Request for Proposal (RFP)

Lilly USA, LLC
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To: Quality Improvement Teams
From: Lilly Grant Office
Date: 5/5/23

This Proposed Quality Improvement Initiative seeks to improve care for patients with HR+, HER2- early breast cancer by implementing strategies to improve identification, management, and timely treatment of patients with a high risk of recurrence.

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>
<tr><td>Clinical Area</td><td>Oncology/Breast Cancer</td></tr>
<tr><td>Clinical Practice Gaps and Supporting Evidence</td><td>Lilly is requesting proposals for a quality improvement project that seeks to improve the ability of healthcare institutions to:
Identify and appropriately treat hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) early breast cancer (EBC) patients with a high risk of recurrence based on clinical, pathological and biological factors
<table>
<tr><th>Clinical Practice Gaps</th><th>Root Causes and Barriers</th></tr>
<tr><td>Approximately 30% of patients with EBC will eventually develop metastatic disease[1,2]
Multiple clinical and molecular markers may be used to evaluate each patient’s risk of recurrence including nodal status, grade, stage, margins,</td><td>New data on prognostic and predictive factors, multigene assays, risk assessment algorithms, biomarkers (i.e. BRCA), and novel therapies are rapidly emerging and may take a considerable amount of time to be integrated into institutional clinical practices[11-21]
Healthcare institutions may not have optimal process, protocols,</td></tr>
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	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] • Patients with high-risk HR+, HER2- EBC who do not receive consistent care from a multidisciplinary team experience a higher risk of relapse and mortality than patients who receive consistent care from a multidisciplinary team throughout diagnosis, treatment, and follow up[9,10]
	and/or tools in place to enable accurate identification of patients at a high risk for recurrence[6] Furthermore, HCPs may not be aware of the need to more closely assess each patient's risk of recurrence if unaware of newer treatments.[6,20] • Institutions may not consistently or effectively use a multidisciplinary team approach for HR+, HER2- EBC management, risk assessment, and treatment decisions.[9,10,22] • Institutions are challenged to keep up with the rapid advances in the HR+, HER2- EBC treatment landscape and translate the available data into clinical practice to effectively target high risk patients in a timely manner [20,23,24]
	The QI Initiative should demonstrate measurable improvements in care for patients with HR+, HER2- EBC by implementing strategies to improve identification, management, and treatment of patients with a high risk of recurrence through Quality Improvement methods
Project Design	It is Lilly's intent to support a Quality Improvement initiative that will lead to timely and measureable improvements in identification, management, and treatment of HR+, HER- EBC patients with a high risk of recurrence. **All proposals should clearly describe and estimate the magnitude of expected improvements in 1) identification of EBC patients with a high risk of recurrence based on clinical, pathological and biological factors, and 2) development of optimal, evidence-based treatment plans for patients with high-risk EBC 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.

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	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- EBC who receive appropriate testing and assessment of risk of recurrence pre and post QI intervention • # / % of patients with HR+, HER2- EBC who are identified at high-risk of recurrence pre and post QI intervention • # / % of HR+, HER2- EBC high-risk patients who receive appropriate Tx according to best evidence • # of MDT members documenting involvement in the care of patients with HR+, HER2- EBC 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- 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 and who may benefit from new treatment options that have been developed.
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- EBC.
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 from partnering institutions that clearly state they will fully participate in all aspects of the project including, supplying all the data required to measure current gaps and changes.

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	Preference will be given to applicants who have the potential and interest in disseminating successful QI interventions to other institutions. Lilly encourages applicants to collaborate with similar healthcare organizations that treat patients with HR+, HER2- EBC cancer to demonstrate the potential for widespread dissemination.
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 as relevant to the QI project and/or any CE component of the intervention.
Timing	Ideally, program will launch in **Q4 2023** with a project length of **12 months**. Interim report/read out is expected **Q2 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 no later than close of business (5:00pm ET) on Tuesday, June 6, 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.

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Specific References for this RFP:

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5. Brandt J., Garne J.P., Tengrup I., Manjer J. Age at diagnosis in relation to survival following breast cancer: a cohort study. World J Surg Oncol. 2015 Feb 7;13(33). doi: 10.1186/s12957-014-0429-x.
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12. Győrffy B,Hatzis S, Sanft T et al. Multigene prognostic tests in breast cancer: past, present, future *Breast Cancer Res*. 2015;17(1):11.
13. Pistilli, B, Paci A,, Arlindo R. Ferreira et al. Serum Detection of Nonadherence to adjuvant Tamoxifen and Breast Cancer Recurrence Risk. *Journal of Clinical Oncology.* 2020;38(4):2762-2772.
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Quality Improvement Resources and Bilbliography:

1. Ihi.org; Science of Improvement | IHI - Institute for Healthcare Improvement Quality Improvement Essentials Toolkit | IHI - Institute for Healthcare Improvement
2. Ahrq.govHome | Agency for Healthcare Research and Quality (ahrq.gov)
3. SQUIRE | HOME PAGE (squire-statement.org)
4. Ogrinc G, Davies L, Goodman D, Batalden P, Davidoff F, Stevens D. SQUIRE 2.0 (Standards for QUality Improvement Reporting Excellence): Revised Publication Guidelines from a Detailed Consensus Process. Perm J. 2015 Fall;19(4):65-70. doi: 10.7812/TPP/15-141. PMID: 26517437; PMCID: PMC4625997.
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6. Davies L, Batalden P, Davidoff F, Stevens D, Ogrinc G. The SQUIRE Guidelines: an evaluation from the field, 5 years post release. BMJ Qual Saf. 2015;24(12):769-775.
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