COVID-19 AND CLINICAL TRIAL ACCRUAL:
AN ENROLLMENT UPDATE
FROM BRIAN SLOMOVITZ, MD, FLORIDA INTERNATIONAL UNIVERSITY, BROWARD HEALTH

As a member of GOG Partners, a GOG Foundation Program, the ability to continue clinical trials to bring lifesaving cancer therapies is of utmost importance. When COVID-19 incidence peaked in early 2020, it was a devastating time for everyone, including our patients and cancer physicians. We were very sensitive and frustrated with the inability to offer the same level of care to our patients that we were providing pre-COVID, due to institutional and loco-regional regulations and restrictions. We always strive to provide the very best for our patients, whether that be the optimal standard of care, or a clinical trial opportunity with access to cutting edge therapies. There were several agents in Phase II and Phase III development that we desired to keep developing. It was critical that we help our patients, but it was also important to continue the trials from a scientific and regulatory perspective, and to fulfill our contractual obligations with our sponsors. Taking these multi-faceted needs into consideration, we altered and adapted our approach to research.

Based on the work of our medical, operations, regulatory, finance and legal teams, the GOG recorded a 50% increase in GOG Partners (GOG-P) accrual. During this dynamic time, we maintained complete compliance with the CDC, FDA, and NIH guidelines with regard to clinical trial management. Our strategies included: allowing for virtual study startup and site initiation visits; emphasizing trials that used oral medications and allowing
for shipment of drug to patients whenever possible; offering remote monitoring and telemedicine visits to our patients; and working with our sponsors and CROs to allow for remote data collection. In addition, we had increased frequency of operations meetings and contact with sponsors to address new challenges.

We leveraged our regional and site diversity to take advantage of those centers that were less impacted by the pandemic. Because of our widespread site locations throughout all regions of the country and significant growth of GOG-Partners, our accrual remained robust during the pandemic, despite many regions being drastically negatively affected. The impact of the second wave on study participation was less significant. Only three regions observed a significant drop in accrual, compared to six during the first wave.

The non-university sites generally were faced with fewer challenges especially during the initial surge; they had less restrictions, more resources, and agility to allow their clinical trials infrastructure to remain intact. Due to financial, institutional and human resource limitations, university sites noted a decline in clinical trial accrual during the initial COVID surge. We are grateful to our Non-university sites to enable continued progress with our GOG-partners during this time. The pandemic has shown the importance to both our non-university and university sites and dedicated investigators working in collaboration to bring new treatments to our patients.

The data was presented at the SGO Annual Virtual Meeting on Women’s Cancer® and a link the presentation to view the data slides can be found here.

The GOG-P is grateful to all our sites for continuing to successfully accrue to these important clinical trials amidst a global pandemic. A well-rounded portfolio, increasingly engaged collection of sites, and growth of GOG-Partners allowed us to continue accrual to our clinical trials. We were able to sustain research and even close certain studies earlier than projected. As always, we appreciate any feedback and concerns as we continue to expand our successful gynecologic oncology research program.

Dr. Larry J. Copeland, President of The GOG Foundation, Inc., stated, "The commitment by our investigators to discover new and better treatments for our patients was clearly displayed when, hindered by various 'shut-down' regulations during the peak occurrence of COVID-19, our accrual to clinical trials held steady. This success reflected a well-rounded portfolio of trials and a particularly robust enrollment from our non-university accrual sites, who were less heavily regulated during the COVID-19 pandemic. The success of our clinical research program is the result of our investigators sharing a common mission to establishing tomorrow’s treatments. Go GOG-Partners!!"

SPECIAL RECOGNITION

SGO Distinguished Service Award
The GOG Foundation, Inc. would like to congratulate OUR LEADERS as this year’s Society of Gynecologic Oncology (SGO) 2020-2021 Distinguished Service Award Winners.

David O’Malley, a colleague and friend of Dr. Copeland notes:
"This recognition is so well deserved. Cope has mentored so many of us and we are better for it. I feel unbelievably fortunate to have worked so closely with him for the last 16 years. I will be forever grateful for his teaching,
Kathleen Moore, a colleague and friend of Dr. Mannel notes: "Dr. Mannel has spent his career developing a culture on the local, national and international level that emphasizes the importance of research in improving the oncologic outcomes of women with gynecologic malignancies. I can think of no one who deserves this distinguished service award more and am so honored to have been mentored by and work along side him."

Congratulations, Dr. Copeland and Dr. Mannel! This award exemplifies the work you do every day to transform the standard of care in gynecologic oncology.

Accreditation Council for Continuing Medical Education
The GOG would like to congratulate the GOG Staff, Foundation CME Programs and the GOG Education & Mentoring Committee members for their ACCME Renewal.

We recognize the hard work you put forth to retain this important accreditation status, and continue to provide medical education credits to our physician leaders.

GOG Foundation CME Program
- Michelle N. Small, Director, Education Programs and CME Compliance
- Jill Reese CME Administrator
- Lauren Calhoun, CME Specialist
GOG Education & Mentoring Committee
- Ronald D. Alvarez, MD, Chair
- Angeles A. Secord, MD, MHSc, Co-chair
- Elise C. Kohn, MD, Head, NCI DCTD Gynecologic Cancer Therapeutics
- Diane Yamada, MD, SGO Representative
- Warner K. Huh, MD, President, SGO
- David G. Mutch, MD, Past Chair, FWC
- Michelle N. Small, GOG-F Administrative Support

GOG FOUNDATION / AAOGF/ CLOVIS ONCOLOGY
MENTORED PHYSICIAN-SCIENTIST AWARD

This GOG Foundation award, in partnership with the American Association of Obstetricians and Gynecologists, and Clovis Oncology identifies future academic physician leaders in the field of Obstetrics and Gynecology and Gynecologic Oncology with an interest in clinical trial development.

Application Deadline is July 1, 2021. Application requirements and additional details can be found in the Scholarship Booklet or on the AAOGF website, on their Research and Training Scholarships page.

CLINICAL TRIALS
The GOG Partners Program is currently recruiting for 20 clinical trials

11 Ovary
3 Cervix
6 Endometrium

To search active trials visit our website by clicking "clinical trials" below.

Clinical Trials

SITE EDUCATION
The GOG Partners will be compiling short vignette videos with tips and education on how to make your accruing site more successful.

As we continue to expand the service GOG Partners provides to our investigators, we have recently identified an unmet need for mentorship and support for our new sites and for established sites seeking to further improve their operations.

The GOG Partners leadership in concert with the Investigator Council has identified investigators at sites with excellent accrual and/or study startup times to educate and support sites in achieving these goals.

Be sure to check the GOG social media sites, see links below, for more
Did You miss the Independent Satellite Symposia during The SGO Virtual Annual Meeting on Women’s Cancer®?

Recordings of the Antibody Drug Conjugates as a New Class of Agents in Treating Recurrent Ovarian Cancer and Improving Care of Women’s Cancer – TiP of the Iceberg sessions will be available at www.gog.org soon!

IIT LOI APPLICATION

Applications should be submitted electronically to the GOG by completing the online application.

Applications will be reviewed as they are submitted.

Please contact GOGPartners@gog.org with any related questions.

WINTER MID-YEAR MEETING RECAP

Thank you for attending the GOG Foundation, Inc. Virtual “Dinner” Meeting. The virtual turnout was a huge success, with almost 350 people registered for the program. This year’s meeting started with a tribute to Dr. James “Tate” Thigpen, a pioneer and influencer in research and clinical trials. We will continue to express our gratitude to Dr. Thigpen for his devotion, immeasurable impact and excellence in gynecologic oncology research.

The program continued with updates from The GOG Foundation, NRG and GOG Partners Leadership.

Thank you to everyone that participated in our virtual photo booth, we loved seeing your photos since we were unable to be together in person. Congratulations again to Dr. Marilyn Huang for her air pod pro winning photo booth post!

We look forward to our Summer Mid-Year Program taking place in July, we will post more details on our website soon.
Thank you for participating in our virtual photo booth! We LOVED “seeing” you!

The GOG Foundation, Inc. 2021 Virtual Dinner Meeting
Thursday, January 28, 2021

How Can We Help?

The GOG Partners Connection Quarterly Newsletter is produced by the GOG Foundation Communications Committee.

Please contact us at info@gog.org with any questions or suggestions regarding future content.