

# **NCCN/AstraZeneca Quality of Care Evaluations in Advanced Ovarian Cancer Request for Proposals (RFP)**

## **I. Introduction**

National Comprehensive Cancer Network® (NCCN) and AstraZeneca Pharmaceuticals (AstraZeneca) are collaborating to offer a new funding opportunity for improving patient care and outcomes in Stage III, Stage IV and recurrent epithelial ovarian cancer (EOC). Multiple factors contribute to the complexity of treating the disease. Women with a diagnosed or suspected diagnosis of ovarian cancer are often not provided guideline-based care and/or do not receive care from those with a subspecialty training experience in gynecologic oncology. Ovarian cancer care is often uncoordinated and fragmented, and patients are not uniformly offered the opportunity to participate in clinical trials. In many treatment settings supportive services required to care for patients are not readily available or are underutilized and/or undervalued. The current system offers limited accountability; thus the goal of consistent high quality care remains elusive.

Supporting health care professionals in their efforts to maintain and improve their knowledge, ability, and performance related to treating patients with advanced stage/recurrent ovarian cancer is critical to improving patient care. Current health care delivery takes place in a very complex system which rewards amount and intensity of therapy rather than proper coordination of care and quality. It is also essential that women receive early access to the health care providers best qualified to help them. 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.

The intent of this RFP is to encourage investigators at NCCN Member Institutions to submit letters of intent (LOIs) describing concepts for developing, implementing, and evaluating initiatives to improve patient outcomes in Stages III/IV and recurrent EOC. Studies aimed at enhancing the quality of multiple aspects of patient interaction and management throughout the clinical care continuum will be eligible. Special consideration will be given to “outside the box” innovative projects, with a special focus on optimizing testing and effectiveness of new healthcare-related paradigms.

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 ovarian cancer to the larger cancer community to help bridge the gap between high volume academic centers and smaller community practices.

NCCN is a not-for-profit alliance of 28 leading cancer centers devoted to patient care, research, and education. NCCN is dedicated to improving and facilitating quality, effective, efficient, and accessible cancer care so patients can live better lives. 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 health care delivery system. By defining and advancing high-quality cancer care, NCCN promotes the importance of continuous quality improvement and recognizes the significance of creating clinical practice guidelines appropriate for use by patients, clinicians, and other health care decision-makers around the world.

AstraZeneca has a deep-rooted heritage in Oncology and offers a quickly-growing portfolio of new medicines that has the potential to transform patients' lives and the Company's future. With at least six new medicines to be launched between 2014 and 2020, and a broad pipeline of small molecules and biologics in development, we are committed to advance Oncology as a key growth driver for AstraZeneca focused on lung, ovarian, breast and blood cancers. In addition to our core capabilities, we actively pursue innovative partnerships and investments that accelerate the delivery of our strategy, as illustrated by our investment in Acerta Pharma in hematology.

By harnessing the power of four scientific platforms – Immuno-Oncology, Tumor Drivers and Resistance, DNA Damage Response and Antibody Drug Conjugates – and by championing the development of personalized combinations, AstraZeneca has the vision to redefine cancer treatment and one day eliminate cancer as a cause of death.

This Request for Proposals (RFP) is issued by NCCN. A review committee of ovarian cancer experts from NCCN Member Institutions will make decisions on which proposals will receive funding. Funding will be provided by NCCN through funding from AstraZeneca. Funding is available only to applicants from NCCN Member Institutions.

## **II. Background**

Advanced stage ovarian cancer is the most lethal gynecologic cancer with limited curative options. Patients with ovarian cancer have extended clinical histories spanning many months to years, thus often requiring highly coordinated, multi-disciplinary, evidence-based care delivered for years to optimize both survival and quality of life. While most will respond to initial treatment, many will experience disease relapse. Some of the challenges of managing ovarian cancer come from the heterogeneity of the disease, the high incidence of recurrence, the limited efficacy of second line chemotherapeutic options and the lack of data on optimal sequencing of available agents. Fragmented delivery of care may lead to poor outcomes in patients with advanced stage/recurrent ovarian cancer.

There is no reliable screening tool for early detection of ovarian cancer. The diagnosis of ovarian cancer is often delayed and multiple suboptimal imaging studies are performed due to lack of awareness of the signs and symptoms of ovarian cancer among many health care providers. Complex referral processes may delay care which can result in worse clinical outcomes. Primary surgery is frequently performed by general surgeons who may not be adequately trained to perform high quality surgery with maximum debulking efforts [1][2]. Primary adjuvant treatment is often delayed due to surgical complications or lack of efficient coordination of care [3].

At least 15% of EOCs are attributable to hereditary mutations. Identifying these patients can direct cancer treatment, alter surgical decision making and help understand cancer risk of other family members. National studies suggest that only 10.5%-31% of women with EOC have undergone genetic testing and most health care providers never discuss genetic testing with their patients [4][5]. Thus large national efforts are needed to improve both physician and patient awareness and identify barriers and lack of motivation to genetic testing. The timing of germline versus somatic testing is also highly variable among large academic centers and community providers, without lack of consensus on best practice. Managing treatment and disease related side effects can also be a challenge in treating EOC. Most health care providers underutilize supportive services such as genetic counselors, clinical pharmacists, survivorship or palliative care services.

The use of clinical pathways in gynecologic oncology is lagging behind other fields in oncology [6]. Clinical pathways have been shown to enhance quality and value by supporting evidence-based clinical decision that offer greatest efficacy and minimize toxicities [7]. Adopting clinical pathways could reduce variability in health care delivery, communicate benchmarks and information on the care delivered to multiple stakeholders and could establish long term payer alignment strategies. It could also provide feedback on adherence to the national standards and assess variation and reasons for deviation from standard of care [7]. Clinical pathways could be used to manage quality of care at multi-site practices and could increase internal referrals to clinical trial enrollment. Unfortunately, the use of clinical pathways is still in its infancy in gynecologic oncology; thus there is a large unmet need to develop and implement disease specific integrated pathways to deliver consistent high quality care on a large national scale.

Patient education and shared-decision making can play an important role in delivering quality cancer care and help patients reach decisions that are consistent with their values. It also improves the communication between patients and their health care providers and help patients maintain a recommended course of treatment and achieve life goals. Thus developing innovative shared decision-making tools are also a key area of focus to improve cancer care.

Dissemination of new clinically impactful information among health care providers is also a major challenge in the rapidly growing field of oncology. Journals, national meetings, emails or social medial platforms have variable effectiveness in reaching all health care providers, thus novel methods for regular provider education are necessary to deliver the highest quality of care based on the newest research findings [8].

### **III. Scope**

The overall aim of this RFP is to develop innovative quality improvement initiatives using clinical care pathways and other mechanisms to improve patient care and outcomes in Stages III/IV and recurrent epithelial ovarian cancer. 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 from NCCN Member Institutions. Collaboration between NCCN Member Institutions is strongly encouraged in order to foster the interactive sharing of knowledge and expertise, and to utilize the combined strengths of members. Although the submitting applicant must be from an NCCN Member Institution, participating institutions do not need to be NCCN Member Institutions.

**Only projects specific to the care of Stage III and Stage IV and recurrent epithelial ovarian cancer patients will be considered for funding.**

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

- Development of innovative technologies and clinical pathway programs or platforms, which facilitate one or more of the following:
  - a. Decrease financial toxicity
  - b. Manage quality of care at multi-site practices and enhance coordination of care
  - c. Increase early internal referrals for symptom management
  - d. Increase early internal referrals for end-of life care

- e. Increase early internal referrals for survivorship care
  - f. Increase the rate of genetic testing, both tissue and germline
  - g. Increase clinical trial enrollment
  - h. Enhance shared-decision making and patient education
- Opportunities to address gaps in knowledge, clinical practice, and/or clinical practice operations (including clinician, patient, healthcare system, financial, organizational factors) through improving:
- a. Healthcare professional competencies (excluding requests for Continuing Medical Education (CME) grants)
  - b. Healthcare system-based management
  - c. Patient oriented solutions
  - d. External factors that impact patient care and clinical outcomes
  - e. Others

**Examples of particular interest include:**

- Quality improvement around adherence to standard of care management (ie: AE management, education)
- Innovative ways of delivering care, including telemedicine and/or coordination of care between large academic centers and smaller community practices
- Improving genetic testing rates
- Strategies for dissemination and communication of novel findings
- Shared-decision making models
- Improving the use of supportive services
- The use of technology to enhance quality of life in patients

**All funded proposals must:**

1. Promote evidence-based care
2. Be sustainable after the award funding is complete
3. Collect data and report outcomes
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:**

- Therapeutic clinical trials
- Continuing medical education proposals
- Correlative studies from clinical trials
- Basic science projects
- Proposals from non-NCCN Member Institutions

#### **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, health care 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 oversaw the development of this RFP and will perform the peer review of applications.

#### **V. Requirements**

<b>Date RFP Issued:</b>	<b>June 7, 2019</b>
<b>Clinical Area:</b>	Stage III & Stage IV or recurrent epithelial Ovarian Cancer
<b>Target Audience:</b>	Members of the health care team and administrators involved in the care of ovarian cancer patients at NCCN Member Institutions.
<b>Applicant Eligibility Criteria:</b>	NCCN Member Institution
<b>Expected Approximate Monetary Range of Applications:</b>	A total of \$840,000 is available. Approximately 4 proposals will be funded.
<b>Estimated Key Dates:</b>	LOI Deadline: <b>July 22, 2019</b> Please note the deadline is 11:59pm Eastern Time.  Anticipated LOI Notification Date: <b>September 9, 2019</b>  Full Proposal Deadline*: <b>October 21, 2019</b> *Only accepted LOIs will be invited to submit full proposals. Please note the deadline is 11:59pm Eastern Time.  Anticipated Full Proposal Notification Date: <b>December 9, 2019</b>  Period of Performance: <b>Two years</b>

<b>How to Submit:</b>	Please email LOI submission to <a href="mailto:NCCNOvarianProject@nccn.org">NCCNOvarianProject@nccn.org</a>  <b>IMPORTANT:</b> Be advised LOIs submitted to the wrong email address or after the due date will not be reviewed by the committee.
<b>Selection Criteria:</b>	Applications will be evaluated on the basis of: <ul style="list-style-type: none"> <li>• Knowledge of and experience with the area;</li> <li>• Capability of carrying out the work;</li> <li>• Collaboration if appropriate;</li> <li>• Scalability and sustainability;</li> <li>• Potential effect and expected outcomes of the project;</li> <li>• Dissemination strategies.</li> </ul>
<b>Questions:</b>	If you have questions regarding this RFP, please direct them in writing to Nicole Kamienski at <a href="mailto:kamienski@nccn.org">kamienski@nccn.org</a> with the subject line “2019 Ovarian Cancer Project”
<b>Mechanism by which Applicants will be Notified:</b>	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 informs 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:
  - i. Institutional overhead and indirect costs may be included within the request.
  - ii. The inclusion of these costs cannot cause the amount requested to exceed the budget limit set forth in the RFP.
  - iii. NCCN and its Member Institutions have an agreement to include a maximum of 25% indirect costs for projects funded by NCCN.

## 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.

### 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.

If a partnership is only proposed, please indicate the nature of the relationship in this section.

## **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 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. Recipients will need to maintain a separate end-user or other license agreement directly with NCCN for use of the NCCN Guidelines.

#### IV. References

1. Bristow, R.E., et al., *High-volume ovarian cancer care: survival impact and disparities in access for advanced-stage disease*. *Gynecol Oncol*, 2014. 132(2): p. 403-10.
2. Chan, J.K., et al., *Influence of the gynecologic oncologist on the survival of ovarian cancer patients*. *Obstet Gynecol*, 2007. 109(6): p. 1342-50.
3. Society of Gynecologic Oncology. *Creating a New Paradigm in Gynecologic Cancer Care: Policy Proposals for Delivery, Quality and Reimbursement*. 2013.
4. Childers, C.P., et al., *National Estimates of Genetic Testing in Women With a History of Breast or Ovarian Cancer*. *J Clin Oncol*, 2017. 35(34): p. 3800-3806.
5. Kurian, A.W., et al., *Gaps in incorporating germline genetic testing into treatment decision-making for early-stage breast cancer*. *J Clin Oncol*, 2017. 35(20): p. 2232-2239.
6. Daly, B., et al., *Oncology clinical pathways: charting the landscape of pathway providers*. *J Oncol Pract*, 2018. 14(3): p. e194-e200.
7. Zon, R.T., et al., *American Society of Clinical Oncology Policy Statement on Clinical Pathways in Oncology*. *J Oncol Pract*, 2016. 12(3): p. 261-6.
8. *IOM report calls for culture of data sharing*. *Cancer Discov*, 2015. 5(3): p. 219-20.