Quality Improvement (QI) Initiative

Request for Proposal (RFP)/Call for Grant Applications (CGA)

Lilly USA, LLC
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Indianapolis, Indiana 46285
U.S.A.

To: Healthcare Systems, Professional Organizations and/or Quality Improvement Providers
From: Anatasha Hayes, Independent Initiatives Grant Officer, Oncology – Breast Cancer
Date: 4/1/24

A Quality Improvement (QI) grant is a proposal that seeks to objectively measure and systematically improve quality of healthcare by identifying gaps and root causes, standardizing processes and structure to reduce variation, and achieve predictable results, yielding improved outcomes for patients, healthcare systems, and organizations.* A quality improvement grant addresses systemic barriers (i.e., ones associated with multi-disciplinary teams, health system, data, and care delivery processes) and objectively measures impact on processes and/or patient outcomes.

Lilly is committed to supporting QI efforts that foster the translation of scientific evidence into evidence-based clinical practice using QI theory, processes, and models to ultimately improve the safe, effective, efficient, equitable, and timely delivery of optimal patient care.** Lilly seeks to support QI programs that demonstrate sustainability and scalability with the potential for widespread transferability and dissemination to other healthcare organizations (e.g., based on insights from Implementation Science (IS), and/or or using IS methods).

For all independent QI grants, the grant requestor (and ultimately the grantee) is responsible for the design, implementation, and supervision of the independent initiative. Lilly shall not be involved in any aspect of project development nor the conduct or execution of the QI initiative. Lilly does not support initiatives or medical activities, for the purpose of encouraging off-label use of our products. It is not the intent of this RFP/CGA to support clinical research projects. Research projects, such as those evaluating novel therapeutic or diagnostic agents, will not be considered.

**CMS AHRQ / **IHI Don Berwicke*

Grant proposals that include collaboration and/or partnerships with relevant professional organizations and societies are encouraged. Multi-supported proposals will be accepted.

PLEASE READ THIS DOCUMENT IN ITS ENTIRETY AND ENSURE THAT YOUR PROPOSAL INCLUDES ALL OF THE REQUESTED INFORMATION. INCOMPLETE PROPOSALS MAY NOT BE FORWARDED TO THE GRANT COMMITTEE FOR CONSIDERATION.

PLEASE DO NOT FORWARD RFP/CGA BEYOND INDIVIDUALS IN YOUR ORGANIZATION UNLESS YOU INTEND TO PARTNER WITH THEM FOR PROPOSAL SUBMISSION

- **Purpose:** Lilly is currently seeking QI Initiative proposals to improve the ability of healthcare institutions to assess and identify patients with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) early breast cancer (EBC) who have a high risk of recurrence based on clinical and pathological factors. Evidence demonstrates the following healthcare gaps that people with HR+, HER2- EBC experience:
  - Approximately 30% of patients with high-risk HR+, HER2, EBC will experience recurrence within 5 years, often with distant metastases[1,2]
  - Multiple clinical, pathological, and patient factors may be used to evaluate each patient's risk of recurrence including nodal status, grade, stage, margins, proliferation rate, age, HR & HER2 status[3-5]
  - Many patients with HR+, HER2- EBC at a high risk of recurrence are not appropriately identified and, as a result, do not receive optimal care[6-8]

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- Patients with high-risk HR+, HER2- EBC who do not receive consistent care from a multidisciplinary team (MDT) experience a higher risk of relapse and mortality than patients who receive consistent care from an MDT[9,10]

- **Budget / Due Date:** The total available budget related to this RFP/CGA is approximately **$450,000**

  Multiple Individual grants of varying budget will be considered and evaluated and may be distributed among more than one provider. The grant amount Lilly will fund will depend upon the evaluation of the proposal and costs involved, and this amount will be stated clearly in a formal Letter of Agreement.

  Institutional overhead and indirect costs ("overhead") may be included within the QI grant request. However, any included overhead should be kept to a minimum, may not exceed 30% of the total grant request, and may not cause the amount requested to exceed the budget limit set forth in the RFP/CGA. NOTE: Lilly Grant Office funding may not be used for entertainment, capital, gifts (monetary or otherwise), or personal travel. For associated QI proposal budget submission, please see attached list of recommended financial components and include this documentation when you submit your QI proposal.

  Proposal due by: 5/27/24

- **Health System Practice Gap(s):** The applicant must describe the health system practice gaps and objective data sources that were used, or will be used, to measure gaps in processes, patient care, and outcomes at baseline and at the conclusion of the QI initiative. The patient outcomes measures may include, but are not limited to:
  - Proportion of patients (# / %) with HR+, HER2- EBC who receive an assessment of risk of recurrence pre and post QI intervention
  - Proportion of patients (# / %) with HR+, HER2- EBC who are identified as high-risk of recurrence pre and post QI intervention

Preference will be given to proposals that:

1) have already undertaken baseline measures of patient outcomes that will be targeted for improvement in the QI initiative (i.e., documented the gap in the system).
2) use objective measures of system changes, process changes and patient care (e.g., data from EHR, direct observation, standardized patients, etc.).
3) estimate the expected magnitude of improvements.
4) provide information on the number of systems/clinics/practices that will be expected to participate.
5) provide estimates of the number and types of clinicians that will be involved.
6) provide the number of potential patients impacted.

- **Root Causes and Barriers:** The applicant must describe the processes and methods that were used, or will be used, to identify the root causes underlying the targeted Health System Practice Gaps that are preventing optimal patient outcomes.
  1. *Literature suggests that some potential root causes underlying these gaps include:*
     - i. *New data on prognostic and predictive factors, multigene assays, risk and assessment algorithms are rapidly emerging and may take a considerable amount of time to be integrated into institutional clinical practices[11-21]*
     - ii. *Healthcare institutions may not have optimal processes, protocols, and/or tools in place to enable accurate identification of patients at a high risk for recurrence[6]*
     - iii. *Institutions may not consistently or effectively use an MDT approach for HR+, HER2- EBC management and risk assessment[9,10,22]*

Please note that these literature-based root cause(s) may or may not be relevant to the specific system(s) targeted in your proposal. They are provided as examples for consideration. It is not

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expected that these will be addressed in the QI initiative. Each system must identify and address root causes of the greatest relevance and potential impact.

Preference will be given to proposals that:

1) use respected and standard root cause methods as recommended by IHI and AHRQ etc.
2) may already have evidence-based insights into the root causes of relevance to the system.

- **Intervention(s):** It is Lilly's intent to support a QI initiative that will lead to timely and measurable improvements in healthcare institution's ability to assess and identify patients with HR+, HER2- EBC who have a high risk of recurrence based on clinical and pathological factors. **All proposals should clearly describe and estimate the magnitude of expected improvements as a result of the QI intervention and include the number of patients who will be potentially impacted each year.**

  If the root causes have not yet been identified, it is not possible to design an effective intervention. Therefore, if root causes have not been identified, the applicant should clearly describe the approach and methods that will be used to design and implement an effective intervention(s) to address the identified root causes; including the roles, responsibilities, and experience of all individuals who will be responsible for designing and implementing the QI intervention(s).

  If a root cause(s) has already been identified, then the applicant should describe in detail the planned intervention(s), the rationale, and the implementation plan.

  Continuing Education activities or credits may be incorporated as part of the intervention if appropriate. (See QI reference #8) If your proposal includes CME/CE, programs must be accredited by the appropriate accrediting bodies and be fully compliant with all ACCME criteria and Standards for Integrity and Independence in Accredited Continuing Education.

- **Outcomes Measures:** All proposals should include detailed description of all the objective outcomes measures that will be used to measure the impact of the QI intervention; including any measures of changes in processes, clinician performance, and patient outcomes targeted by the initiative.

- **Initiative Timing:** Ideally, program will launch **Q4 2024** with a project length of **12 months**. Interim report/read out is expected **Q2 2025** and long-term sustained results should be reported as appropriate to the setting and the initiative.

  Please explain the rationale for suggested start/end dates, duration of the program and timeline for reporting any long-term results.

- **Geographic Scope:** The intended target healthcare settings for this initiative are US healthcare institutions who manage patients with HR+, HER2- EBC, but who do not have optimal or updated processes, systems, protocols, and/or multidisciplinary teams in place to ensure identification of all HR+, HER2- EBC patients who are at high risk of recurrence.

- **Eligible Applicants:** Preference will be given applicants who have a vested interest in improving the care of their patients with high-risk HR+, HER2- EBC, including those who are:
  - large integrated health delivery systems – or who partner with such entities.
  - ACOs
  - hospital systems
  - insurers who can use healthcare data to measure current gaps and outcomes.
  - Others who can directly measure and implement interventions to address gaps.

- **Qualification and Eligibility:**

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- Provide information on the QI qualifications and experience of the project leader and collaborators and include any certifications (i.e., Black Belt, Science of Improvement training), recognitions (ex: Baldridge award) and the number and type of QI projects you or your organization have successfully executed in the past.
- Provide a robust example of a past completed QI project.
- Explain any methods that will be used to ensure those expected to participate are fully trained in the program expectations and any skills that may be needed to ensure effective execution of the project.
- If you are not in direct control of the data used for measurement, please provide letters of commitment from those with direct control of data indicating full support to participate and to supply data to measure baseline and outcomes measures in a timely manner.
- If you are not in direct control of the personnel and clinicians who will likely be involved in implementing changes, please provide letters of commitment to ensure their full and timely participation from appropriate leaders in your organization.

Preference will be given to applicants who have the ability and interest in implementing successful QI interventions at other institutions. If you have the intent to scale a successful approach at other institutions, please describe your interest, ability, and overview of potential plans for subsequent dissemination in 2024-25 should your proposal be supported and successful.

Lilly encourages applicants to collaborate with similar healthcare organizations that manage patients with HR+, HER2- EBC who are at a high-risk of recurrence to demonstrate the potential for widespread dissemination of a successful approach.

Other considerations will be clinical feasibility, applicability to a variety of healthcare settings, strength of process(es) and outcomes assessments, and methodologic rigor.

- **Communication/Publication Plan:** Include a description of how the results of this QI intervention will be presented, published, or disseminated.

- **Conflict Resolution:** The proposal should briefly describe methods for ensuring fair and balanced content and identification and resolution of conflict of interest.

- **Mandatory Submission Instructions & Requirements:**

1. When submitting your proposal, you must include "QI RFP: [title of program]" in your grant submission.
2. Please limit the length of your grant proposal to **30 pages or less** (not including references and budget).
3. All responses to this QI RFP/CGA are to be submitted online through the Lilly Grant Office grant application system at https://portal.lillygrantoffice.com no later than close of business (5:00pm ET) on **May 27th, 2024**
4. ***For grant application and portal questions, please contact the lillygrantoffice@lilly.com***

Recipients of this RFP/CGA are required to treat the RFP/CGA and its contents, and any information derived there from, as CONFIDENTIAL and PROPRIETARY information.

We look forward to your response.

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SPECIFIC REFERENCES FOR THIS RFP/CGA

Healthcare Gap and Root Causes References

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Quality Improvement Resources and Bibliography:

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5. SQUIRE | HOME PAGE (squire-statement.org)
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