To: Quality Improvement Teams
From: Lilly Grant Office
Date: 6/15/2023

This Proposed Quality Improvement Initiative seeks to improve care for patients with HR+, HER2- breast cancer by implementing strategies to improve tolerability, adherence, and persistence to oral anti-cancer therapies.

Background:
A QI grant is a grant which Lilly funds to support independent projects with systematic and continuous actions that lead to measurable improvements in the delivery of care that improve the health outcome of targeted patient groups within specific health systems.

Lilly is committed to supporting QI efforts that foster the translation of scientific evidence into evidence-based clinical practice using QI theory, process and models to ultimately provide patients and providers with new ideas and insights on how to more effectively and efficiently receive and deliver optimal care. Lilly seeks to support a QI program that has the potential for widespread transferability and dissemination to other healthcare organizations.

For all independent quality improvement grants, the grant requestor (and ultimately the grantee) is responsible for the design, implementation, and supervision of the independent initiative. Lilly must not be involved in any aspect of project development nor the conduct of the quality improvement program. Lilly does not support initiatives or any medical activities, for the purpose of encouraging off-label use of our products.

<table>
<thead>
<tr>
<th>Clinical Area</th>
<th>Oncology/Breast Cancer</th>
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Lilly is requesting proposals for a quality improvement project that seeks to improve the ability of healthcare institutions who care for patients with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) breast cancer to:
- Implement strategies to improve adherence and persistence to oral therapies
- Establish/optimize organizational structures and processes regarding adherence and persistence
- Appropriately monitor, recognize and treat side effects associated with oral anti-cancer therapies
- Incorporate communication and shared-decision making (SDM) best practices and tools
- Coordinate care and communicate with the multidisciplinary team

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<tr>
<th>Clinical Practice Gap #1</th>
<th>Root Causes and Barriers #1</th>
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- Oral anticancer therapies may be a treatment option for certain patients with HR+, HER2- breast cancer.¹⁻⁷
- The reasons for nonadherence and early discontinuation of treatment in patients with HR+,
however, the primary challenge of oral therapies is ensuring patients take their medication as indicated (adherence) and for the recommended duration (persistence).8-14

- Patients who do not take their medication as prescribed or who discontinue their treatment early may not receive the full intended therapeutic benefits and consequently may be at increased risk for poorer outcomes.14-18

- HER2- breast cancer are multifactorial8,13,27
  - Barriers to adherence and persistence can be specific to type and duration of therapy, treatment toxicity, and inadequate monitoring and management of side effects 28-33
  - Healthcare institutions may lack the appropriate systems and processes to identify and manage poor adherence and persistence in patients with HR+, HER2- breast cancer27

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<tr>
<th>Clinical Practice Gap #2</th>
<th>Root Causes and Barriers #2</th>
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<tr>
<td>- Oral therapies for HR+ breast cancer are associated with diverse side effect profiles 19-22</td>
<td>- Multidisciplinary teams within healthcare institutions may find it difficult to keep up with the rapidly evolving influx of data regarding adverse events (AEs) and management strategies of available and emerging oral therapies for HR+, HER2-breast cancer35-37</td>
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<td>- Lack of routine monitoring and early recognition of side effects may contribute to suboptimal toxicity management, poor treatment adherence, as a result, poor patient outcomes19-22</td>
<td>- The increasing number of agents targeting novel pathways and in combination regimens increases the complexity of the safety data and management guidelines that HCPs need to understand to effectively manage AEs 2,35,36</td>
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<td>- Inadequate management of side effects could result in decreased QOL and early discontinuation of therapy23,24</td>
<td>- Institutions may not have systems and processes in place to appropriately monitor, recognize, and treat the side effects associated with oral therapies35-38</td>
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Clinical Practice Gap #3

- Patients are often uninformed about their disease state, treatment efficacy, and expected side effects. This may lead to poor persistence and adherence for HR+, HER2- breast cancer patients on self-administered medication plans.23,25
- The relationship of the patient with the clinician impacts the patient’s ability and willingness to report and manage side effects.23,25,26

Root Causes and Barriers #3

- Institutions may lack experience in side effect management as well as patient education and communication strategies.23,25,38,39
- Problematic patient-clinician communication and a perceived lack of clinician availability to answer questions are known factors associated with non-adherence.25-27
- Gaps in care coordination and collaboration may also impact adherence. Coordination of care and communication among the multidisciplinary team within an institution has been found to improve adherence.40-42

The QI Initiative should demonstrate measurable improvements in care for patients with HR+, HER2- breast cancer by implementing strategies to improve tolerability, adherence, and persistence to oral anti-cancer therapies through Quality Improvement methods.

Project Design

It is Lilly’s intent to support a Quality Improvement initiative that will lead to timely and measurable improvements in the care for patients with HR+, HER2- breast cancer by implementing strategies to improve tolerability, adherence, and persistence to oral anti-cancer therapies. All proposals should clearly describe and estimate the magnitude of expected improvements in 1) adherence and persistence to oral medications for patients with HR+, HER2- breast cancer, and 2) side effect management for oral therapies for these patients, through optimization of structures and processes that have been demonstrated to improve medication adherence and persistence as a result of the QI intervention.

It is expected that standard Quality Improvement methods will be used as recommended by major organizations such as the Institute for Healthcare Improvement, the CDC, the Agency for Healthcare Quality, the AAFP etc. (see examples of QI resource sites below). These methods include:

- data that quantify current practice gaps using evidence-based measures,
- identification of the root causes underlying the gap(s),
- an intervention(s) and implementation plan to close the gap,
- and re-evaluation of measures to document changes and improvements in care, processes, and outcomes.
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 fully compliant with all ACCME criteria and Standards for Integrity and Independence in Accredited Continuing Education.

The following measures for baseline and final evaluation may include but are not limited to:

- # / % of patients with HR+, HER2- breast cancer who are monitored and treated for side effects associated with oral anti-cancer therapies pre and post QI intervention
- # / % of patients with HR+, HER2- breast cancer who take their prescribed oral medication as indicated pre and post QI intervention
- # / % of patients with HR+, HER2- breast cancer who take their prescribed oral medication for the recommended duration pre and post QI intervention
- # of MDT members documenting involvement in the care of patients with HR+, HER2- breast cancer

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

**IMPORTANT:** It is not the intent of this RFP to support clinical research projects. Research projects, such as those evaluating novel therapeutic or diagnostic agents, will not be considered.

**Geographic Scope**

The intended target healthcare settings for this initiative are US healthcare institutions who diagnose and treat patients with HR+, HER2- breast cancer, but who do not have optimal or updated processes, systems, protocols, and/or multidisciplinary teams in place to ensure appropriate adherence and persistence to oral therapies.

**Eligible Applicants**

Preference will be given to: applicants who are – or partner with - large integrated health delivery systems, ACO’s, hospital systems or insurer’s who can use healthcare data to measure current gaps and outcomes, and who have a vested interest in improving the care of their patients with HR+, HER2- breast cancer.

**Qualifications/Eligibility**

Please provide information on the Quality Improvement qualifications and experience of the project leader and collaborators. Please include any certifications (i.e. Black Belt, Science of Improvement training), recognitions (ex: Baldridge award) and the number and type of quality improvement 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 to fully participate and supply data to support the project.

Preference will be given to applicants who have the potential and interest in disseminating successful QI interventions to other institutions.
### Communication/Publication Plan
Include a description of how the results of this quality improvement 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.

### Timing
Ideally, program will launch on **Q1 2024** with a project length of **12 months**. Interim report/read out is expected **Q3 2024** 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.

### Budget Guidance
Please complete the attached budget template.

The total available budget related to this RFP is approximately **$500,000**.

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

The attached Grant Request Budget and Reconciliation template will categorize the financial components of the QI programs in a consistent way. This template is not yet required by the Lilly Grant Office, but we request that you use this template to represent the budget for your RFP submission. It should be submitted in our portal following the normal upload process.

Should a grant be awarded as a result of this RFP, certain payments may be subject to reporting by Lilly pursuant to the U.S. Physician Payment Sunshine Act (“Open Payments”) - a subpart of the Patient Protection and Affordable Care Act of 2010.

### Submission Instructions
All responses to this RFP are to be submitted online through the Lilly Grant Office grant application system at [https://portal.lillygrantoffice.com](https://portal.lillygrantoffice.com) no later than close of business (5:00pm ET) on **Monday, August 7, 2023**.

**NOTE:** When submitting your proposal, please be sure to include "QI RFP: [title of program]" in your grant submission.

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

We look forward to your response.

Anatasha Hayes  
Lilly Grant Office  
hayes_anatasha@lilly.com
Specific References for this RFP:


Quality Improvement Resources and Bibliography:
1. Ihi.org; Science of Improvement | IHI - Institute for Healthcare Improvement
2. Ahrq.govHome | Agency for Healthcare Research and Quality (ahrq.gov)
3. SQUIRE | HOME PAGE (squire-statement.org)


