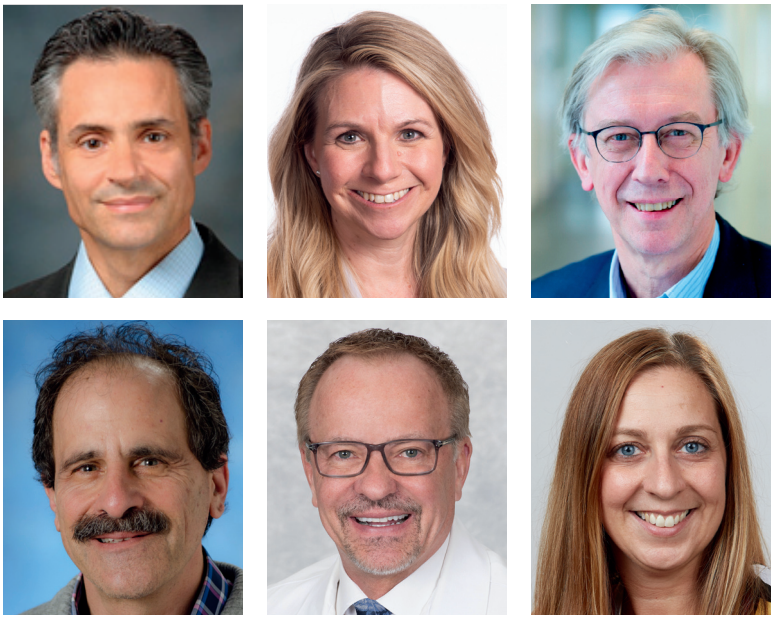
Chapter 13 |

The GOG Foundation, Inc. International Collaborations



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To address the needs of patients in diverse settings throughout the world, the the Gynecologic Oncology Group Foundation (GOG-F) collaborates with other gynecologic cancer research organizations and international groups. Clinical trials organizations such as the Gynecologic Cancer Intergroup (GCIG) [gcigtrials.org], and the European Network of Gynecological Oncological Trial groups (ENGOT) [engot.esgo.org] promote global research initiatives in collaboration with academic institutions and pharmaceutical industry sponsors. Collaborative guidelines are in place with these organizations to define the relationships, roles, and the responsibilities of conducting high-priority international trials. Professional societies, such as the International Gynecologic Cancer Society (IGCS) [igcs.org] provide additional opportunities for engagement, education, and mentorship. These relationships are coordinated by the GOG-F International Relations Committee and the ENGOT/GOG Liaison Committee.

GOG-F is one of 34 full members of GCIG, which functions as a collective organization of national research groups. The GCIG was founded in 1993, and officially incorporated in 2011, after international investigators recognized that the investigators and patients under individual clinical trial groups faced many of the same questions and challenges. The GCIG filled the need for investigators of all nations to have a central organizing group that could harmonize similar studies, boost accrual by cooperation, develop consensus guidelines for research, work through common challenges, and collectively elevate the quality of design, collection and analysis. In addition, the leadership of the GCIG became populated with the leadership from the collective groups, providing a global continuity of expertise and, in turn, an ability to anticipate variation in global regulatory requirements and post-marketing implications of successful trials. The organization structure of the GCIG includes disease site committees as well as phase II, statistics, symptom benefit, translational research, rare tumor, harmonization and operations in addition to incorporating patient advocacy to facilitate trial enrollment and impact. An additional core value of GCIG is to include and support lower-income or low-resource countries in making trials accessible in these regions of the globe. The Cervical Cancer Research Network, (CCRN) is a notable and productive example of this effort. The CCRN has not only fostered conduct of many of our key clinical trials such as TACO, INTERLACE, SHAPE,

SENTICOL, and CONTESSA, it has also provided educational symposia to new investigators from all backgrounds.

The GCIG currently consists of 34 individual groups from spanning five continents; nearly half (17) from Europe, eight from Asia, five from North America, three from South America, and one from Australia/New Zealand.

This robust infrastructure was not without its challenges, however, with the greatest of these being the complexities of funding sources for individual trials. To manage this, a structure was created to classify trials based on their source of funding which would determine scientific flexibility and in turn the focus of participating sites. The structure followed the ENGOT terminology,[1] where Type A or "academic" trials are funded locally or by cooperative groups, had maximal investigator scientific input from the GCIG infrastructure, and are prioritized within the group. Type C trials are industry-sponsored but, in most cases, the scientific design and statistical sections are significantly informed by members of the respective GCIG groups. The GCIG also embraces translational research as an important part of any clinical trial and strongly supports collection of appropriate specimens. Translational plans can be addressed at any time in clinical trials and such plans need to be a collaboration between the sponsor and the GCIG participating groups.

"The ENGOT and GOG-F Liaison Committee was created in June 2016 to provide a venue where discussion of the best research framework whereby resources, with patients being the most important, would be most effectively engaged in order to best strategically answer key clinical and scientific questions that advance the care of women afflicted with gynecologic cancers."[2] The mission of this liaison committee is to ensure that collaborations with industry partners are established early in the process and to promote continuous and transparent communications between both organizations. With the global regulatory complexities, there was a need to have some clear and concise guidance to help prioritize and operationalize common objectives between the two organizations. Guidelines were established and published in Gynecologic Oncology,[2] to illustrate the relationship between ENGOT and the GOG-F, but more importantly, to present the framework of how to operationalize a trial when both organizations are collaborating on the same clinical trial. By promoting international cooperation with solidarity and trust, the ENGOT/GOG Liaison Committee's success is because of the efficient relationships with trial investigators, industry partners and other relevant stakeholders.

With the collaborative success of the ENGOT/GOG Liaison Committee, relations with industry partners have successfully granted more opportunities for both organizations, clinical research sites and the patients. These relations have allowed both organizations to bring the best clinical treatment to women with gynecologic cancers through the best science by ensuring that globally, women have access to a clinical trial.

To increase the GOG-F footprint, Gynecologic Oncology Group Partners (GOG-P) recently created alliances with other countries; most recently, Canada, and Brazil. It was determined that these were areas of significant need given the competitive landscape and clinical trial numbers. With these new collaborations, it allows for greater global impact to women with gynecologic cancers. To build a framework with Canada and Brazil, Liaison Committees have been established with both countries so clinical trials can be strategically identified where there is an unmet need.

GOG-F members have also contributed to and/or have held leadership positions in the IGCS, which has served as another global stage upon which education, mentorship, communication and networking is fostered and conducted. These attributes consistently align with the Foundation's efforts to harmonize clinical trial communication and importantly, interpretation and application of clinical trial findings among the global heterogeneity of health care for patients with gynecological malignancies. While the clearest interaction between GOG-F and IGCS has been in providing faculty level curriculum guidance, participation in abstract presentation, and educational sessions (debates, master classes, symposiums), there is clear synergy in networking with IGCS's global partners as GOG-F executes trials in the global community, learning from unique challenges and opportunities in different health care environments and resources. In light of the increasing global footprint needed for GOG-F clinical trials, this interaction has gained heightened focus.

As the GOG-F mission states, "... the GOG is dedicated to transforming the standard of care in gynecologic oncology [gog.org]." To continue that mission, the GOG-F will continue to unite globally with other organizations and countries to fight against gynecologic cancer by contributing to the prevention and treatment of gynecologic malignancies.

References

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