

2017: THE CRISIS IN GYNECOLOGIC CANCER CLINICAL TRIAL ACCESS

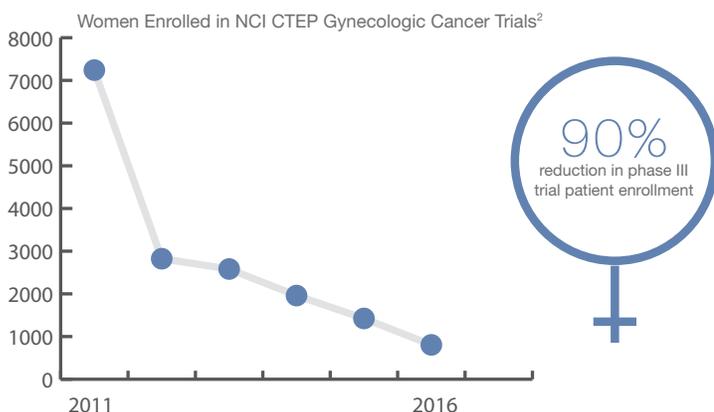
Randomized clinical trials have significantly improved survival for women with gynecologic cancers, including cervical, ovarian, endometrial, and vulvar cancers. The gynecologic cancer community has a 50-year history of developing trials, many by the Gynecologic Oncology Group (GOG) in partnership with the National Cancer Institute's Cancer Therapy Evaluation Program (NCI CTEP). The successful completion of these trials has resulted in peer-reviewed publications that have advanced care for women with gynecologic cancer. Two examples of these trials, both of which resulted in NCI-issued clinical alerts¹ are:

- *The addition of chemotherapy to radiation in the treatment of patients with cervical cancer:*
40-50% improvement in survival
- *The adoption of intraperitoneal chemotherapy in advanced ovarian cancer:*
improvement in survival from 50 months to 65 months

Clearly, clinical trials are necessary to advance the field of gynecologic cancer prevention and treatment affording women with gynecologic cancers the opportunity of improved outcomes, better quality of life and better survival.

However, in 2017, a robust clinical trials platform to achieve these goals is in crisis.

THE CURRENT STATE: A SEVERE DECLINE IN AVAILABILITY OF CLINICAL TRIALS FOR WOMEN WITH GYNECOLOGIC CANCER



ANALYSIS: WHY HAS THIS OCCURRED?

1. National Institutes of Health budget reduction and stagnation
2. Restructuring of NCI-sponsored cooperative groups, with formation of NRG Oncology in 2012. In response to the NCI directive to consolidate the previously independent cooperative groups for budget purposes, NRG Oncology was created and includes the GOG, the National Surgical Adjuvant Breast and Bowel Project (NSABP), and the Radiation Therapy Oncology Group (RTOG). Previously, the GOG and the Gynecologic Cancer Steering Committee (GCSC) were independent entities, solely dedicated to develop and promote trials in gynecologic cancers.
3. There is shifting emphasis to smaller biomarker-driven studies, with concomitant reduction of clinical trials.

GOING FORWARD: HOW CAN WE ADDRESS THIS CRISIS?

1. **Immediately increase funding for the National Cancer Institute for clinical trials.**
2. **Annual Summit for Clinical Trials in Gynecologic Cancer.** Establish annual summit with members to include CTEP, SGO, Advocacy groups and other stakeholders in order to develop partnerships with NCI-CTEP and NRG-GOG leaders, align priorities for the gynecologic oncology scientific agenda, streamline infrastructure for review and approval of gynecologic cancer trials, and increase the number and availability of trials for patient access.
3. **Create a partnership at the National Center for Advancing Translational Sciences/NCI** for the development of industry- and NCI-sponsored, investigator-initiated, multi-site phase I and phase II clinical trials.
4. **Establish a Clinical Trialist Career Development Program with NCI and CTEP**, and develop grants for mentored research to increase investment in young investigators that represent the future in gynecologic cancer trial research.
5. **Make gynecologic cancers a priority in any NIH-supported biomarker development programs.**

Never before has medical science had such a wealth of knowledge in the areas of genetic determinants and molecular signatures that drive gynecologic tumor cell growth. Clinical trials hold the promise of translating this scientific knowledge into identification of actionable drugs, preventative strategies, enhanced patient outcomes, and improved survival. We **must** chart a new course together to increase the availability of Clinical Trials for Women's Cancers.

Now is the time for Action, Awareness, & Funding. Together we have a powerful voice!

For more information or to join these efforts, please email info@SGO.org with "Clinical Trials Crisis" in the subject line.

¹NIH Clinical Alerts and Advisories, www.nlm.nih.gov/databases/alerts/clinical_alerts.html

²Gynecologic Oncology Group, www.gog.org