Symposium, "*Challenges in Design and Control for Clinical Trials in Gynecologic Cancer*"

January 25, 2018 – Phoenix, Arizona

Program Chairs	Program Chairs Robert L. Coleman, MD/Kathleen Moore, MD

Presentation Agenda

Time	TOPIC	SPEAKER/MODERATOR
7:00 AM	REGISTRATION	
8:00 AM	WELCOME	Program Chairs
8:05-8:45	SESSION I: "Background: why this, why now?"	Moderator: Ronald Alvarez, MD
8:05-8:25	The treatment landscape – control arms (how do we design?)	Michael Bookman, MD
8:25-8:45	Alternatives to the Phase I, Phase II, Phase III strategy	Deborah Armstrong, MD
8:45-9:05	How we study maintenance therapy (Pure vs front-line (methods))?	Amit Oza, MD
9:05-9:20	Panel Discussion	All
9:20-11:00	SESSION II: "Efficient Trial Design: Early Phase and Inclusion of PROS"	Moderator: Robert Coleman, MD
9:25-9:45	Phase I trials – what's the best way to design this kind of trial?	Shannon Westin, MD
9:45-10:05	Can we do Phase I trials in curative situations (e.g. front-line cervix, ovary, endometrial, radiation, etc)?	Gottfried Konecny, MD
10:05-10:25	Composite endpoints with PROS	Angeles Secord, MD
10:25-10:45	PRO's (2) – how can they be interpreted for regulatory approval/practice changing?	David Cella, MD
10:45-11:00	Panel Discussion/Questions	All
11-11:15	BREAK	
11-:15-1:00	SESSION III: "Special topics"	Moderator: Kathleen Moore, MD
11:15-11:35	How to design a study with no standard of care control? (Rare tumor)	Jubilee Brown, MD
11:35-11:55	Incorporating biomarkers into clinical trials – integral and integrated…what has worked and how do we move forward?	Christina Annunziata, MD, PhD
11:55-12:15	Stats: How to interpret what you see in a journal article. (HR's, restricted means, subgroup analyses, multiple comparisons -	Paul DiSilvestro, MD
12:15-12:35	Mid trial "bogies": how do you deal with discontinuations, withdrawal of consent, endpoint changes, and altering the sample size	William Brady, PhD,
12:35-12:45	"Impact of Race on Survival and Toxicity for Women with Locally Advanced Cervical Cancer Treated with Chemotherapy and Radiation" – Young Investigator Presentation	Jennifer Pierce Young, MD
12:45-1:00	Panel Discussion	All
1:00-1:45	BREAK (LUNCH)	
1:45-3:00	SESSION IV: "Endpoints and Future Directions"	Moderator: Robert Mannel, MD
1:45-2:05	Debate: Co-primary vs. single primary endpoint	Krishnansu Tewari MD versus Thomas Herzog, MD
2:05-2:25	What are the best trial designs for primary ovarian, endometrial and cervix cancer?	Carol Aghajanian, MD
2:25-2:45	What are the best trial designs for recurrent ovarian, endometrial and cervix cancer? E.g. physician choice designs	Ursula Matulonis, MD
2:45-3:00	QUESTIONS AND ANSWERS	

PROGRAM DESCRIPTION:

Program Chairs
Robert L. Coleman, MD
Kathleen Moore, MD

The *Winter 2018* GOG Foundation, Inc. Educational Symposium is titled "**Clinical Trial Design – Have we lost control?**" with noted Oncologists and Scientists serving as speakers and moderators. The targeted audiences are members and non-members of the NRG research teams to include: Gynecologic Oncologists, Medical Oncologists, Radiation Oncologists, Pathologists, and other MDs engaged in oncology research and/or clinical practice; Oncology Nurses, Nurse-practitioners, and other interested Allied Health professionals. The speakers will focus their presentations on topics brought to light from recent clinical trials balanced against the expanding menu of therapeutic options and limited patient and financial resources. The perceived need to develop "me to assets" in overlapping treatment indications, particularly in the context of adequate and clinically-relevant controls, is profoundly limiting the potential throughput of the investigative progress. These and other topics will be addressed in an attempt to engage the audience in a discussion of the best next steps forward in clinical trials.

LEARNING OBJECTIVES:

1. **To recognize the challenges and processes in the current treatment landscape**
2. **To better define the scope of clinical trial design and opportunities to make them more informative and efficient**
3. **To interpret the options for treatment evaluation in rare tumors and with non-traditional endpoints**
4. **To summarize a perspective on the best potential road map for investigation in primary and recurrent ovarian, uterine and cervix cancer**

GOG COMMITTEE ON EDUCATIONAL ACTIVITIES

Ronald Alvarez, MD (Committee Chair) University of Alabama School of Medicine Birmingham, AL Frederick Stehman, MD (Co-Chairman) Indiana University School of Medicine Indianapolis, IN Sarah Bernstein, RN, MS, AOCN Walter Reed National Military Med Ctr. Bethesda, MD John Farley, MD St. Joseph Hospital and Medical Center Phoenix, AZ	Neil Horowitz, MD Brigham and Women's Hospital Dana Farber Partners Cancer Care Boston, MA William Tew, MD Memorial Sloan Kettering Cancer Center New York, NY Michelle N. Small, BSHA (Staff) Assoc. Director, Education Programs & CME Compliance GOG Education Program msmall@gog.org Jill Reese (Staff) CME Administrator GOG Education Program jreese@gog.org