



GYNECOLOGIC ONCOLOGY GROUP Newsletter EARLY SPRING 2007

Philip J. DiSaia, MD – Group Chair

Larry Copeland, MD – Group Vice Chair

Chairman's Corner

Philip J. DiSaia, MD

ADMINISTRATIVE OFFICES

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

STATISTICAL & DATA CENTER

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

FINANCE & DEVELOPMENT

2127 Espey Court, Suite 104
Crofton, Maryland 21114
410-721-7126

INSIDE THIS ISSUE

Statistical Corner
2

GOG Regulatory Affairs
Department
3

Science Corner
5

Protocol Corner
6

2006 Young Investigators
Awards
7

Financial Gifts
8

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The good news is that the GOG is thriving! The number of publications that have been extracted from GOG data continues to rise with greater numbers being produced each year. These quality papers have been published in some of the leading peer-review journals in the field of Oncology. At a recent international meeting held in England it was very gratifying to me to hear foreign colleagues repeatedly refer to GOG data as the richest source of knowledge in the field of clinical Gynecologic Oncology. Everyone participating in the Group enterprise should be proud and deserves a share of the credit.

The bad news is that we may have to adjust to budget cuts in the next two years which could be as high as ten percent. I'm very hopeful that it will not be as high as ten percent, but we won't know for several months. These cuts are pretty much across the board throughout the NIH including the NCI. All of us who have administrative roles have a contingency plan which we will adjust when we know exactly the magnitude of the reductions necessary. Everything will be done to make it possible to have the transition appear seamless and, hopefully, minimally apparent to the Group as a whole. Closure of poorly accruing studies may be necessary and opening new studies may have to be prioritized.

The Coalition of National Cooperative Groups is working hard to lobby for minimal cuts. You may have seen some of the articles appearing in magazines as well as newspapers such as USA Today. Some of the other groups have dropped entire committees. The Southwest Oncology Group has discontinued studies in head and neck cancers, and soft tissue sarcomas. Other groups such as CALGB have stopped studying brain tumors and will continue to limit their group-wide meetings to one meeting in order to save additional revenue.

As my grandfather used to say, "This too will pass." We in Administration will do everything we can to bridge this period of budget reductions. I am anxious that the momentum we have built-up over the last 36 years not be lost during this interval. ✨



GOG SDC Clinical Data Coordinators Play A Vital Role

One of the strengths of the GOG Statistical and Data Center has been the experience, dedication, and longevity of its members. This has been particularly true of the Clinical Data Coordinators in the Data Management section. I would like to provide some details about the varied responsibilities of this hard-working, most capable group. Individually, each is capable of independently managing the data on an ever-increasing volume of data, interacting with study chairs in the conduct and review of their protocols, and coordinating with responsible statisticians for timely analysis and publication. Collectively, they enable the SDC to efficiently process the continually increasing complex array of GOG protocols. All attend and participate in semi-annual GOG Meetings.

Patty Brehm is currently responsible for the management of GOG Corpus studies. This monumental task includes both large scale Phase III studies and Protocol 210 with its thousands of patient entries. Patty joined GOG in 1977 in a clerical position, subsequently assumed responsibility for all patient randomization, and in

1988 was assigned primary responsibility for all Phase II trials. In 2006, in recognition of her outstanding performance in this area, she was asked to assume responsibility for the Corpus portfolio and join the parent committee. She has excelled at every undertaking for 30 years.

Suzie Baskerville has been responsible for GOG ovarian trials since accepting a position in the SDC in 1990. Initially, she was assigned selected studies. In a very short time, she was able to assume responsibility for all trials developed by the GOG Ovarian Committee. During this time, she has experienced a phenomenal growth in both caseload and study diversity. Her expertise enabled her to adapt to the demands of Protocol 182 and allow the trial to be completed expeditiously. Current studies, Protocols 198, 212, and 218 are critical to the success of GOG, and profit from the level of pride and perseverance exhibited in Protocol 182.

Angela Vasquez also joined the SDC in a clerical position in 1998. Her ability to grasp GOG procedures and her dedication to high level performance led to a promotion to Clinical Data Coordinator in 2003. Upon the retirement of Barbara Saczynski, Angela assumed responsibility for trials developed by the Cervix Committee. This includes Protocols 191, 195, 204, 205, 219, and 222. Additionally, she is responsible for the coordination of all aspects of modality review by the Radiation Oncology Committee. Angela's expanded roll will ensure the continuity of excellence achieved by the Clinical Data Coordinators.

Sandy Dascomb joined the SDC in 2001 to assist in the management of a rapidly growing number of Phase II trials developed by the Developmental Therapeutics Committee. While the number of trials has continued to grow and many now have translational research components, Ms. Dascomb now has responsibility for all such studies. This attests to her rapid growth and efficiency in managing these trials. Her ability to coordinate such diverse entities as translational research components, requests from industry partners, study chairs, statisticians, and journal revision requests has enabled us to accomplish more with dwindling resources. She is also involved in the management of large-scale trial, LAP-2.

Linda Gedeon is the most recent arrival, having been hired in 2003 to manage the studies developed by the Cancer Prevention and Control Committee. This effort focuses on complicated Protocol 199, but also encompasses Protocols 197, 207, 215, and 220. Her efforts on behalf of Protocol 199 have been tireless and essential to the success of this undertaking. She has continued the GOG tradition of rapid acquisition of knowledge which fosters further growth in responsibility.

In summary, the knowledge, dedication, and expertise of the GOG Clinical Data Coordinators is an attribute of the SDC in which I take great pride. These folks are a true asset to GOG and integral to the SDC commitment to the GOG Mission statement.



Additional copies are available. Please contact nadona@gog.org or call 410-721-7126

New OHRP Guidance for Continuing Review

The Office for Human Research Protections (OHRP) has issued new policy guidance for the continuing review of human subjects research by an Institutional Review Board (IRB). The complete guidance document can be found on the OHRP website at: <http://www.hhs.gov/ohrp/human-subjects/guidance/contrev0107.htm>

In particular, the OHRP offers guidance on the following topics:

- What constitutes substantive and meaningful continuing review;
- What are some additional considerations for continuing review of multi-center trials monitored by a DSMB, DMC, or other similar body or sponsor;
- When may expedited review procedures be used for continuing review;

dures be used for continuing review;

- How is the continuing review date determined;
- What occurs if there is a lapse in continuing review; and
- What is the required composition of IRBs specifically designated to conduct continuing review.

Institutions are reminded to submit documentation of continuing review approval to CTSU (for non-industry trials) or to the GOG Administrative Office (for industry trials) as specified in Section 5.0 of the protocol.

Please contact Shawn Griffin (non-industry trials) or Katie Fisk (industry trials) with questions regarding continuing review.

Responding to AdEERS Serious Adverse Event (SAE) Reports

The Data Safety Monitoring Board (DSMB) Committee has requested that each Study Chair provide written assessment of the attribution determined by the treating physician for all Serious Adverse Event (SAE) reports generated for a specific protocol. While reviewing the SAEs at the last DSMB meeting, it was difficult for the committee to determine whether the Study Chair agreed with the treating physician's determination of the attribution for an event, as many of the responses received from the Study Chairs were "No Comment" or "Report Reviewed."

Effective immediately, each Study Chair will be required to give their opinion on the attribution of all SAEs reported on their studies. This information will give the DSMB Committee a better idea of the Study Chairs' thoughts on the event, and assist them in determining whether or not an event is related to the protocol treatment.

Please contact Shawn Griffin or Aisha Parks at 215-854-0770 with any questions.



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Amgen, Inc.

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Bristol-Myers Squibb

Cell Therapeutics, Inc.

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Geisinger Health Systems

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Mgi Pharma, Inc.

Novartis Oncology

Oncotech, Inc.

Ortho Biotech

Osi Pharmaceuticals

Pfizer Oncology

Precision Therapeutics

Sanofi-Aventis Pharmaceuticals

Tripath Imaging, Inc.

Wyeth Pharmaceuticals

GOG Superstars!

Dr. Philip J. DiSaia was presented The Frederick Naftolin Award for Mentorship during the 54th Annual Meeting of the Society for Gynecologic Investigation in Reno, Nevada. Dr. Linda Giudice, MD, PhD congratulates Dr. DiSaia for his contributions to training and career development of investigators in the field of reproductive and women's health. The award is named in honor of Dr. Naftolin, a former President of the society.



Dr. DiSaia congratulates Dr. Hoskins on his outstanding service to the Data Monitoring Committee.



Dr. DiSaia congratulates Dr. Moore on his outstanding service to the Cervix Committee.



John Blessing, PhD presents Barbara Saczynski and Fran Valvo the GOG Distinguished Award for over 25 years of service to the GOG.

Arizona Cancer Center Director David S. Alberts, M.D. Named 2006 Salsbury Award Winner

The Arizona Hospital and Healthcare Association awarded Arizona Cancer Center Director David S. Alberts, M.D., their highest honor, the 2006 Salsbury Award. The award, presented at the AzHHA annual banquet in Scottsdale, is given to an individual for making an outstanding contribution to healthcare in Arizona.

“Dr. Alberts’ pioneering work in cancer research has benefited thousands in Arizona and millions of people around the world,” said John Rivers, AzHHA’s president and CEO. His tireless efforts to prevent illness and cure cancer continue to this day.”

Dr. Alberts began working as a cancer researcher more than 30 years ago at

the National Cancer Institute’s Baltimore Cancer Research Center, where he helped develop and test anti-cancer drugs and prevention agents. At the Arizona Cancer Center, he has championed clinical trials to prolong the lives of women suffering from stage III ovarian cancer.

Earlier this year, the NCI issued a rare clinical announcement encouraging treatment pioneered by Dr. Alberts, which calls for the administration of anticancer drugs via two methods after surgery for women with advanced ovarian cancer. The combined treatment methods are called intraperitoneal, or IP, for chemotherapy delivered into the abdominal, or peritoneal, cavity, and intravenous, or IV, for

chemotherapy delivered into a vein. Thanks to the leadership of Dr. Alberts, the Arizona Cancer Center is home of one of the largest Cancer Prevention and Control Programs among the nation’s 40 comprehensive cancer centers, with leading research in breast, colon, lung, prostate and skin cancer prevention.

The Salsbury Award is named in honor of the Association’s founder, Clarence Salsbury, M.D., a physician who founded Sage Memorial Hospital in Ganado, Ariz.



Ideas: The Wealth of the GOG

The GOG has long fostered an open system which permits any GOG investigator to submit ideas for clinical trials. Oversight and direction for this flow of ideas falls to the purview of the Protocol Development Committee under the new organization. Each of our eight major scientific committees (Ovary, Cervix, Corpus, Developmental Therapeutics, Experimental Medicine, Cancer Prevention and Control, Quality of Life, and Rare Tumors) is a venue through which new ideas can be placed on the table for consideration by the protocol development process. There are a number of commonly asked questions regarding access to this process:

- 1. What is the best approach to becoming a study chair for a GOG study?**

Phase III trials are major undertakings and generally result from input from a number of sources including industry, the NCI, the Gynecologic Cancer Steering Committee of CTEP, perhaps the FDA, etc. It is very difficult to break into the circle of study chairs as the chair of a phase III study. The best way is to visit with the Chair and Co-Chair of the Developmental Therapeutics Committee about becoming the study chair of a phase II trial. Experience gained through the development of a less complex phase II trial concept, defending the concept at committee sessions, and shepherding the proposal through the regulatory maze will serve the study chair well as he or she subsequently undertakes the development of a phase III study. In addition, if the phase II agent for which
- 2. Am I likely to spend time developing a concept which will subsequently be rejected?**

The short answer is yes. A majority of concepts reviewed by the GOG do not eventually become protocols since there are always more ideas than patients. The experience gained, however, gives the investigator a better understanding of the process and increases, in most instances, the likelihood of future success.
- 3. What are the major factors in determining which concepts are approved?**

There are three major factors: the quality of the idea (in terms of scientific merit), the priority the GOG places on that study relative to other possible studies, and the quality of the presentation of the idea to the responsible committee. All three of these factors can be influenced by a well-prepared study chair.
- 4. How much time is required for the preparation of a study?**

Again, the short answer is a lot. Each study must include all information necessary to the conduct of the trial and must meet all regulatory requirements. The required information is outlined in the Protocol Procedures Manual which is available from your principal investigator or from the
- 5. Is the effort to become a study chair worth it?**

This may depend on what your own priorities are. We can imagine no greater professional satisfaction for a physician than that associated with the design and conduct of a study which makes a difference in the lives of thousands of patients. The advantage of GOG trials is that these trials will be large enough and focused enough to make that difference.

Administrative Office or the SDC.

5. Is the effort to become a study chair worth it?

This may depend on what your own priorities are. We can imagine no greater professional satisfaction for a physician than that associated with the design and conduct of a study which makes a difference in the lives of thousands of patients. The advantage of GOG trials is that these trials will be large enough and focused enough to make that difference.

We hope that each investigator, especially the new and younger investigators in the GOG, will become active participants in the study process by not only putting patients on study but also contributing ideas through the study development process. If you have further questions about this process, please feel free to contact either Dr. Thigpen (jtthigpen@att.net) or Dr. Alvarez (RDALVAREZ@aol.com).

Protocol Department

With the ever increasing complexity of the GOG Phase II Queue, it is hoped that the following review of the three active ovarian series will clarify what studies are available for these patients.

The 126 series evaluates patients with platinum-resistant disease. The 146 series evaluates patients with platinum-sensitive disease. The 170 series evaluates biologic agents in patients with platinum-sensitive and platinum-resistant disease. The 126 and 146 series allow only one prior chemotherapy regimen (front-line only). The 170 series allows two prior chemotherapy regimens (front-line therapy plus one for recurrent/persistent disease). There are plans in place for future phase II studies to allow one prior biologic as part of front-line therapy. This will allow patients who have participated in GOG-0218 to be eligible for phase II studies.

With the availability of treatment programs that involve extended taxanes and biologics, it has become more difficult to classify patients. When a patient has been found to have recurrent/pro-

gressive disease, the following guidelines should be used for GOG studies.

- Platinum-resistant is defined as a platinum-free interval of < 6 months.
- Platinum-sensitive is defined as a platinum-free interval of 6-12 months.

It is important to remember to count the time interval from the last platinum treatment, NOT from the last dose of non-platinum extended or consolidation therapy. The 170 series is open to both platinum-sensitive and platinum-resistant patients (platinum-free interval < 12 months). Patients with a first recurrence and a platinum-free interval of > 12 months are felt to be best served by platinum-based chemotherapy and are not eligible for these three series.

In order to conduct more studies and to do them more quickly, the 126 series is broken into groups A and B. The 146 series studies are currently open group wide (146-O and 146-Q). A site can accrue to only one trial in a series at a time. When 146-O and 146-Q complete accrual, the 146 series will be suspended in order to run phase III studies

in the platinum-sensitive population. Therefore, new concepts are not being accepted for the 146 series.

The 170 series studies were broken into groups A and B and one study, GOG-0170F, is currently open to Group A. However, in order to evaluate new biologic agents as expeditiously as possible, accrual to the 170 series studies is no longer going to be done in this manner. For the newer 170 series studies, any site can accrue patients but to only one 170 series study at a time. It is permissible to initiate IRB approval on a second study when suspension after first stage or completion of a trial approaches in order to avoid having gaps in accrual. Affiliate and parent institutions do not have to accrue to the same 170 series studies; each site is able to make this decision independently.

The current GOG Phase II Queue is on the GOG member website and can be found under "Committees", "Developmental Therapeutics and Phase I".

The Protocol Department would like to thank Dr. Carol Aghajanian for her assistance in preparing this article.

Meeting Highlights



Registration



2006 Young Investigators

Many thanks to all that participated in the 2006 Young Investigators Award projects. GOG would like to congratulate the winners:

KATHLEEN MOORE, MD

Study: Second Line Chemotherapy in Patients with Endometrial Cancer: Does Treatment and Platinum-free Interval Predict Response, Progression-free Survival, and Overall Survival?

ABRAXISTM
ONCOLOGY

GEZA ACS, MD, PHD

Study: Prognostic Value of Pretreatment Podoplanin Expression in Cervix Carcinoma Treated with Primary Radiation.

AMGEN

Oncology

**ANGELES ALVAREZ
SECORD, MD**

Study: Targeting the VEGF Cancer-Specific Pathway in Ovarian Cancer

**THE OVARIAN CANCER
RESEARCH FUND, INC.**

JOHN K. CHAN, MD

Study: Early Stage Epithelial Ovarian Cancer at High Risk of Recurrence: A

Meta Analysis of Gynecologic Oncology Group Trials

**THE OVARIAN CANCER
RESEARCH FUND, INC.**

AMIR ANTHONY JAZAERI, MD

Study: Chemotherapy Induced Molecular Changes in Epithelial Ovarian Tumors and their Relationship to Clinical Chemoresistance

**THE OVARIAN CANCER
RESEARCH FUND, INC.**

THOMAS KRIVAK, MD

Study: Predicting Response to Platinum Based Therapy Using the ERCC1 Codon 118 Polymorphism

**THE OVARIAN CANCER
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Opening Session



ICT Dinner

In Loving Memory of Elaine Alberts

Anita & Monroe Rackow
Ann Cohen
Art and Toby Schuman
Becky & Steve Handler
Bonita Carboski
Carol Ullery
Carole Fink
Cheryl Wesberg
Constance Fraser
Craig Bolotsky & Marlene Coplow
Dr. Herb & Judy Silver
Edgan & Barbara Einhorn
Ellie & Harold Cohan
Gail & Alan Weinstein
Gale Terrill
Hilary & David Silver
Howard & Ellen Landua
Irene Makiaris
Jackie Weisenberg
Jay & Lauren Gordon
Jerome & Harriet Gilson
Jo-Ann Boehm
Judy & Allan Greenstein
Judy & Dr. Melnick
Julie & Daniel Berger
Kathleen Hedlund
Leslie & Sam Silverman
Lynn & Joel Perlmutter
Marlene Gaty
Melissa & Mark Bildner

Muriel Denowitz
Pat & Arthur Roth
Perry & Lorraine Ury
Congregation B'nai Isreal
Rachel & Ephraim Cohen
Robert & Harriet Berland
Ron Rotem, DDS
Sandra & Arnold Chase
Sandy & Steve Brown
Gordon & Karen Binkhorst
Saul & Marcia Bolotsky
Shelby Palmer
Sheldon & Jessie Chafetz
Shelly & Ray Lynnworth
Sherry & Robert Cohn
Sousa/Jepsen/Winn Family
Susan Banks
Susan & Howard Fierberg
Susan Jacobs
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Judy & Jerry Cohen
Kathleen Flaherty
Kenneth & Silvia Davis
Lois Ellovich
Marjorie Kravitz
Max & Barbara Schloff
Michelle Repole



In Loving Memory of Dorothy Elizabeth Dugan

Donors wish to remain anonymous

*The Gynecologic Oncology Group
would like to thank
JustGive.org for their contribution
in the name of Eleida.*



Supporting the GOG financially helps provide the much-needed financial resources which will allow GOG to develop and deliver essential research tools to enrich our efforts in the quality of life aspects to our trials as well as in basic research activities.

NEWS AND INFORMATION

Please forward
any news or suggestions to
Kathy Shumaker
GOG Development Manager
kshumaker@gog.org

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information,
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