



March, 2004

Volume 1, Issue 4

# THE GOG NEWSLETTER

## The Gynecologic Oncology Group

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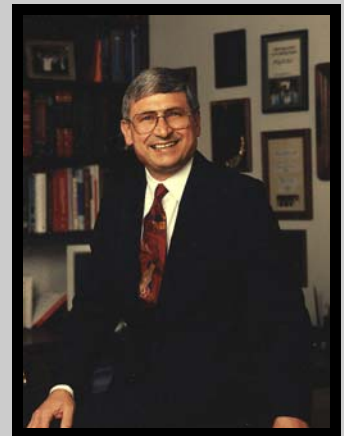
Philip J. DiSaia, MD  
GROUP CHAIR

Larry Copeland, MD  
VICE CHAIRMAN

### Chair's Corner

Philip J. DiSaia, MD

I am happy to report that our October 2003 site visit (five-year review) went well and we received a score of 170, which is an excellent result. All members of the GOG should be proud of this achievement and I wish to personally thank each of you. During the review, three of our committees achieved an outstanding designation and those three were Nursing Committee, Quality of Life Committee, and Developmental Therapeutics Committee. The bad news is that overall funding for Cooperative Groups will not be increased this fiscal year, and the best we can hope for (in view of this excellent score) is that our portion of the CTEP budget is increased. Independently, Cooperative Group Chairmen have met with the NCI Director to discuss our prolonged under-funded status, and he has suggested a reorganization of all therapy oriented contracts, grants and agreements. A committee has been named by the NCI Director to study the Cooperative Groups, SPORES, and Cancer Centers involved in clinical trials and come up with suggestions for increasing efficiency. At the same time, the Cooperative Group Chairs have submitted a "White Paper" which will outline our suggestions for improving the future of clinical trials in this country. Please stay tuned for more information as these processes unfold. In the meantime please continue your excellent performance and I promise to leave no stone unturned in our efforts to enhance funding.



Philip J. DiSaia, MD  
GOG Group Chair

**PHASE I WORKING GROUP      Protocol & Development Department****Phase I Working Group**

The following information is being provided in a continuing effort to keep our Group membership informed and updated.

The GOG Phase I Working Group performs clinical trials utilizing new agents, combinations of agents, and agents used as radiation sensitizers to determine Maximum Tolerated Dose (MTD) and feasibility of therapies before moving them into the Phase II or III arena.

Phase I participation is limited to a group of institutions that are chosen because of the investigators' experience with drug toxicity testing, ability to conform to the rigorous real-time reporting procedures required by phase I trials and proven ability to accrue patients to GOG trials. Moreover, phase I institutions are expected to generate phase I protocols and be equipped to perform pharmacokinetic sampling. Participation is currently limited to 20 institutions.

A traditional phase I trial will open at a starting dose to three patients; a hold is then imposed on new entries on the trial in order to observe toxicity. Real-time reporting of toxicities is ongoing between the treating physician or the nurse, Study Chair, and Statistical and Center (SDC) via fax, phone and e-mail in order to capture and communicate all adverse events, expected or otherwise. This reporting is in addition to reporting required by the NCI, and/or FDA. Deciding what constitutes excessive toxicity is an on-going dynamic process.

Participation on phase I trials is limited for the following reasons: (1) Adequate safety monitoring is feasible only with a small group of institutions. (2) The logistics of coordinating the "slots" for a phase I trial can be cumbersome; only a small fraction of the phase I institutions usually participate in the dose-escalation phase of any given trial. Phase I trials may have long delays between dose levels, and the incentive to submit a trial to an individual IRB can be low when an institution may never enter a patient. (3) The trials can compete with higher priority GOG studies.

**Participation is generally limited to Parent institutions. Affiliates of a parent phase I member are NOT automatically phase I members. When a Study Chair's institution is an affiliate institution the affiliate institution is able to participate on that one trial only. A selected few affiliates are phase I members; this is evaluated on a case-by-case basis. Membership is evaluated by the Chair of the Phase I Working Group and the Chair of Developmental Therapeutics, and is re-competed periodically via a formal application process as new institutions show interest in participation.**

**Future contributions from the Protocol Development Section to the Newsletter will include an explanation of the Phase II queue and the breakdown into Groups A and B.**

## **STATISTICAL CORNER**

**John Blessing, PhD**

**In response to several requests, I would like to briefly outline the process by which a manuscript is prepared within the Statistical and Data Center (SDC). When the data are sufficiently mature, a final analysis is prepared for dissemination in the GOG Statistical Report. A preliminary draft of this report is provided to the primary Study Chair with the indication that the analysis can serve as the basis for a manuscript. Simultaneously, the GOG Publications Office, a component of the Administrative Division of the SDC, is notified and tracking of the manuscript progress begins. At each successive step deadlines are assigned to ensure timely publication.**

**Upon receipt of the first draft of the paper, it is given to the appropriate statistician for review and /or incorporation of additional data required. When required interaction has occurred with the primary author, the first draft is assigned to an Editorial Specialist who formats for the intended journal, and creates the working document that will be circulated through all remaining phases of preparation. (It is essential that there be only one official version in circulation.) Potential co-authors are assigned according to the GOG Publications criteria and the Editorial Specialist circulates the current draft to these individuals for review and critique. Again a deadline for responding to this review is given. (Based upon appropriate completion of the review process, authorship may then be confirmed.) The Editorial Specialist then interacts with the primary author and/or statistician, as necessary, to determine the need for further revision based upon co-author feedback and a deadline is established. Next, the manuscript is distributed to**

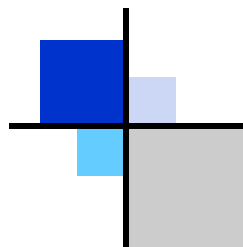
# STATISTICAL CORNER

the Publications Subcommittee for editorial review. Once again, the results of this process are discussed with the primary author to finalize the document for journal submission. The paper is submitted by the Publications Office on behalf of the first author.

Following journal review, the paper may be accepted, accepted with modifications required, or rejected. If revision is required, this is coordinated by the Editorial Specialist. If the paper is rejected, discussion is required among all the principals to determine an appropriate plan for alternative submission and incorporation of issues raised in the critique.

Inherent in this process is the continual updating of the Publications Database which tracks deadlines, completion of critical phases of preparation, and ultimately the GOG Bibliography. The Chair of the Publications Subcommittee meets quarterly with the Administrative Division of the SDC to review and update deadlines and monitor progress. These actions have been instrumental in increasing the timely publication of GOG data. This discussion has been presented as a generic overview. There are various individual nuances, such as the process for incorporating translational research and quality of life. Nonetheless, the overall developmental process is similar.

During 2003 the GOG had 25 papers published or in press. The average number of publications for the period 1999-2001 was 15 papers. The GOG is committed to building upon this success!



## The Challenge: To Adapt and Grow or To Die

**“No living entity, be it plant or animal, man or woman, physical or metaphysical, can long be static. To live is to change, to adapt, to grow; the only alternative is to die.” - Anonymous.**

The founding of the Gynecologic Oncology Group resulted from the marriage of the funding resources from the National Cancer Institute to the desire of the gynecologic oncology community to better serve patients with gynecologic cancer. To a great extent, the GOG depended almost exclusively on these resources throughout the first part of its existence. To be sure, significant progress resulted. The addition of first the platinum compounds and then the taxanes resulted in a marked improvement in treatment outcomes for patients with ovarian carcinoma. Concurrent chemoradiation brought substantial reductions in mortality for patients with locally advanced carcinoma of the cervix. Staging studies of endometrial carcinoma together with concerted study of systemic options for treatment have resulted in major progress in the treatment of patients with advanced or recurrent endometrial carcinoma.

Dramatic changes in the nature of clinical research and the sources for innovative new approaches to the treatment of cancer have mandated a change in the approach of the GOG to the study of gynecologic cancer. Increasing involvement of the GOG with the pharmaceutical industry has characterized the developments of recent years. Some have deplored this as “interfering with the integrity of research.” Others have suggested that such involvement be only to a limited degree. There are, however, cogent reasons for an expanding relationship with private industry as a part of the GOG mandate.

First, the GOG, as the premier cooperative clinical research group in gynecologic cancer, must seek to study the most promising leads. A majority of those leads no longer come from public or governmental sources. Active pipelines for drug development in multiple pharmaceutical companies now produce a majority of drugs with great potential as cancer therapies. It is imperative that the GOG have access to these exciting new molecules so that they may be properly developed in large, randomized trials which truly test the efficacy of these new agents. Only through well-developed cooperative relationships with industry will this be possible. The most important reason for a growing GOG relationship with industry is therefore a scientific one: access to the most promising new agents.

Second, if GOG clinical research is to produce innovative approaches to the management of disease, it is mandatory that the research produce meaningful data on the underlying mechanisms by which therapy effects a positive outcome. Such research requires funding support which is not a part of the GOG’s NCI grant. Industry can and does provide such support. The second reason for the evolving GOG-Industry partnership is thus a pragmatic one: the combined resources of the two manifested as funding from Industry, the GOG’s access to large numbers of patients for trials, and medical and scientific expertise from both lead to results which teach us more about the biology of the cancer and identify more effective therapies for our patients.

The future of the Gynecologic Oncology Group includes a vibrant relationship with Industry as well as with the National Cancer Institute. This is a vital part of adaptation to an ever changing set of challenges that we must meet if we are to continue to grow and to meet the major purpose of the GOG to arm physicians with better ways to help our patients with gynecologic cancer. To do otherwise is to die as an effective weapon in the fight against cancer.

## ***"NOVEL THERAPEUTICS IN GYNECOLOGIC ONCOLOGY"***

**GOG Host: Michael Birrer, MD**

**Sponsored by the Platinum  
Educational Underwriters**

**Alex Adjei, MD, PhD  
Andrew Berchuck, MD  
Angeles Alvarez-Secord, MD  
Richard Pazdur, MD  
Mark Pegram, MD  
Eric Rowinsky, MD  
Jeffrey Trent, MD, PhD  
Jeffrey Trent, MD**



The first corporate symposium was conducted on Thursday prior to the GOG Semi-Annual Meeting. The symposium focused on novel therapeutics in gynecologic oncology and included a panel of international recognized experts in this field. Leading off was the keynote speaker Dr Jeffrey Trent who was the Scientific Director of the National Institute of Human Genome Research and is now the President of the Translational Genomics Research Institute. Dr. Trent discussed the impact of the genomic revolution on cancer diagnosis and therapy. He clearly demonstrated that our approach to cancer patients would be dramatically different in the coming years due to our knowledge of the human genome. Following Dr. Trent was a session moderated by Dr. Eric Rowinsky on some of the new therapeutic agents and their targets. Included among these speakers was Dr. Andy Berchuck discussing on expression profiling in ovarian cancer, Dr. Angeles Secord speaking on angiogenesis targets and Dr. Alex Adjei discussing cytotoxic agents. In the afternoon session, there was a series of presentations on the problems and challenges with clinical trials on biologically targeted therapies. A spirited discussion followed focused on the best approaches to efficiently test these agents on patients with Gynecologic cancers. Overall, it was a very interesting and informative start to this symposium series. We look forward to next one!



**SAVE THE DATE**

**THURSDAY, JULY 15, 2004**

***"CONTROVERSIES IN GYN CANCER"***

***"NOVEL THERAPEUTICS IN GYNECOLOGIC  
ONCOLOGY" attracted a full house.***





## FIRST SILENT AUCTION ENJOYED BY ALL!

The first-ever GOG Silent Auction was enjoyed by all. The Gynecologic Oncology Group received a total of 75 items. Dr. DiSaia expressed his appreciation and was happy with the overall outcome of the auction and is very appreciative of the support it has received, not only from the outside, but from own members. The quality of the items donated exceeded our expectations! The success of the auction is stimulating the early planning for a second, even bigger event next year. Watch for exciting details, with a totally different theme.



A surprise visit from the Atlanta Falcon Cheerleaders spiced things up during the auction.



Dr. Stehman did a fantastic job auctioneering. Did he miss his calling?



Items were displayed in the Registration area prior to the auction.



A happy and excited auction winner!

**Silent Auction  
Planned for  
January 20, 2005**

Put your thinking caps on! We are in the process of planning next year's auction, with a very different feel. Since we will be in sunny California, we will have a California theme. We will have more viewing time to ensure high energy and enthusiasm for the event.

If your institution is interested in donating a product or service, please contact Kathy Shumaker @ Kshumaker@gog.org for information. Bidder numbers will also be issued via email starting in December. We will have a special prize for the institution who donates the most unique item. Popular items donated included: unique wines, vacations, golf outing, and autographed sports memorabilia. Let's all pool together, and exceed our expectations!

AMGEN  
ASTRA-ZENECA  
AVENTIS  
BRISTOL-MYERS SQUIBB  
CELL THERAPEUTICS  
ELI LILLY & COMPANY  
EMD PHARMACEUTICALS  
GENENTECH, INC.  
GENZYME BIOSURGERY



GLAXOSMITHKLINE  
IMPATH  
MEDIMMUNE ONCOLOGY  
MGI PHARMA  
NOVARTIS  
ORTHO BIOTECH  
OSI PHARMACEUTICALS  
PFIZER ONCOLOGY  
TRIPATH IMAGING, INC

PLATINUM EDUCATIONAL UNDERWRITERS

AVENTIS PHARMACEUTICALS	CELL THERAPEUTICS	GLAXOSMITHKLINE
BRISTOL-MYERS SQUIBB	ELI LILLY & COMPANY	ORTHO BIOTECH



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