



Newsletter

FALL 2009

Philip J. DiSaia, MD - Group Chair

Larry J. Copeland, MD - Group Vice Chair

ADMINISTRATIVE OFFICES

Four Penn Center
1600 JFK Boulevard, Suite 1020
Philadelphia, PA 19103
215-854-0770

STATISTICAL & DATA CENTER

Roswell Park Cancer Institute
Elm & Carlton Streets
Buffalo, NY 14623
716-845-5702

FINANCE & DEVELOPMENT

2127 Espey Court
Suite 100
Crofton, MD 21114
410-721-7126

INSIDE THIS ISSUE

Chair's Corner
1

Protocol Department
2

GOG Regulatory Affairs
Department
3

In Memorium
4

New Horizons
Cancer Research Fund
6 & 7

Chair's Corner

Philip J. DiSaia, MD

Recently I had to prepare a statement outlining the accomplishments of the Gynecologic Oncology Group over the last forty years. I must tell you that I was very impressed when I looked at the list, in spite of the fact that I have lived those forty years in the GOG. It is particularly impressive when you know that even good scientific concepts undergo a volatile birthing process with a 12-to-24 month gestation and then face hurdles such as the Central IRB and the Steering Committee and CTEP. However, many protocols have been successfully completed due to our dedicated membership and our institutions that function with substandard resources.

Over the last several years, David Dilts, a PhD in management science, and Alan Sandler, an Oncologist, co-directors of the Vanderbilt University's Center for Management Research in Healthcare have been working to develop a more detailed understanding of the processes currently required to conduct a clinical trial for patients with cancer. They have studied a few cooperative groups in detail and not surprisingly they have found that it takes between 295 to 1248 days for initial conception to activation of a group trial. In one CALGB protocol that they studied there were 317 work steps and 42 decision points of which 63 percent were beyond the direct control of the principal investigator and the cooperative group. This has



Philip J. DiSaia, MD - Group Chair

stimulated the NCI to formulate a task force in an attempt to produce guidelines for streamlining the process for all Groups. Hopefully this will result in improving the process. In future newsletters I will try to detail some of the work product from this task force.

CHAIR continued on Page 6

Satellite Symposium being held during the GOG San Diego Annual Meeting

Please consider attending the free satellite dinner symposium being conducted during the 80th Annual Meeting of the Gynecologic Oncology Group. The symposium will take place on Friday, January 29, 2010, from 6:30 PM – 9:00 PM in the Manchester Grand Hyatt Hotel, San Diego, CA. For more information and to register online, Visit <http://www.IMERonline.com/gynonc>

Protocol GOG-0259 : Nurse-Delivered WRITE SYMPTOMS® vs. Self-Directed WRITE SYMPTOMS® vs. Care as Usual for Optimal Symptom Management For Women With Recurrent Ovarian, Fallopian Tube, or Primary Peritoneal Cancer- Study Chair Heidi Donovan: was distributed to the Group as an Advance Copy in July 2009 and will activate later this Fall.

As institutions have prepared to submit the protocol to their IRBs, some questions have been generated. The following is the current list of frequently asked questions with answers as provided by the Study team.

Frequently Asked Questions

Question 1: Must women be on active treatment and/or have active disease to be enrolled in the study?

Answer 1: No, women do not have to be on active treatment or have active disease to be enrolled. The primary eligibility criteria are a) a history of recurrent ovarian, fallopian or primary peritoneal cancer and b) experiencing three or more symptoms associated with cancer or treatment. Therefore, those in remission following a recurrence would still be eligible as long as they were experiencing three or more symptoms.

Question 2: Can nurses be listed as the PI or sub-investigator at their institutions for this study?

Answer 2: This is up to individual institutions. There are no GOG policies that would prevent nurses being the PI or sub-PI for this study. GOG nurses have been criti-

cal to the development of this protocol and will be essential to its success. The GOG-0259 research team is in full support of nurses taking leadership roles on this study within their institutions.

Question 3: What kinds of symptom management recommendations are you making to patients? What if a physician disagrees with your recommendations or what if a recommendation is contra-indicated for a patient (example: exercise or dietary supplements)?

Answer 3: All self-care guides and symptom management strategies contain only recommendations that are supported by research evidence or, in the case of some self-care strategies, are supported by expert clinician consensus. No specific medication/dosage recommendations are made, but discuss instead types of medications that can be used for specific symptoms. Patients are encouraged to discuss the possibilities with their local health care team. In the case of the self-directed (computer module) group, patients are asked to read the self-care guide for their symptoms, and then select some strategies that they would like to try. Any time a strategy includes a medication, the strategy is listed as “discuss the use of new medications at my next Dr.’s appointment”, or “call my Dr.’s office to make an appointment to talk about medications for xxx symptom”. Some self-care strategies don’t have this specific language, e.g. “try to go to sleep and get up at the same time every day” for sleep disturbances. But every summary set of recommendations says “please print out this summary and share

with your health care provider at your next visit.” With respect to any kind of exercise, all recommendations (from nurses, self-care guides, computer program, etc.) include the statement, “please check with your doctor before starting any new exercise program.” No specific dietary supplement recommendations are made, but instead someone who has poor nutritional intake is encouraged to discuss the need for nutritional supplements or a dietary consult with their physician. (This would be in addition to general “healthy eating during cancer treatment” recommendations). The bottom line is that in every situation patients are encouraged to discuss recommendations with their healthcare team.

Question 4: How are institutions notified of the recommendations that the research team is giving to patients?

Answer 4: The patient’s healthcare team is not sent a summary of the patient’s selected symptom management strategies, but instead patients are encouraged to print the summary and take it to their health care provider. Throughout the intervention, one of the primary aims is to help patients communicate effectively with their health care team and to establish patterns of reporting and following up on their symptoms. It is hoped that health care providers will encourage and support these conversations throughout the study.

Please notify Project Manager: Howard Stein at hos12@pitt.edu once you have submitted GOG-0259 to your IRB.

Registration For IRBs Reviewing FDA-Regulated Research

The following notice was circulated on August 31, 2009 by the Office for Human Research Protections (OHRP) on behalf of the Food and Drug Administration (FDA):

If your IRB reviews FDA-regulated research and you have not submitted an initial registration or provided the FDA-specific information required by FDA's new IRB Registration rule in the modified OHRP database since July 14, 2009, you are not registered with FDA.

If you have not previously registered your IRB in the OHRP database, you may do so using the new IRB registration submission page at <http://ohrp.cit.nih.gov/efile/IrbStart.aspx>.

If you are updating your information to provide the FDA-specific information, use the electronic submission system page for updating registrations at <http://ohrp.cit.nih.gov/efile/IrbRn-wStart.aspx>. After obtaining a submission number from the system, you will begin the new registration or update process. To enter information for each separate IRB, access the pull-down list of IRB type and select either "FDA only" or "OHRP/FDA" and enter the required information. If you are already registered with OHRP, the information you previously entered will appear, plus data-entry fields to enable you to enter the FDA-specific information required by the new IRB registration rule.

Please note: To be compliant with the FDA IRB Registration Rule, IRBs currently reviewing FDA-regulated research must register by September 14, 2009. Due to the number of new and updated registrations, receipt of your registration confirmation may be slightly delayed.

For further information on the FDA's IRB registration requirements contact Jean Toth-Allen, Ph.D., Office of Good Clinical Practice, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, HF-34, Room 16-85, Rockville, MD 20857. You can also contact her by telephone at (301)827-1585 or email at: jean.toth-allen@fda.hhs.gov

Abraxis Oncology

Advaxis

Amgen, Inc.

**Bayer/Onyx
Pharmaceuticals**

BD Diagnostics-TriPath

Bristol-Myers Squibb

Caris/MPI

Celgene Corporation

Cell Therapeutics, Inc.

Eli Lilly & Company



Exiqon Dx

Genentech BioOncology

Genzyme Biosurgery

GlaxoSmithKline

ImClone Systems, Inc.

Merck

Morphotek, Inc.

**Novartis
Pharmaceuticals**

**Ortho Biotech
Products, LP**

OSI Oncology

Pfizer, Inc.

Ponard Pharmaceuticals

**Precision
Therapeutics, Inc.**

**Regeneron
Pharmaceuticals**

**Sanofi-Aventis
Pharmaceuticals**

Remembering John (Jack) Kellner

By George C. Lewis, Jr., M.D.
and Robert C. Park, M.D.

This year the GOG lost another good friend. Jack Kellner, long time Executive Director of Operations, passed away on April 24, 2009. Jack served in this position from 1980 to 2006. He then became an active Gynecologic Oncology Group (GOG) consultant until he passed. During the period of 1980-2006, Jack worked with three Group Chairs (Drs. George C. Lewis, Jr., Robert C. Park and Philip J. DiSaia). Among his many accomplishments, he was instrumental in the formation of the GOG Data Management Subcommittee established in 1982. He recognized the significant and essential roles Data Managers serve in the overall success of the GOG trials. Jack was also responsible for hiring Denise Mackey in 1983. As Director of Administration and Meetings, Denise remains as a valuable asset to the structure and function of the GOG today.

Jack was hired by Dr. George C. Lewis, Jr. in 1980, after a 20-year career with the U.S. Navy. He began his Navy career as an Ensign and worked his way up through the ranks to a Commander. Jack served in the Vietnam era and also served in combat as a medic in helicopter evacuation. Along with his experience in administration and a Business Administration degree from George Washington University, Jack appeared to be an ideal fit for the GOG. Jack had retired from a very busy career in the Navy and found himself restlessly sitting around at home and happened to look in the paper at the same time that The American College of Obstetricians and Gynecologists put an advertisement out for a GOG group manager.

Jack turned out to be a miracle worker. He spent

many miles on the road performing meeting site inspections and handling other GOG business that was requested of him. As a result, his dachshund (which he dearly loved) was constantly being transported to other family members while Jack was away. He had a great rapport with staff from the NCI and this helped often in grant negotiations. Jack had a very engaging personality. He had both the people skills and the business competence to run GOG affairs smoothly, while getting along well with everyone.



Jack Kellner accepts an award from Dr. DiSaia

Jack assisted in monitoring the GOG budget closely, which occasionally led to the GOG hosting meetings in hotels that were under renovation and construction. Some of the construction took place right down the hall from our meeting rooms. We were given great room rates in return for our business. Speakers just had to raise their voices a bit to be heard over the construction.

Jack loved sports cars, and always managed to have the newest models. He also liked electronic gadgets and cutting edge technology.

George and Betty Lewis came to regard Jack not only as a great business associate, but as a very dear friend; as did most of us who through the years were privileged to know and work with him.

The GOG and all its participants will sorely miss the presence of Jack Kellner. Anyone who would like to remember Jack can make a donation to the "Jack and Jan Kellner's Memorial Fund" which benefits the Data Management Subcommittee. The contribution form can be found on the GOG website at www.gog.org.



BALTIMORE JULY 2009

79th Annual Meeting Gynecologic Oncology Group



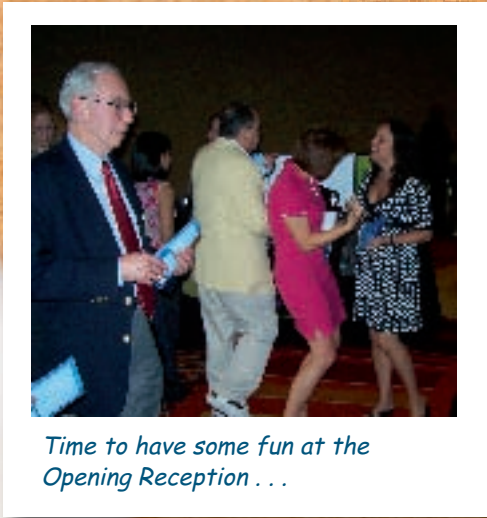
Checking out the exhibitors



Mingling at the ICT Reception . . .



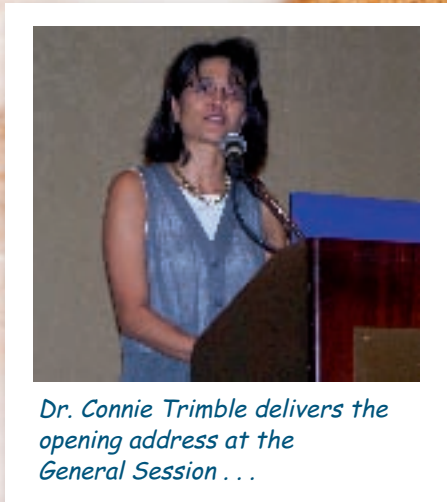
The GOG staff prepares for another successful meeting . . .



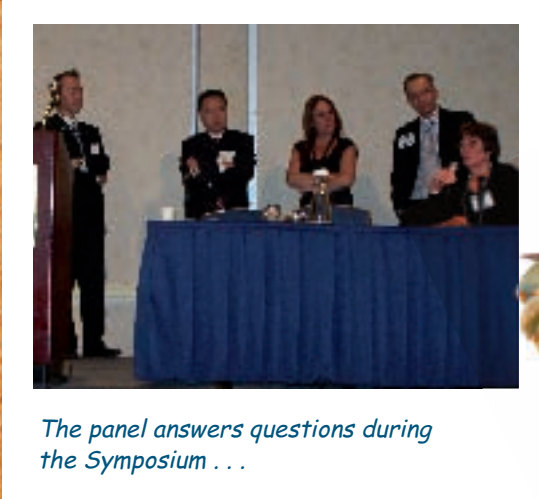
Time to have some fun at the Opening Reception . . .



A captive audience at the Symposium



Dr. Connie Trimble delivers the opening address at the General Session . . .



The panel answers questions during the Symposium . . .



“Steppin’ Out” Kicks Off With Its Inaugural “Strut”

The “Steppin’ Out Strut” probably won’t be seen on *Dancing with the Stars*, but it was seen at the Tennessee County Fairgrounds in Knoxville, TN on September 19, 2009!

Ashton Doane, a Univ. of Tennessee sophomore, doesn’t take the name of her school’s football team for granted – the Volunteers. Ashton decided to host a

benefit race for cancer research to honor the memory of her grandmother, Mitti Gouge, who died of ovarian cancer before Ashton was born. She got the idea for a race with stiletto heels from a celebrity-fundraiser she heard about and decided the Gynecologic Oncology Group (GOG) would become the benefactor after researching various websites related to ovarian cancer. She told the GOG that when she saw the “Steppin’ Out” stiletto charm,



Photo by Joe Rector

Ashton and Cheri Doane showing off their stilettoes

combined with the fact that her grandmother loved shoes . . . the GOG was the perfect fit!

The GOG wishes to thank Ashton Doane and her family, friends, and all race participants for their time and efforts that helped make the inaugural “Steppin’ Out Strut” a memorable event. The GOG thanks them for their

generous gift to benefit gynecologic cancer research, and their goal of making the “Steppin’ Out Strut” an annual Knoxville event.

If you are interested in your own “Steppin’ Out Strut” please contact Kathy Shumaker at kshumaker@gog.org for details! See [Page 7](#) for photos and more from the race.

CHAIR from page 1

The complexity of the approval process at an institutional level and more demanding requirements for successful submission of data have led to a strain on all our resources. Our investigators have not had an increase in their per capita for a very long time. The administration of the GOG is working diligently to find resources from industry and also the NCI. We began our relationships with industry seven or eight years ago and they are maturing at a satisfactory rate. I believe that CTEP is also aware that additional resources are necessary but they too find themselves with budgetary constraints. Recently we have found a mechanism for improving the amount of capitation money through a stipend for follow up of patients on protocol. The GOG administration is also discussing

with CTEP the possibility of additional stipends for features such as translational research and quality of life research. In addition, Dr. Jeffrey Abrams, Associate Director of CTEP, has suggested the possibility of raising the capitation dollars on Phase II studies.

The bottom line is that everyone is well aware of the need for increasing the revenue stream. There are multiple mechanisms under study to achieve this goal but for now they are a “work in progress.” Hopefully, additional details will be forthcoming in future correspondence.

Philip J. DiSaia, MD, Chair
Gynecologic Oncology Group

Chasing The Cure For Cancer – One Step At A Time



"Steppin' Out Strut" photos provided by Marlene & Co., Inc.



Ashton Doane and the Gynecologic Oncology Group would like to thank the following race participants, contributors and sponsors for making the 2009 "Steppin' Out Strut" a success:

Race Participants and Contributors:

Susan and Meghan Elrod; Bethany Hendricks; Ashley York; Jaymi Sammons; Jennifer Rihardson; Chelsea Welch; Rhonda Garrison; Theresa Wright; Erin Wright; Stephanie Smith; Teresa French and Leslie French; Kelli French; Mary Catherine Gouge; Jennifer Jennings; Catherine V. Norton



Additional Contributors:

Teresa Williams; Perry Gouge; Spicys-North; Beacon Finance Corporation; Dr. Kristi Newton; Barbara Bowers; JoAnn N. England

Race Sponsorship Partners:

Tennessee Valley Fair; New Balance-Knoxville; 1 Source Printing and Graphics; Star 102.1; Knoxville Gynecologic Cancer Specialists; Travelers; Mercy Health Partners; St. Mary's Health and Fitness Center; Media Prints



Race Prize Contributors:

Regas Restaurant; Sole in the City; The Cupcakery; Artist's Touch Hair Salon

Walking to Break the Silence on Ovarian Cancer



The National Ovarian Cancer Coalition (NOCC) mission is to raise awareness and promote education about ovarian cancer. This includes the annual 5K Run/Walk To Break the Silence on Ovarian Cancer.

This year's 9th Annual Run/Walk conducted by the Dallas-Fort Worth Chapter on September 26, 2009 was record breaking year. The race was also a notable one for the Gynecologic Oncology Group (GOG). This year the GOG awarded four lucky recipients (pictured above with Debbie Miller) with "Steppin' Out" charms after their names were chosen in a drawing after the race. Congratulations to the winners and to the NOCC.

New Horizons GYN Cancer Research Fund

The GOG would like to thank the following individuals and families for their generous contributions to the **New Horizons GYN Cancer Research Fund**:

In Honor of Lisa W. Meitlin

Jerry L. Meitlin

In Memory of Carol Reese and Jan Bur

Steven Schneberger

In Memory of Janice Gause

Nell Lawirmore

In Memory of Dorothy Geyer

Kathleen Couling

Jack and Jan Speaker Fund

GOG JAPAN (C/O Kazunori OchiaiMD)
Donald & Pamela Gallup, MD

UAB School of Medicine
(C/O Ronald Alvarez, MD)
Richard Lieberman, MD
William Hoskins, MD
Howard Homesley, MD
KCCOP (DISC)
James Condon

Women's Cancer Care Associates, LLC
Thomas Counts

Mr. and Mrs. Sidney Couling
The University of Chicago
(C/O Diane Yamada, MD)
Sidney and Kathleen Couling
David Couling
(From Matt, David and Megan)
Paul Altieri

Bruce and Barb Ladewski
Alisa Vanryn
Tery Schooler
Colleen Calcaterra
Jane Homesley
Lynne Lippman
Eriko Aotani

Linda Havenar
Janice Miller
Patricia Brehm
Sharon Stockman
Bette Stonebraker
Debra Christie
Susan Turner
James Larson, MD
April Vaughan
Barbara Buening
David Moore, MD
Philip J. DiSaia, MD
Robert C. Park, MD
Ed and Gayle Lundbald
Gregory Sutton, MD
Thomas Roceroeto, MD
Nader Husseinzadeh, MD
Cecelia Boardman
Ben Greer, MD

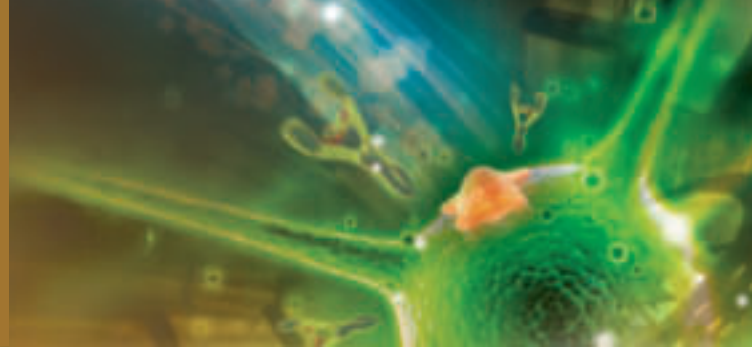
"Steppin Out" Donation

Debra Frick





**PRACTICE CHALLENGES AND
NOVEL TARGETED THERAPIES
FOR GYNECOLOGIC CANCERS:
OVARIAN, ENDOMETRIAL, UTERINE
AND CERVICAL CANCER**



**NEW FOR 2010,
A CME-CERTIFIED SATELLITE DINNER SYMPOSIUM TO
BE HELD DURING THE GOG SEMI-ANNUAL MEETING**

**Friday, January 29, 2010
6:30 pm – 9:00 pm
Manchester Grand Hyatt Hotel
San Diego, California**

TARGET AUDIENCE

This activity has been designed to meet the educational needs of gynecologists, medical oncologists, oncology nurses, oncology researchers, and other healthcare professionals interested in learning the latest data on biologic therapies being evaluated for the treatment of gynecologic cancers.

REGISTRATION

To register and view detailed agenda information visit www.GOG.org

CHAIRPERSON

Bradley J. Monk, MD, FACOG, FACS
University of California, Irvine

PHYSICIAN CONTINUING EDUCATION

This activity has been approved for *AMA PRA Category 1 Credit*.

Jointly sponsored by:



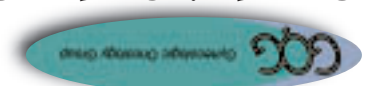
Postgraduate Institute
for Medicine

This activity is not part of the official
GOG Semi-Annual Meeting.

This activity is supported by an independent educational grant
from Genentech BioOncology.

**For the latest news and information,
visit www.gog.org**

Gynecologic Oncology Group
2127 Espy Court
Suite 100
Crofton, MD 21114



NON-PROFIT ORGANIZATION
U.S. POSTAGE PAID
CROFTON, MD
PERMIT NO. 19