**NCCN/Eli Lilly and Company Quality of Care in Gastric Cancer Request for Proposals (RFP)**

**I. Introduction**

National Comprehensive Cancer Network® (NCCN®) and Eli Lilly and Company (Lilly) are collaborating to offer a new opportunity seeking proposals to bridge the gaps in care for gastric and gastroesophageal junction (GEJ) cancer patients in the United States. Multiple factors contribute to the complexity of treating the disease, including managing treatment and disease-related side effects; nutritional challenges after gastrectomy or in advanced disease; optimizing health outcomes in survivorship, communicating with patients, caregivers and family members about quality of life, treatment options, and goals of care; as well as navigating employment, insurance and financial toxicities, and healthcare system-based challenges.

The intent of this RFP is to encourage US organizations to submit letters of intent (LOIs) describing concepts and ideas for developing, implementing and evaluating programs that close clinical practice gaps and improve the quality of care for patients with gastric/GEJ cancer through increased adherence to evidence-based medicine guidelines, and improved competence and performance of healthcare providers and healthcare systems. Investigations aimed at improving quality of gastric/GEJ cancer care at all stages of disease, and at all timepoints along the clinical care continuum for gastric/GEJ cancer, will be considered. Special consideration will be given to projects that address gaps in clinical care with interventions that are easily scalable, reproducible, and rapidly implementable in multiple clinical practice sites (i.e. academic, community, urban, rural, etc.). The committee will consider other proposals of interest if a compelling rationale to study a specific issue is provided. Through improving the quality of cancer care, this RFP aims to improve translation of best practices and current data in gastric/GEJ cancer to the larger cancer community.

Cancer care delivery systems are often inefficient and require optimization to allow for more effective patient care. NCCN and Lilly recognize the need to improve collaborations between comprehensive cancer centers and community hospitals in the treatment of gastric/GEJ cancer patients, as well as to ensure that all providers are knowledgeable about the complex needs and treatment options for this disease. Supporting healthcare professionals in their efforts to maintain and improve their knowledge and ability to treat gastric/GEJ cancer patients is critical to improving patient care by attaining the best outcomes in survival and quality of life. In addition, providing resources and education to patients, their caregivers, and family members is crucial to help ensure they are informed and can participate in the shared decision-making process.

Lilly is a global healthcare leader that unites caring with discovery to create medicines that make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease and give back to communities through philanthropy and volunteerism. For more than 50 years, Lilly has been dedicated to delivering life-changing medicines and support to people living with cancer and those who care for them. Lilly is determined to build on this heritage and continue making life better for all those affected by cancer around the world.
NCCN, a not-for-profit alliance of twenty-seven (27) leading cancer centers, is dedicated to improving the quality, effectiveness and efficiency of care provided to patients with cancer. 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 healthcare delivery system. World renowned experts from NCCN Member Institutions, who diagnose and treat patients with a broad spectrum of cancers and are recognized for dealing with complex, aggressive, or rare cancers, are integral to the execution of this program.

This Request for Proposals (RFP) is being issued by both organizations. NCCN is the lead organization for review and evaluation of applications. A review committee, led by NCCN, will make decisions on which proposals will receive funding. Project funding will be provided directly by Lilly, subject to mutual agreement of project terms and conditions. This RFP is open to all interested parties, regardless of NCCN affiliation.

II. Background

Gastric cancer is the third leading cause of cancer-related deaths globally. Risk factors for gastric cancer include genetic risk, gender, race, geographical location, specific infections, and poor health behaviors including obesity, which affects at least 30% of the US adult population. Treatments for gastric/GEJ cancer may include gastrectomy or esophagectomy, use of multi-agent chemotherapy, radiation therapy, need for enteral (tube) or intravenous (TPN) feedings, and modified eating and dietary habits requiring alterations in food preparation or eating schedules. The long-term effects of these therapies can include physical symptoms such as neuropathy, weight loss, nutritional deficiencies or dumping syndrome; psychologic effects including distress and anxiety around eating; practical challenges including employment re-entry, sleep disruption, and financial burden; and other issues that ultimately affect quality of life and other clinical outcomes.

Current standards of care are defined by three clinical practice guidelines, each informed by a large body of evolving clinical data. NCCN publishes guidelines that are updated in real-time and define the US standards of care. The European Society of Medical Oncology (ESMO) and the Japan Gastric Cancer Association have published similar guidelines in the past four years. These guidelines define standards of care around the world, and typically inform insurance reimbursement and clinical pathway development. Yet, despite the presence of guideline-recommended clinical care, there is wide variation in the delivery of front-line and second-line therapies, with only 61% and 40% of GEJ and gastric cancer patients receiving any therapy in the metastatic setting. In addition, of those who receive front-line therapy, only 64% go on to receive second-line therapy despite multiple studies now demonstrating a survival benefit for single agent and combination therapies. Recent data suggest that novel agents may have clinical benefit in later line settings. Thus, optimizing clinical care to ensure that gastric/GEJ cancer patients receive all appropriate therapies could improve long-term survival.

Oncology providers and gastric/GEJ cancer patients and survivors must understand and navigate the myriad of nutritional and other practical challenges posed by this diagnosis. Survivorship care is complex and may be delivered in a number of different ways that could involve oncologic physicians, advanced practice clinicians, primary care providers, and allied health professionals. Understanding the nutritional needs and potential symptom burden of patients who have undergone a gastrectomy or distal esophagectomy requires familiarity with symptom burden and management, management of vitamin
deficiencies, dietary and physical activity guidelines, and available resources within a given community and nationally. Survivors and those living with metastatic disease may also face practical challenges such as cost of cancer care and addressing work ability after or during treatment, as only 53% of gastric cancer patients remain employed two years after diagnosis.³

Current data reveal that 21% of gastric cancer patients are treated at academic centers; 31% in hospital-based clinics and 48% in private practice.⁴ With a private or community-based practice, gastric/GEJ cancer patients may represent only a small fraction of the total volume of patients seen annually. Each of these practice settings has specific benefits and challenges, in addition to challenges presented by the disease and current healthcare environment. This RFP seeks to identify and address any one or number of these patient/survivor, provider, or healthcare system-level challenges.

III. Scope

The overall aim of this RFP is to develop innovative strategies to improve the quality of care received by gastric/GEJ cancer patients through novel, reproducible, scalable and implementable solutions. It is hoped that results from projects funded can be quickly disseminated to other practices and settings to rapidly improve delivery of cancer care. The goal is to provide funding to projects that, ultimately, are aimed at helping healthcare professionals deliver the best treatment to each patient at the optimal time.

This RFP is open to investigators within the United States and is not limited to NCCN Member Institutions. Investigators from community settings, support organizations, patient advocacy organizations, and other forums are encouraged to apply. Collaboration between entities and inclusion of a community practice co-investigator is encouraged.

Only projects specific to the care of gastric/GEJ patients will be considered for funding.

The areas of research emphasis identified for this RFP include the following:

1. Opportunities for innovative programs, *tools, technologies and clinical pathways or platforms to improve:
   - Adherence to evidence-based medicine guidelines, including, when appropriate, choosing systemic regimens based on current, best practices for the treatment of gastric/GEJ cancer.
   - Collaboration between comprehensive cancer centers and community hospitals.
   - Patient safety during treatment and patient adherence to treatment.
   - Holistic and integrative or evidence-based complementary medicine support programs that may include but not limited to nutrition, physical activity, psychosocial counseling, and financial counseling.
   - Multidisciplinary collaborations within the community setting. May include partnerships with businesses, foundations or organizations whose mission is to improve the everyday life of persons with gastric/GEJ cancer and their caregivers.

*Such tools, however, would not be of a nature typically core to the operation of a medical practice (capital equipment, staff, etc.). Such tools should also not focus on outcomes, which target metrics specific to increasing reimbursement by government programs.
2. **Opportunities to address gaps in clinical practice (including clinician, patient, healthcare system, financial, organizational factors) through improving:**
   - Healthcare professional competencies (excluding requests for Continuing Medical Education (CME) grants).
   - Healthcare system-based management.
   - Patient oriented solutions.
   - External factors that impact patient care and clinical outcomes.

**Areas of particular interest include:**
1. Quality Improvement around adherence to evidence-based standards of care for gastric/GEJ cancer.
2. Use of technology to improve quality of care, supportive care and overall quality of life in gastric/GEJ cancer patients.
3. Survivorship care planning specific to this patient population. May include aspects mentioned in the areas of research emphasis identified above.
4. Rational use of integrative medicine and optimal multi-disciplinary care of gastric/GEJ patients.

NCCN and Lilly encourage proposals to improve clinical processes and improve the quality of gastric/GEJ cancer patient care. Proposals should focus on quality improvement in all stages of gastric/GEJ cancer. They may be pilot projects or build on already existing pilot projects.

**All proposals funded must:**
1. Promote evidence-based care.
2. Be sustainable after the award funding is complete (such that Lilly will have the right without further payment to use any and all materials from the project for any purpose).
3. Collect data and report outcomes and permit sharing of data with Lilly.
4. Have a goal to enhance clinical outcomes, patient satisfaction, or provider satisfaction.
5. Be flexible enough to address patient variability.
6. Promote administrative and system efficiency.

In addition, proposals that are scalable, reproducible, and quickly implementable, with tangible outcomes, are preferred. Ideally, proposed projects will offer a roadmap with a short runway to launch and demonstrate the ability to stick to timelines for deliverables.

**Specific exclusions from this RFP include:**
1. CME
2. Therapeutic clinical trials addressing the treatment of gastric/GEJ cancer, for example with investigational agents
3. Correlative studies involving evaluation of novel biomarkers
4. Basic science, modeling, or virtual experiments

**Researchers seeking funding for therapeutic clinical research projects will not be considered under this RFP.**
IV. Letters of Intent/Proposals

This RFP model employs a 2-stage process: Stage 1 is the submission of the 3-page LOI. If an LOI is selected, the applicant will be invited to Stage 2 to submit a full proposal.

Successful applicants will be able to describe the specific clinical practice gaps that exist for their own providers, healthcare system, or patient community and describe what they will do to close these gaps or problems. Site-specific obstacles to success should be identified and coupled with strategies to overcome the obstacles.

Programs must describe how the intervention, when implemented, will directly affect patient care and provide evidence of scalability (e.g., integration with an electronic medical record system), sustainability (e.g., plan for dissemination/applicability beyond the proposed institution), and can be completed within the timeframe specified.

The NCCN Peer Review of Proposals Committee (PRPC) has been formed to oversee this process and will utilize a formalized review procedure to accept LOIs and subsequently select the proposals of highest scientific merit. The NCCN PRPC has overseen the development of the RFP and will perform the peer review of applications.

V. Requirements

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<thead>
<tr>
<th>Date RFP Issued:</th>
<th>September 12, 2018</th>
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<tbody>
<tr>
<td>Clinical Area:</td>
<td>Gastric/GEJ Cancer</td>
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<tr>
<td>Target Audience:</td>
<td>Members of the healthcare team and administrators or any business, advocacy group, organization or individual involved in the care of gastric/GEJ cancer patients. Specific populations may include those living in underserved communities, the elderly, patients lacking supportive care or designated caregiver(s) during treatment, younger persons with children, patients who wish or must continue to work while undergoing treatment, and patients struggling with post-treatment related issues.</td>
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<td>Applicant Eligibility Criteria:</td>
<td>Healthcare institutions, large and small, healthcare professional organizations, advocacy groups, and other organizations or businesses with a mission related to healthcare or overall improvement of wellness and quality of life for persons diagnosed with gastric/GEJ cancer.</td>
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<td>Expected Approximate Monetary Range of Applications:</td>
<td>Individual projects requesting up to $250,000 will be considered; smaller, lower-cost projects are strongly encouraged.</td>
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### Estimated Key Dates:

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<th>Event</th>
<th>Date</th>
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<tr>
<td>LOI Deadline</td>
<td>October 24, 2018</td>
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<tr>
<td>Anticipated LOI Notification Date</td>
<td>December 12, 2018</td>
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<tr>
<td>Full Proposal Deadline</td>
<td>January 23, 2019</td>
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<tr>
<td>Anticipated Full Proposal Notification Date</td>
<td>March 13, 2019</td>
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Projects will be contracted directly with Lilly & may require assessment and approval per Lilly internal processes prior to execution.

*Funding distributed following execution of fully signed Letter of Agreement with mutually acceptable terms and conditions describing project scope, Lilly's involvement, and specific delineation of responsibilities.*

Period of Performance: Two years

### How to Submit:

Please email LOI submission to [NCCNGastricProject@nccn.org](mailto:NCCNGastricProject@nccn.org)

**IMPORTANT:** Be advised LOIs submitted to the wrong email address or after the due date will not be reviewed by the committee.

### 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;
- Dissemination strategies.

### Questions:

If you have questions regarding this RFP, please direct them in writing to Nicole Kamienski at [kamienski@nccn.org](mailto:kamienski@nccn.org) with the subject line “2018 Gastric Project”.

### Mechanism by which Applicants will be Notified:

All applicants will be notified via email by the anticipated dates noted above.

Applicants may be asked for additional clarification if needed by the PRPC.

### VI. Letter of Intent Submission Guidance

The LOI is a brief concept document that describes the proposed project at a **high level**. The Proposal Review Committee will select LOIs that are best aligned with the purpose of the RFP. All applicants will be notified with either an acceptance or a declination. Successful applicants will be asked to submit a full proposal for funding consideration.
LOIs should be single-spaced using Calibri 12-point font and 1-inch margins. There is a 3-page limit for the main section and a 1-page limit for organizational detail. If extensive, references may be included on 1 additional page. Final submissions should not exceed 5 pages in total (3 pages for the main section, 1 page for organizational detail, and 1 page for references).

All required sections should be combined in one document (MS Word or Adobe PDF). There is no need to submit the organization detail or references in a document separate from the main section of the LOI.

Please note the formatting and page limit for the LOI. The LOI is inclusive of additional information of any kind. A submission exceeding the page limit WILL BE REJECTED and RETURNED UNREVIEWED.

LOIs should include the following sections:

Main Section (not to exceed 3 pages):

1. Project Title
2. Organization(s) involved
3. Principal Investigator
4. Focus of Project:
   • Program, tool, technology or clinical pathway
   • Addresses gaps in clinical practice
5. Goal 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 organization(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.
6. Assessment of Need for the Project
   • Please include a quantitative baseline data summary, initial metrics (e.g., quality measures), or a project starting point (please cite data on gap analyses or relevant patient-level data that inform the stated objectives) in your target area. Describe the source and method used to collect the data. Describe how the data was analyzed to determine that a gap existed. If a full analysis has not yet been conducted, please include a description of your plan to obtain this information.
7. 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.
8. 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.

9. 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.

10. 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 analyze 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.

11. Anticipated Project Timeline

12. Requested Budget
• 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:
  o Institutional overhead and indirect costs may not be included within LOI. However, operational costs, which can be assessed for a fair market value to support the services required to execute the project, may be included. Examples include project expenses such as costs for publication, IRB / IEC review fees, software license fees, and travel. Please note: Lilly does not provide funding for capital equipment, staff or other items deemed transfers of value in a manner that would violate the Anti-Kickback Statute.
  o The inclusion of these costs cannot cause the amount requested to exceed the budget limit set forth in the RFP.
  o It should be noted that project awards through Lilly cannot be used to purchase therapeutic agents (prescription or non-prescription).

13. Additional Information
If there is any additional information you feel the PRPC should be aware of concerning the importance of this project, please summarize it in within the page limitations.

14. Organizational Detail (not to exceed 1 page)
Describe the attributes of the institutions/organizations/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 organizations will be required at the Full Proposal stage only and should not be included with the LOI.
Please note that any project partners listed in this section should also be listed within the online system. If a partnership is only proposed, please indicate the nature of the relationship in the Organizational Detail section of your LOI.

VII. Full Proposals

A limited number of applicants will be invited to submit for consideration a full proposal of no more than 10 pages, accompanied by a line-item budget. The full proposal format will be shared with the invitation to submit.

VIII. Terms and Conditions

This RFP does not commit Lilly or its partners to award a project of any particular size if one is awarded, nor to pay any costs incurred in the preparation of a response to this request.

Lilly reserves the right to accept or reject any or all applications received as a result of this request, or to cancel this RFP in part or in its entirety, if it determines it is in the best interest of Lilly to do so.

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. Project recipients will need to maintain a separate end-user or other license agreement directly with NCCN for use of the NCCN Guidelines.
IV. References


