Sharing Progress in Cancer Care

Lilly

Improving Care of Early Breast Cancer (EBC) Patients in Europe 2023 RFP Project

BACKGROUND

Sharing Progress in Cancer Care and Lilly are collaborating to offer a grant opportunity seeking proposals in support of improving care of early breast cancer (EBC) patients in Europe. A **Quality Improvement 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 status of targeted patient groups within specific health systems. Proposals that have the most potential to directly impact the quality of care for EBC patients within European health systems will be prioritised.

Sharing Progress in Cancer Care (SPCC) is an independent non-profit organisation, registered in Switzerland, dedicated to providing projects, programmes and initiatives (live and online) to share and integrate knowledge and information on scientific progress, innovation, and best practices in the Cancer Care Continuum from prevention to early diagnosis, treatment, and support after treatment. SPCC's vision is to promote both multiprofessional and multidisciplinary dialogue, understanding and collaboration as well as the sharing, integration, and implementation of the knowledge between all stakeholders across the Cancer Care Continuum, listening and answering to patients' diverse needs across continents.

Lilly is committed to supporting Quality Improvement (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 programme that has the potential for widespread transferability and dissemination to other healthcare organisations.

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 programme. Lilly does not support initiatives or any medical activities for the purpose of encouraging off-label use of any product.

This Request for Proposal (RFP) is being issued by both organisations. SPCC is the lead organisation for review and evaluation of proposals. A review committee, led by SPCC, will make decisions on which proposal(s) will receive funding. Grant funding and general oversight of the funded projects will be provided directly by the Lilly Grant Office. A total of $500,000 USD is available for award.

The intent of the RFP is to encourage European healthcare systems, cancer care centres or networks to submit Letters of Intent (LOIs) describing concepts and ideas for the implementation of strategies which will measurably improve the quality of care of early breast cancer (EBC) patients.

SCOPE

SPCC and Lilly are committed to funding projects that:

- Bring the health care team together, including innovative organisations, to understand gaps in practice and develop strategies to improve care/close the gap.
- Further identify quality and performance gaps in the treatment of EBC with deeper analyses and understanding of gaps and needs of those targeted and/or included in the intervention. These can encompass a broad set of areas. Needs may include improved provider knowledge regarding clinical aspects and extend to organisational, logistical, as well as technological gaps.
- Facilitate health care systems and providers to engage patients, their caregivers, and families in shared decision-making.
- Use evidence-based educational strategies that are aligned with the desired results of the intervention.

Other considerations include, but are not limited to, the following: clinical feasibility, applicability to a variety of healthcare settings, strength of process and outcomes assessments, and methodologic rigor.

This RFP is open to investigators from European institutions and networks (members or not of OECI) will be considered as well as professional societies and patient advocacy groups. Collaboration between institutions and across European countries is strongly encouraged in order to share knowledge and expertise. Preference will be given to applicants 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 early breast cancer.

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.

CLINICAL PRACTICE GAPS

HCPs involved in the management of EBC have to consider several factors when evaluating recurrence risk and treatment options for patients with early stage potentially curable breast cancer. New data and guidelines are rapidly emerging to guide patient assessments to inform recurrence risk (i.e., clinical and pathological factors validated in clinical trials) and optimal individualised treatment planning. [1–6]

Because of the time it can take for new and emerging data to be effectively integrated into practice, patients with EBC may not receive optimal treatment. [7–8]

A gap in clinical practice is considered to be the difference between current practice and the optimal standard of care. Gaps are associated with a combination of:

- Clinician factors (e.g., knowledge, competencies, attitudes or preferences).
- Patient factors (e.g., access to care, clinical characteristics, comorbid conditions, preferences, Quality of Life (QOL), work, family).
- Clinician and patient communication (e.g., clinical trial recruitment, genetic counselling, access to genetic testing).
- Health system organisation including care processes (integrated breast cancer care vs. practice-based EBC care), resources, availability of all required aspects of care including access to genetic testing.

Gaps in clinical practice may relate to the ability or competencies of the health care professionals themselves, the abilities or competencies of the systems in which they work to promote or allow proper management, or other factors related to the external environment or patient population.

This RFP seeks to provide funding to projects that, ultimately, are aimed at helping health care providers deliver the best treatment to each patient at the optimal time.

Needs may include improved provider knowledge regarding clinical aspects (i.e., pathology, psychosocial aspects of care, and mechanism of action and toxicities of treatment choices) and extend to organisational, logistical, as well as technological gaps. (i.e., inequities in access to care, disparities in digital or basic infrastructure).

AREAS OF INTEREST

- Optimal treatment strategies to individualise care for patients with EBC through timely and measurable improvements in the identification of biological and clinical features indicating a higher risk of recurrence.
- Delivering optimal treatment regardless of HCP discipline and wherever there is a point of interaction for a patient with EBC (surgeons, gynaecologists, oncology nurses, pharmacists).
- Leveraging a multi-disciplinary team and approach to improve patient quality of EBC delivery of care.
- Therapy management strategies supporting adherence and persistence to treatment.
- Supporting patient education and HCP communication, shared decision-making best practices and tools for discussing treatment goals and risks/benefits of treatment.
- Patient reported outcomes in EBC patients.

LOIs addressing topics in addition to those listed above will be considered.
A plan for long-term sustainability should be included within the submission.

LETTER OF INTENT/PROPOSALS

This RFP model employs a 2-stage process:

Stage 1 is the submission of the LOI (see Submission Instructions section below for how to submit LOI). If an LOI is selected, the applicant will be invited to

Stage 2 to submit a full programme proposal into the Lilly Grant Office portal.

The SPCC Request for Proposal Development Panel (SFPDP) has been formed to oversee this process and will utilise a formalised review procedure to accept LOIs and subsequently select the proposals of highest scientific merit and will perform the peer review of applications.

Members of the SFPDP are (* members who have been previously paid by Lilly for investigation or consulting services):

***Luis Costa**, Oncology Division, Hospital Santa Maria, Centro Hospitalar Universitário Lisboa Norte; Faculty of Medicine, Universidade de Lisboa; Instituto de Medicina Molecular João Lobo Antunes, Faculty of Medicine, Universidade de Lisboa, Lisbon, Portugal
Amanda Drury, EONS Board, Chair of the Research Working Group, Dublin, Ireland
Martina Fontana, EUROPA DONNA Policy and Research Officer, Milan, Italy
Joseph Gligorov, Hospital Tenon Ap-Hp, Paris, France
***Nadia Harbeck**, Breast Center, LMU University Hospital, Munich, Germany
Roberto Orecchia, IEO European Institute of Oncology IRCCS, Milan, Italy
Frederique Penault-Llorca, Jean Perrin Center, Clermont-Ferrand, France
Isabel T. Rubio, Breast Surgical Unit, Clínica Universidad de Navarra, Madrid, Spain

REQUIREMENTS

Clinical Area	Oncology - Early Breast Cancer
Eligible Applicants	Healthcare institutions, large and small, health care professional organisations, academic/research centres in the areas of healthcare management, health policy and health economics and other organisations with a mission related to health care improvement. Academic and Community Centres. Professional Societies and Patient Advocacy Groups. Open to any type of care delivery system with the exception of individual physician-owned practices. To ensure this unique independent programme is aligned with various country-specific legal and compliance requirements, we are only accepting **proposals from Germany, Austria, Poland, Switzerland, Spain, Portugal, and Italy at this time. No other proposals will be evaluated.**

Key Dates	**LOI Deadline:** 26 May 2023 **Anticipated LOI Notification Date:** 14 July 2023 **Full Proposal Deadline:** 1 September 2023 **Only accepted LOIs will be invited to submit full proposals.* **Anticipated full proposal notification date:** 15 November 2023 **Anticipated period of performance:** November 2023 to October 2025 (projects may have a shorter timeline but must not be longer than 2 years). Please explain the rationale for suggested start/end dates, duration of the programme and timeline for reporting any longterm results.
Budget Guidance	The total available budget related to this RFP is approximately $500,000 USD. Individual projects requesting up to $250,000 USD (including direct and indirect costs) will be considered; smaller, lower-cost projects are also strongly encouraged. Institutional overhead and indirect costs may be included within the grant request but the inclusion of these costs cannot cause the amount requested to exceed the budget limit set forth in the RFP. 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. 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 or other applicable country-specific reporting requirements. The "Improving Care of Early Breast Cancer (EBC) Patients in Europe – 2023 RFP Project" will be conducted in accordance with the EFPIA code requirements. More information via working-together-for-patients-grants-and-donations.pdf (efpia.eu).

Submission Instructions	Letter of Intent (LOI) should be submitted using this **Form (click here to access)** no later than 11:59 pm U.S. Eastern Time (New York) on 26 May 2023 / 05:59 am CEST (Central European Summer Time) on 27 May 2023. Complete all sections of the linked form referring to the included guide and available in the Appendix of this RFP.
Questions	If you have questions regarding this RFP, please direct them in writing to Lilly's Grant Officer, Rebeccah Bodine, at rbodine@lilly.com with the subject line "SPCC Lilly EBC QI Initiative".
Applicant Notifications	All applicants will be notified via email by the anticipated dates noted above. Applicants may be asked for additional clarification or to make a summary presentation during the review period. Following LOI submission, if invited to apply with a full proposal, instructions for Stage 2 full proposal submission will be communicated from the Lilly Grant Office.

APPENDIX: LETTER OF INTENT SUBMISSION REQUIREMENTS

The Letter of Intent (LOI) will be accepted using the form linked in the Submission Instructions section earlier in this document. We kindly ask that submission be succinct. When answering the LOI questions in the form, please keep the following in mind:

Goals and Objectives	Briefly state the overall goal of the project. Also describe how this goal aligns with the focus of the RFP and the goals of the applicant organisation(s). List the overall objectives you plan to meet with your project both in terms of learning and expected outcomes. Objectives should describe the target population as well as the outcomes you expect to achieve as a result of conducting the project.

Assessment of Need for the Project and Preliminary Data	Please, 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 how measures will be re-evaluated to document changes and improvements in care, processes, and outcomes. Other considerations will be clinical feasibility, applicability to a variety healthcare setting, strength of process and outcomes assessments, and methodologic rigor.
Target Audience	Describe the primary audience(s) targeted for this project. Also indicate whom you believe will directly benefit from the project outcomes. Describe the overall population size as well as the size of your sample population.
Project Design and Methods	Describe the planned project and the way it addresses the established need. If your methods include educational activities, please describe succinctly the topic(s) and format of those activities.
Innovation	Explain what measures you have taken to assure that this project idea is original and does not duplicate other projects or materials already developed. Describe how this project builds upon existing work, pilot projects, or ongoing projects developed either by your institution or other institutions related to this project.
Evaluation and Outcomes	In terms of the metrics used for the needs assessment, describe how you will determine if the practice gap was addressed for the target group. Describe how you expect to collect and analyse the data. Quantify the amount of change expected from this project in terms of your target audience. Describe how the project outcomes will be broadly disseminated.
Anticipated Project Timeline	Provide an anticipated timeline for your project including project start/end dates.
Additional Information	If there is any additional information you feel SPCC and Lilly should be aware of concerning the importance of this project, please summarise here.

Organisation Detail	Describe the attributes of the institutions / organisations / associations that will support and facilitate the execution of the project and the leadership of the proposed project. Articulate the specific role of each partner in the proposed project. Letters of support from partner organisations will be required at the Full Proposal stage only and should not be included with the LOI. 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 organisation 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 programme 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.
Budget Detail	A total amount requested is the only information needed for the LOI stage. Full Budget is not required. This amount can be adjusted at the Full Proposal stage as applicable. The budget amount requested must be in U.S. dollars (USD). While estimating your budget please keep the following items in mind: • Institutional overhead and indirect costs may be included within the grant request but the inclusion of these costs cannot cause the amount requested to exceed the budget limit set forth in the RFP. • Lilly does not provide funding for capital equipment.

Specific References for this RFP:

1. Dowsett, M, Turner, N. Estimating Risk of Recurrence for Early Breast Cancer: Integrating Clinical and Ge-nomic Risk. Journal of Clinical Oncology 2019 37:9, 689-692
2. Regan, M. Risk stratification according to stage and pathology The Breast 48S1 (2019) S23–S25
3. Dowsett, M, Turner, N. Estimating Risk of Recurrence for Early Breast Cancer: Integrating Clinical and Ge-nomic Risk. Journal of Clinical Oncology 2019 37:9, 689-692
4. Fasching PA, Gass P, Häberle L, et al. Prognostic effect of Ki-67 in common clinical subgroups of patients with HER2-negative, hormone receptor-positive early breast cancer. Breast Cancer Res Treat. 2019;175(3):617-625.doi:10.1007/s10549-019-05198-9
5. Cardosa, F, Kyriankides S, Curigliano G, et al. Early Breast Cancer: ESMO Clinical Practice Guidelines Ann Oncol. 2019 30: 1194-1220
6. Krauss K, Stickeler E: Endocrine Therapy in Early Breast Cancer. Breast Care 2020; 15:337-346
7. Morris ZS, Wooding S, Grant J. The answer is 17 years, what is the question: understanding time lags in translational research. J R Soc Med. 2011;104(12):510-520.
8. Hanna T, King W, Thibodeau S, et al. Mortality due to cancer treatment delay: systemic review and meta-a-nalysis. BMJ 2020; 371 doi: https://doi.org/10.1136/bmj.m4087

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.gov Home | 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.
5. Goodman D, Ogrinc G, Davies L, et al. Explanation and elaboration of the SQUIRE (Standards for Quality Improvement Reporting Excellence) Guidelines, V.2.0: examples of SQUIRE elements in the healthcare improvement literature. BMJ Qual Saf. 2016;25(12): e7.
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.
7. Davidoff F, Batalden P, Stevens D, Ogrinc G, Mooney S; SQUIRE Development Group. Publication guidelines for quality improvement in health care: evolution of the SQUIRE project. Qual Saf Health Care. 2008 Oct;17 Suppl 1 (Suppl_1): i3-9. doi: 10.1136/qshc.2008.029066. PMID: 18836063; PMCID: PMC2773518.
8. http://jeffline.jefferson.edu/Jeffcme/Quality/pdfs/CME%20and%20QI%20A%20Match%20Made%20in%20Heaven%20Annals%20of%20Medicine%202012.pdf