and the NCCN Scientific Review Committee composed of this group will perform the review of applications. All reviews, evaluations and award decisions are independent of the Funder.

Applicants will be notified via email with the information regarding submission and/or funding status by the dates noted above.

Proposals duplicative of completed, ongoing, or planned studies will not be considered. If you wish for additional information or have questions, please e-mail Zion@nccn.org or call Nicole Zion at 215-690-0230.

Studies that have safety issues, are already well-funded concepts, or are not consistent with the strategy for investigation as written in this RFP will not be reviewed by the SRC.

7.0 Funding

NCCN and its member institutions have an agreement to include a maximum of 25% indirect costs for trials funded by the NCCN. Direct funding will include all costs. For example, $80,000 direct costs and $20,000 indirect costs for a total budget of $100,000. Any funds in excess of the limits stipulated in this section for direct funding will require detailed justification and review.

NCCN shall make Funding disbursements to Institutions for each approved study as follows:

- Twenty percent (20%) of total award after commencement of Project for start-up activities.
- Twenty percent (20%) of total award after first patient enrolled for project.
- Twenty percent (20%) of total award after fifty percent (50%) of patients enrolled for project.
- Twenty percent (20%) of total award after last patient enrolled for project.
- Twenty percent (20%) after submission of a final report or manuscript for publication.

The goal is to have rapid submission of a manuscript so as to have the data available to the wider scientific community.

Studies that do not meet the time frame requirements as stipulated in Section 5.0 will have funds rescinded and will be required to return any and all unused funds previously disbursed.

8.0 Proposals

In order to respond to the RFP, investigators will submit a proposal in the format delineated below to NCCN, which will be evaluated by the NCCN Scientific Review Committee (SRC).

Proposals are required to be submitted electronically to the NCCN research portal at https://nccn.envisionpharma.com/ienv_nccn **and include letters of support from the governing groups of the institution verifying:**

1) Office of Sponsored Research approval
2) Department Chair/Division approval
3) Institutional budgetary review and approval
4) Documentation to support feasibility of clinical trials with at least one of the following:
   - Letter from institution's Feasibility Committee if applicable
   - Documentation by previous studies and accrual (if available, publications and abstracts)
5) Letter(s) of support from participating institutions including name of PI at participating institution and their feasibility

Letters should be on letterhead and addressed to Crystal S. Denlinger, MD, FACP, CEO, National Comprehensive Cancer Network, 3025 Chemical Road, Suite 100, Plymouth Meeting, PA 19462

Proposals will provide concise documentation of the research plan and should be the equivalent of no more than 10 pages. The proposal is expected to contain sufficient information to allow the reviewers to fully assess the scientific rigor of the proposed study. A full research project plan may be submitted as an attachment, but the required information in iEnvision must also be completed. A robust review of the statistical plan will be conducted.

Proposals should contain detailed information regarding the following areas:

8.1 Study Information

A. General Information: Title/Type of Support/Subsite(s)
   - Select "**No**" for Letter of Intent
   - Select "**NOV1**" for RFPID
   - Select "**Funding**" for Type of Support

B. Investigators and institutional affiliations
   - Include academic title and rank

C. Site Information
   - Primary and Sub-site information as applicable

D. Concept information
   - Enrollment Target
   - Design (proposals for projects being performed within a larger basket/umbrella study must be clearly identified at time of submission)
   - Phase
   - Study Type
   - Estimated time of completion

- Overview/Hypothesis/Abstract
- Background/Rationale
- Overall Goals & Objectives
- Current Assessment of Need in Target Area
- Target Audience
- Project Design and Methods
- Innovation
- Evaluation and Outcomes
- Anticipated Project Timeline
- Organizational Detail
- Detailed Work Plan
- Evaluation Design
- References
- Additional information

E. Outcome/ Oncology analysis
   - Tumor Type/Stage
   - Body Systems
   - Correlative study information
   - Budget Justification

F. Planned publications: Journal/Congress/Anticipated Dates

8.2 Requested Funding Information (See iEnvision User Manual for additional instructions)

A. Complete the **NCCN Budget Template** (attached) and submit the **full budget** via the attachments folder.
   - Breakdown costs by major cost categories
   - Provide justification of major costs with enough detail to demonstrate how funding for major elements in the study will be allocated
   - Salaries are capped at the current NIH salary cap
   - No travel or publication costs will be covered

B. Complete the remainder of the Funding Page:
   - Total direct and indirect costs (see instructions)
   - Requested currency (US Dollar)
   - Overhead %
   - Amount Requested
   - Additional sources of funding

8.3 Ancillary Documentation

A. Current CV of the Principal Investigator
B. Supportive literature may be provided
C. Feasibility Letter/Document
D. Department Chair or Division Letter of Support

E. Budget Review and Approval Letter
F. Any additional information to support proposal submission

9.0 Proposal Submission Process

9.1 Submission

All proposals must be submitted electronically using the directions below and are due by **5:00 PM (Eastern) on July 15, 2025.** No exceptions will be granted.

A. Please use the link below to register in the system: https://nccn.envisionpharma.com/ienv_nccn
B. Select "Register for New Account" in the upper right corner of the page, above the "Log In" button.
C. Complete all fields (Note: Fields with an asterisk are required)
D. You will receive a confirmation email. Click on the link in the email to activate your account.
E. Enter your username and password (Note: Your user name is your email address. Do not copy and paste).
F. Set up your security questions.
G. Submit your study under the "**Non-Clinical Research**" Application Type.
    1. Select "**No**" for Letter of Intent
    2. Select "**NOV1**" for RFPID
    3. Select "**Funding**" for Type of Support

For technical assistance with the iEnvision system, please contact iEnvision_general_request@envisionpharmagroup.com.

For questions or issues, please e-mail Nicole Zion at zion@nccn.org with the subject line **"NCCN Novartis Breast QI RFP".**

10.0 Additional Terms and Conditions

10. 1 IRB requirements (as applicable): If a study requires IRB review and approval, the following applies:

10.1.1(a) Draft protocols will be reviewed by NCCN and the Funder **prior** to IRB review (if applicable). **A copy of the draft protocol must be submitted to NCCN within 4 weeks after the study approval letter.** The protocol must be consistent with the approved proposal and all reviewer comments must be addressed.

10.1.2(b) All investigators will submit protocols for IRB review and document approval to NCCN prior to study activation and all collaborators will furnish evidence of IRB approval (if applicable). It is expected that IRB review and approval be completed **within 9 months** following NCCN notification of funding for the project.

10.2 Human Biological Specimens (if applicable): If specimens are collected, informed consent and IRB approval must be obtained as appropriate for the study. Compliance with all federal regulations is required.

10.3 Serious Adverse Event Reporting (if applicable): All serious adverse events will be reported to NCCN and the Funder in addition to local regulatory authorities.

10.4 Institutional Monitoring (if applicable): All studies will be internally monitored in accordance with appropriate committees (e.g. institutional Data Safety and Monitoring Plan in the case of human studies). As required by institutional policy, a copy of any applicable Data Monitoring Plan for the study must be submitted to NCCN prior to NCCN approval of study activation.

10.5 Progress Reports: Investigators will provide interim progress reports to NCCN detailing the progress of studies quarterly, and a final study report or manuscript within 9 months following study completion. These reports will be used administratively for funding purposes. If study progress or accrual lags behind the expected rate, the SRC may be asked for suggestions to improve study progress, or alternatively, to terminate the study and any further funding.

10.6 Abstracts and Manuscripts: Abstracts for presentation at scientific meetings and all publications of study results will be submitted to NCCN and Funder for review related to protection of companies' intellectual property and confidential information **prior to any submission**. Abstracts must be submitted at least 15 days prior to submission and manuscripts at least 30 days prior to submission. Manuscripts must be submitted to NCCN and Funder for review within 9 months of study completion.

10.7 NCCN Multi-Institutional Studies: Collaborative studies between NCCN Member Institutions are encouraged. For these studies, the proposal feasibility section should provide information about data management and statistical analysis.

10.8 NCCN institutions and investigators will be responsible for conducting all studies in accordance with the applicable research plan, GCP Guidelines, and all applicable laws and regulations. NCCN institutions and investigators will be responsible for all data collection, statistical analysis and safety reporting.

10.9 Investigators must provide reasonable assurance that submitted studies will be able to reach completion within the time frames specified in Section 5.0.

10.10 Final protocols must be consistent with approved proposals. Funds will be rescinded if there are significant changes without prior NCCN approval. There will be no exceptions.

10.11 The Principal Investigator (PI) listed on the protocol must be the same PI listed on the proposal submission unless approved by NCCN.

11.0 Study Agreement

A study agreement will be signed between NCCN and each participating institution.

If an institution requires a separate agreement with another pharmaceutical company for a study, that agreement must be fully executed by the time of final agreement execution with NCCN.

All aforementioned points between NCCN and the participating institution must be strictly adhered to.

12.0 Permissions

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.

Funding recipients will need to maintain a separate end-user or other license agreement directly with NCCN for use of the NCCN Guidelines, Compendia, or Chemotherapy Order Templates.

13.0 References

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