



September, 2004

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THE GOG NEWSLETTER

The Gynecologic Oncology Group

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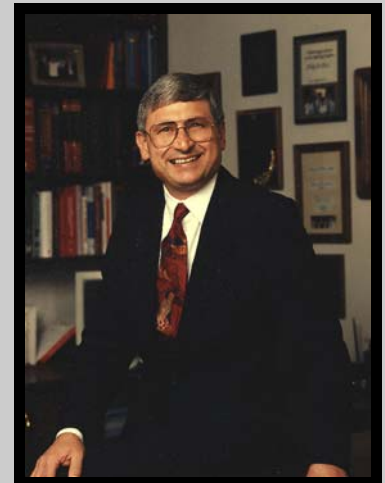
Philip J. DiSaia, MD
GROUP CHAIR

Larry Copeland, MD
VICE CHAIR

Chair's Corner

Philip J. DiSaia, MD

Our recent meeting in July at the Hyatt Regency, Orange County was very successful. Over 800 participants enjoyed good science, friendships and great weather. A great deal of work was successfully completed at the meeting at a time when our Group is about to close major protocols that have accrued large numbers of patients. It is vital that our replacement protocols get opened to patient entry as soon as possible; over the past year we accrued close to 4000 patients (an all-time high) and we must not lose this momentum.



Philip J. DiSaia, MD
GOG Group Chair

Although our site visit scores were excellent, our funding is essentially flat due to cuts to the CTEP budget. The answer for our Group is to create new sources of income, e.g. industry assisted trials, philanthropy, etc. We are anxious to find trials which embrace good science and at the same time generate income which can be used to increase the revenue to principal investigators, and also help support our increasing translational research studies. Our industry partners have developed and will be developing many exciting molecules, and I am very confident that we can accomplish these goals.

I welcome comments on the organization of our meeting and other suggestions on the operation of our Group activities. Please do not hesitate to send me your

PROTOCOL DEVELOPMENT AND REGULATORY DEPARTMENT

CONFLICT OF INTEREST

Definition: A Conflict of Interest (COI) is any type of arrangement, financial or otherwise, that has the potential to threaten the integrity of the clinical research being performed.

Institutions and Institutional Review Boards (IRBs) must be vigilant in checking and updating the appropriate documentation to avoid any occurrence of a conflict of interest. In addition to ensuring that research is performed with integrity, institutions, researchers and IRB members must maintain the public trust.

GENERAL GUIDELINES

- Investigators, IRB members, and institutions are encouraged to refrain from taking part in a study if their participation can be detrimental to the research process either directly or indirectly due to a COI; perceived conflict of interests have to be prevented since they can result in public mistrust.
- The Code of Federal Regulations (CFR) requires that the possibility of coercion or undue influence be minimized (45 CFR 46.116, 21 CFR 50.20). All titles of the CFR can be found at <http://www.gpoaccess.gov/cfr/index.html>
- IRBs are responsible for ensuring that members who review the research proposals have no conflicting interest.
- For HHS conducted or supported research, the funding agency may impose additional conditions as necessary for the protection of human subjects.
- Although the CFR requires that the possibility of coercion be minimized, financial interests are not prohibited; not all financial interests are considered to be a conflict of interest.

The Office of Public Health and Science (OPHS), Department of Health and Human Services (HHS) GUIDANCE DOCUMENT

Definition: A guidance document is intended to provide guidance; it represents current thinking on the topic. It does not create or confer rights for or on any person and does not operate to bind HHS, FDA, or the public. An alternative approach may be used if it satisfies the requirements of the applicable statutes and regulations.

- The OPHS, HHS issued a new guidance for dealing with financial interests in research on May 12th, 2004.
 - The guidance is meant for IRBs, investigators, research institutions, and anyone associated with research.
 - It recommends that IRBs, etc., consider whether specific financial interests may adversely affect the rights and welfare of subjects.
 - It raises points to consider in determining whether specific financial interests would affect the rights and welfare of human subjects, and if so, what actions could be taken to protect those subjects.
 - It applies to human subject research conducted or supported by HHS or regulated by the FDA.
 - General considerations are proposed for evaluating financial interests and their effects on human subject research.
 - It does not confer or create rights.

VARIOUS CAUSES OF CONFLICT OF INTEREST

- COIs are not caused by monetary interests alone. Various circumstances can lead to a COI. Here are some examples:
 - Pressure/desire to have an article published.
 - Institutions that specialize in certain areas of medicine may demand high accrual goals.
 - Institutions that specialize in certain areas of medicine may demand high accrual goals.
 - Complex cases can lead to uncertainty about whether or not a COI exists.
Example: An institution is conducting research with a corporation and at the same time it has a favorable relationship with a subsidiary of that same corporation. This practice may be innocuous such as when large corporations acquire other companies. A perceived COI could develop, but researchers with an interest in any newly acquired companies would have had no prior knowledge of the corporate maneuvering.
 - Many times institutions have to act on perceived COIs due to public response.

CONSEQUENCES

- A COI can lead to:
 - An alteration of data.
 - Making ethical concerns secondary to project goals.
 - Public mistrust.

PREVENTION THROUGH REPORTING

- **COI reporting should not be left to individuals or individual institutions.**
 - Individual IRBs are best suited for this process. It is recommended that IRBs take a more proactive role.
 - If the onus is left to an individual or an individual institution, when a COI exists, they may choose to refrain from reporting the COI. This process allows for abuse.
 - Individuals with a COI may feel that they will not allow the COI to influence them, so they continue without reporting.



The Jerry Rice 127 Foundation and the Women's Cancer Center Research Foundation made a donation of \$7,500 to the GOG Development Fund at the July 2004 GOG Meeting. This funding was raised at the 2004 Playmakers Celebrity Golf Classic and Dr. Nick Spirtos, PI, Women's Cancer Center presented the check. Dr. Spirtos also presented a picture of Jerry and Jackie Rice signed by many celebrities from the Golf Classic. This picture is now proudly displayed in the Conference Room of the Administrative Office.

STATISTICAL CORNER

John Blessing, PhD

Electronic Data Entry on Protocol 212

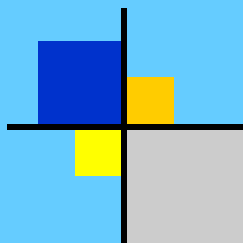
One of the primary goals of the GOG Statistical and Data Center (SDC) during the present grant period is to foster electronic data submission. To that end, several significant steps have occurred. First, is the development of SEDES (SDC Electronic Data Entry System). Integral to this system is the use of TELEform software for Case Report Form (CRF) creation. The creation of each form is an elaborate process involving IT, data management, statistical, (translational research, where applicable), and Administrative Office personnel. Aspects include not only form content, but also allowable data range and logical consistency checking.

Following the development of SEDES, we initiated its use on the patient registration form (Form A or R) for all protocols in 2001. Virtually all GOG institutions had the capability to use this option. In 2001, 54% of all A Forms were submitted electronically; that percentage has risen to 72 % for 2003. Next came the electronic version of follow-up forms (Form Q). Thus, both the SDC and the entire GOG has had the opportunity to gain experience.

With this experience, it is now time to focus on managing an entire protocol. For this reason, Protocol 212 will be managed electronically. This protocol was selected for several reasons: the volume of data anticipated; the timing of its activation; the experience obtained from each form will be maximized by a large scale study. In contrast to the utilization of Forms A and Q, electronic submission on this study will be mandated. All CRF's have been developed for electronic submission (path reports and operative reports will still be submitted via hard copy) and final preparations are being made to ensure the availability of the system at protocol activation.

Our intention is to continue to build upon the success that we have had and will have as future protocols are developed. Certainly, there will be training sessions at GOG Meetings and the IT Support Line will be a valued resource. We are investigating the possibility of having a separate training session for interested parties. However, due to expense issues, this remains in limbo.

While we are all excited about this undertaking, we realize it is a joint effort with the entire GOG. On behalf of the entire SDC staff, I would like to express our appreciation for the cooperation and efforts of the member institutions!



**January
13, 2005**

“FUTURE DIRECTIONS IN GYNECOLOGIC MALIGNANCIES”

Sponsored By:
The GOG Educational Underwriters
and the GOG Symposium Committee

GOG is pleased to announce that the next industry sponsored educational symposium will be entitled “Future Directions in Gynecologic Malignancies.”

The morning session will focus on identification of questions with the highest scientific and clinical priority for evaluation in the next front-line phase III trial in advanced ovarian cancer. The lectures will be followed by a panel discussion to assess the advantages or disadvantages of each approach, together with innovative options for clinical trial design. The afternoon session will consist of a staged competition among three clinical investigators, each of whom will be assigned responsibility for Development and FDA approval of a new chemotherapy agent in ovarian cancer. The individual drug development plans will be critiqued by an industry panel, including presentation before a surrogate ODAC-FDA panel. This symposium should prove to be very educational as well as entertaining.

CONTINUING MEDICAL EDUCATION CREDITS “CME”

Many of you have asked why an evaluation form is needed for each GOG committee meeting you attend and why we are now asking that you specifically register for each GOG meeting session you plan to attend.

The answers are as follows:

- GOG applies to an ACCME accredited organization such as The American College of Surgeons (ACS). The accrediting organization determines the amount of credit awarded for each session by way of agenda and educational materials submitted with the original application. We must provide to the accrediting organization proof of your attendance by way of sign-in sheets and we must evaluate the effectiveness of the meeting by completing self-evaluations. Therefore, please remember that you may only receive credits for one concurrent session at a time.

Please remember to sign the attendance sheets and turn in your evaluation forms so that GOG can continue to provide continuing medical educational credits to its members. January 2005, we will provide a booth next to the registration area for validation and evaluation return.

SCIENCE CORNER

J. Tate Thigpen, MD

Trials and Tribulations

Over the last three decades, the GOG has evolved an approach to the design of clinical trials which has served us well. This approach has depended on several critical fundamentals: (1) New agents and approaches should be tested thoroughly in phase I and II trials before incorporation into phase III trials. (2) Phase III trials should examine questions which have the potential to advance significantly response and survival, quality of life, and science. (3) The process by which these trials are set and executed should afford all GOG members with legitimate input to trial design. These fundamentals have served us well and have permitted us to have a major impact on the standard of care of patients with gynecologic cancers.

Events of the last two years have placed major stresses on the GOG approach. Our trials have become immensely more complex with the inclusion of translational objectives and quality of life components and with the ever increasing size of the accrual goals. Financial realities resulting from the dwindling support from government have finally forced us to look to the private sector for a major portion of the support for our efforts. Statistical and administrative resources are required to cope with an ever increasing load without a proportionate increase in funding. Finally, pressure to produce major advances now is eroding the will to test new agents thoroughly in phase I and II trials before undertaking a phase III study.

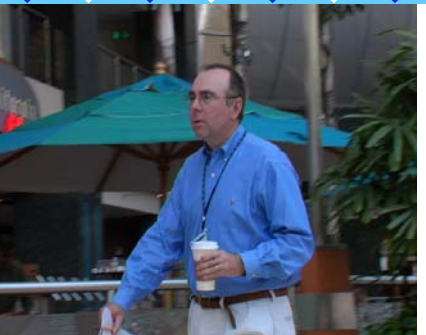
These stresses have necessitated changes in how we do business. Because we must now respond to not only rapidly evolving science but also a rapidly changing market place, we must develop mechanisms which allow us to respond rapidly to these demands. Even our dealings with the National Cancer Institute have changed as more pressure is exerted on the Cancer Therapy Evaluation Program (CTEP) to show progress in the area of biologicals, an area into which the NCI has poured large amounts of money without a resultant large amount of progress to date.

What are the practical implications of all of this? First, we must insist on good science even as we reach compromises necessitated by our dealings with industry. This is a delicate balancing act which requires that we all have patience with each other as we learn to perform well in this new environment. We must remember that good science can include ideas with which we may not agree. Secondly, we cannot wait on the semi-annual business meeting to conduct much of our scientific dialogue. Committee conference calls will be required to respond to changing needs and negotiations; and much of our business may be conducted outside the twice yearly meetings. Thirdly, and most importantly, we must be flexible enough to meet the challenges of an ever-changing set of circumstances which dictate changes in how we do things while at the same time remaining true to our three basic fundamentals as stated above.

We have accomplished much to advance the management of gynecologic cancers over the last 34 years. We are continuing and will continue to achieve improvements in the standard of care as a result of the foundation on which GOG has been built. GOG depends, for its foundation, not on individuals but on an effective system in which each member has valid input. That system and the people who carry it out (each and every member of GOG) position us well to meet these challenges and to continue progress in the care of the woman with gynecologic cancer.

MEETING HIGHLIGHTS

GARDEN GROVE, CALIFORNIA
JULY 16-18, 2004



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 *
 SANOFI-SYNTHELABO
 TRIPATH IMAGING, INC

** Denotes Educational Underwriter*

A NOTE OF SADNESS....

With sadness we inform you that on August 19, 2004, our very own John Kellner, known to most of us as "Jack," lost his beloved wife Janet ("Jan") to cancer. Our warmest sympathy goes out to Jack and his family. Jack has requested that in lieu of flowers, donations can be made to the Gynecologic Oncology Group. The donations should be sent to:

The Gynecologic Oncology Group
 Development Office
 2127 Espey Court, Suite 104
 Crofton, Maryland 21114

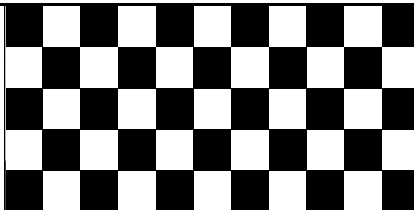


All donations should indicate that they are "In Memory of Jan Kellner."

Also, many of us knew Bob Salvo from Novartis pharmaceuticals. We were very sorry to hear that he passed away earlier this month. Bob was a great friend of the GOG and many of the investigators.



Dr. Bookman presented his ideas for the corporate symposium.



WWW.GOG.ORG



The GOG Educational Underwriters hosted the symposium.

FUTURE MEETING SITES:

JANUARY 14-16, 2005	MANCHESTER GRAND HYATT	SAN DIEGO, CA
JANUARY 13, 2005	CORPORATE SYMPOSIUM	
JULY 8-10, 2005	BALTIMORE MARRIOTT	BALTIMORE, MD
JULY 7, 2005	WATERFRONT HOTEL	
	CORPORATE SYMPOSIUM	

Newsletter articles or information should be sent to:

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