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-About SWOG-

The Southwest Oncology Group (SWOG) is a national clinical research organization dedicated to the measurable improvement of outcomes for patients with cancer through the conduct of clinical trials.

For more information about SWOG, please see our web site at

swog.org

Cancer Control and Prevention Program Reorganization Announced

The reorganization of the Cancer Control and Prevention Program was announced on February 10 at the Committee Review Retreat in Phoenix. Associate Chair, Frank Meyskens M.D., Associate Vice Chancellor of the College of Health Sciences, University of California, Irvine, presented the reorganization structure along with the mission and future plans of the committee.

At the Phoenix Retreat, Dr. Meyskens stated that "The mission is to integrate cancer control and prevention into the fabric of SWOG and oncology - doing studies because the results matter. Cancer is a continuum from risk to metastases and the underlying biology should drive the management paradigm. The results should be doable in the real world."

The group aims to increase Cancer Control and Prevention Program representation in disease committees, provide outreach to clinical pharmacology, and develop training in cancer prevention and control for the next generation of SWOG investigators. The first two volunteers to serve as liaisons are Robert S. Krouse, M.D. of the Southern Arizona Veterans Healthcare System and Lisa K. Hansen, R.N., M.S. from Legacy Good Samaritan Hospital. Dr. Krouse will be the Surgery Committee liaison and Ms. Hansen will be the liaison for the Nursing Committee.

The future goals of the program are to leverage SWOG strengths to do hypothesis-driven trials and to redefine special populations by ethnicities, risk identification, pharmacoecogenomics, and health behaviors. These new committees will focus their efforts on bringing forward new proposals within SWOG.

The Cancer Control and Prevention Program has been reorganized into the following committees:

- Prevention Committee – co-Chairs Powel Brown, M.D., Ph.D., Baylor College of Medicine and Gary Goodman, M.D., Swedish Medical Center Cancer Institute
- Health Disparities and Outcomes Committee – co-Chairs Allan Hubbell, M.D., M.S.P.H., UC Irvine Medical Center and Dawn Hershman, M.D., M.S. Columbia University
- Molecular Epidemiology Committee – co-Chairs Regina Santella, Ph.D., Columbia University and Christine Ambrosone, Ph.D., Roswell Park Cancer Institute
- Cancer Survivorship Committee – co-Chairs Kathy Albain, M.D., Loyola University Medical Center and Carolyn Gotay, Ph.D., University of British Columbia
- Symptom Control & Quality of Life Committee – co-Chairs Carol Moinpour, Ph.D., Fred Hutchinson Cancer Research Center and James Wade, III, M.D., Cancer Care Specialist of Central Illinois CCOP

SELECT, PCPT and PCPT P01 will remain the same. Powel Brown, M.D. and Dr. Meyskens will co-Chair the Executive Committee.

On February 25, 2008, the first Cancer Control and Prevention Research Retreat will be held in Chicago. This meeting will allow for discussion of goals for the newly formed committees as well as discuss the direction of cancer control and prevention research. More information about the outcomes of the retreat will be discussed at the SWOG Group Meeting in Atlanta in April, 2008.





Important Changes to Spring Group Meeting Schedule

The Group Meeting schedule has been redesigned in an effort to be more efficient with our time and resources. Shortening and rearranging the schedule is expected to reduce the amount of time individuals have to spend at the meetings, enhance collegiality, and encourage greater scholarship.

Be sure to review the revised agenda on the SWOG website **before** making airline reservations. Changes to the traditional schedule may affect your travel plans.

Registration for the Spring Group Meeting in Atlanta will open on February 26 on the SWOG website swog.org.

Highlights of Committee Review Retreat

On February 10 and 11, 63 SWOG committee chairs, vice chairs, faculty statisticians, and members of administrative staff met in Phoenix to assess where we stand as a Group and to provide an early perspective for the competing renewal of the CTEP grant. The retreat offered an opportunity for an overview of what we have accomplished as a Group, planning for what we need to do as we go forward, and learning more about the scientific focus of each committee.

The Group was fortunate to have Robert Chapman, M.D., Director, Josephine Ford Cancer Center at Henry Ford Hospital and Chairman of the National Cancer Institute's Clinical Group's Subcommittee H, attend the retreat. The purpose of Subcommittee H is to review new and competing cooperative group applications. Dr. Chapman discussed Subcommittee H's expectations, how the process has changed since the last SWOG competing renewal, and his insights into the review process.



Dr. Baker opened the retreat by stressing that what we do is important. In 2007, 1,444,920 Americans were diagnosed with cancer, 559,650 Americans died of cancer, and \$206.3 billion was spent on cancer. The economic challenge is that the stagnation of funding by the NCI has resulted in a 12% decrease in purchasing power. SWOG as a Group needs to maximize efforts within this economic challenge.

Dr. Baker announced the following SWOG news at the retreat. Chris Takimoto, M.D., Ph.D. Assistant Professor of Medicine at the University of Texas Health Science Center at San Antonio, will be leaving his position as Early Therapeutics Chair. Dr. Takimoto has taken a translational medicine position with Johnson & Johnson. Charles Sawyer, M.D., Chair, Human Oncology and Pathogenesis Program, Memorial Sloan Kettering has agreed to chair the search committee for a new Early Therapeutics Chair. Anna Schork has also left SWOG to accept the position of Administrative Director for the Institute of Social Research at the University of Michigan. A national search will be conducted for her replacement. And finally, Eric Clausewitz, Meeting Manager in the Operations Office has decided to accept a position in the Office of GME at the University of Texas Health Science Center at San Antonio. Courtney Wille has been named as the Meetings Manager in the SWOG Operations Office. New additions to the SWOG Chair's Office are Pat Arlauskas as Publications Manager and Karen Giles as Public Relations Representative.

Potential grant themes were put forward for consideration: quality improvement as a continuous process, translational medicine and protocols, and antibody vs. small molecule rational drug development.

Prior to the retreat, Dr. Baker charged each chair with presenting the achievements and future plans for their committee. Over the two days, each committee presented and was reviewed by the executive officer assigned to the committee and then discussion was opened up to the Group. The strengths and weaknesses of each committee were acknowledged and items were identified that need to be addressed as the grant application process progresses. The two days provided a solid base as we move forward in our efforts.

IMPORTANT CTEP GRANT RENEWAL DEADLINES:

| | |
|-------------------|--|
| August 15, 2008 | Chapters due to Group Chair's Office from Committees |
| October 13, 2008 | Chapters returned to Committees with comments |
| December 12, 2008 | Final chapters due to Group Chair's Office from Committees |

Concurrence of Melanoma Meetings Leads to Discussions of Future Intergroup Collaborations

This past fall, the 11th Annual Perspectives in Melanoma meeting and the fall meeting of the Southwest Oncology Group both met the same week in Huntington Beach, California. This juxtaposition provided an ideal opportunity for the Melanoma Prevention Working Group to convene just prior to the SWOG Melanoma Committee session on October 5, 2007. The Melanoma Prevention Working Group is an interdisciplinary, intergroup consortium of academic dermatologists, epidemiologists, surgeons, oncologists, and research nurses dedicated to melanoma prevention and control. The working group has been in existence for the past 6 years and meets annually. Membership consists of 30 intergroup sites and more than 60 members.

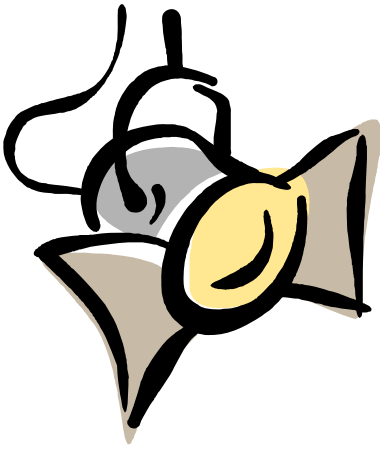
The meeting was organized by Drs. John Kirkwood from ECOG, Lex Eggermont from EORTC, and our own Dr. Vernon Sondak and was chaired by Drs. Marie-France Demierre and Sondak. Several of the presentations in the Perspectives Meeting had relevance to projects ongoing or in discussion by the melanoma committee, including the assessment of autoimmune endpoints and immunogenetic aspects of biological therapy in the adjuvant setting. As the S0008 study of adjuvant α -interferon vs. biochemotherapy was on the verge of completing its accrual, discussions of a replacement study included consideration of CTLA-4 blockade with one of the promising human antibodies currently being studied in advanced disease, as well as opportunities to further characterize the immunogenetic and autoimmune components of α -interferon therapy. These discussions were enhanced by the presentations of Dr. Christine Falk from the Comprehensive Cancer Center in Heidelberg, who was an invited speaker at the Perspectives Meeting. Dr. Falk, who graciously agreed to speak to the melanoma committee at the last moment, shared with us the principles of immunogenetics that govern autoimmune diseases as well as graft-vs-malignancy following allogeneic hematopoietic cell transplant. The importance of the MHC system as well as its interaction with activating and inhibitory receptors on natural killer cells and other aspects of T and NK cell biology were discussed, and potential opportunities

for future collaborations in studies of patients undergoing adjuvant therapy on SWOG trials were identified. The discussions were lively, leading to several collaborations that are now in development as a direct result of this meeting.

Group Banking Committee Defines Unified Biospecimen Repository Reporting and Query Mechanism

The Group Banking Committee (GBC) of the National Cancer Institute (NCI) recently defined the need to harmonize specimen collection standards and centralized inventory functions across all cooperative oncology groups to facilitate biospecimen usage. A centralized reference and repository data warehouse was designed and developed to establish common data elements (CDE's). The GBC offered funding to cooperative group banks to map their specimen inventory in a unified database structure and to develop an inventory query process that is user friendly.

SWOG currently has the following tissue banks: the Solid Tumor Bank located at the University of Colorado and directed by Wilbur Franklin, M.D., the Leukemia Bank located at the University of New Mexico and directed by Cheryl Willman, M.D., the AML/MDS Bank located at Fred Hutchinson Cancer Research Center and directed by Jerry Radich, M.D., and the Lymphoma/Multiple Myeloma Bank located at the University of Arizona and directed by Lisa Rimsza, M.D. All SWOG repositories have received funding to develop software tools to enable communication with the GBC's website inventory system. All banks have completed the inventory and defined the basic terms that will relate to biospecimen collection. The next step is to develop the appropriate software for the linking of data, coordinating with SWOG's Statistical Center and each database. SWOG's Statistical Center has developed and implemented a biospecimen collection platform, known as Specimen Tracking or "SpecTrack" that has been rolled out to SWOG sites and intergroup partners. The initial phase of the project is targeted to be completed within 6-9 months as part of an ongoing collaboration between the NCI and cooperative oncology groups to harmonize biospecimen collection databases.



SPOTLIGHT

SWOG Renews Focus on Gynecologic Malignancies

After a four year hiatus, the Southwest Oncology Group is reactivating its efforts in the gynecologic malignancy arena through the creation of the SWOG Gynecologic Cancer Working Group (GCWG). The focus of the committee will be on innovative phase 2 trials and the group is actively soliciting ideas for clinical trials.

"Since the close of the SWOG Gynecologic Cancer Committee in 2003, oncologists caring for women with gynecologic cancers have had only one NCI-sponsored Cooperative Group in which to propose and carry out clinical trials for their patients. This fact severely limited the number and type of clinical studies available for these women, especially women with advanced disease," says SWOG Executive Officer, Anne Schott, M.D., who oversees the committee.

Despite the long-standing and highly successful role played by SWOG in gynecologic cancers for more than 20 years, the group elected to close its gynecologic cancer clinical research efforts due to inadequate accruals onto SWOG-initiated phase 3 clinical trials. The reactivation of this initiative, along with a modified focus of the GCWG on innovative phase 2 trials, will provide a necessary and critically important new venue for the conduct of clinical research in the United States in the area of gynecologic malignancies.

SWOG is happy to announce that Maurie Markman, M.D., Professor and VP of Clinical Research at the University of Texas MD Anderson Cancer Center will serve as Chair of the SWOG GCWG and David Alberts, M.D., Professor, University of Arizona and Director of the Arizona Cancer Center will be Vice-Chair.

Dr. Markman commented that "the revitalization of the Gynecologic Committee has been met with great enthusiasm from the research community, from within SWOG, as well as the NCI. The [GCWG] will allow us to work with both medical oncologists and gynecologic oncologists involved in the care of women with gynecological cancer". Dr. Markman further noted "that a real strength in this committee is the ability to work with the SWOG statistical group".

Past members are encouraged to renew their participation and to help spread the word to solicit new members. "Special memberships" are available to interested gynecologic cancer investigators across cooperative groups, cancer centers, and SPORes regardless of affiliation with SWOG.

Dr. Schott added, "The unique thing about the GCWG is that 'special membership' has been encouraged from the time of its conception. Extension of 'special membership' privileges to physicians and nurses in Cancer Centers outside of the established SWOG network further strengthens the scientific expertise of the group, and provides more women with gynecologic cancers opportunity for trial participation."

The GCWG will be meeting at 8:00 a.m. on Friday, May 2, 2008 during the Group Meeting in Atlanta. All interested parties are invited to attend.

The Role of the Study Coordinator



Joe Pater, M.D., who until recently had been the chairman of the NCI-Canada clinical trials group, has been engaged with us as a SWOG Quality Consultant specifically charged with reviewing our data for its quality and making suggestions for improvement. He has reported his initial findings following a review of our systems, visiting with our Statistical Center, Operations Office and Group Chair's Office and reviewing best practices. I look forward to sharing with you these findings.

Within our Group, we tried to develop mechanisms to streamline the process of getting a protocol developed and opened. Throughout 1996 a strategic planning effort for SWOG's 1997 competitive renewal took place which resulted in templated forms for data collection; forms that have seen little change over the years. Those forms continue to dictate, with minimal variation, information collected for a protocol. These agreed upon template forms allows us to develop studies more quickly. However, as our research questions have grown in complexity and the fields we research change, we have not necessarily kept up with those changes.

Dr. Pater raised some interesting points; the role of the Study Coordinator was the most thought provoking for a number of reasons - most importantly because they represent perhaps the single greatest untapped resource in our Group. Study Coordinators are asked, once a study is opened, to review data. Joe makes the point that the Study Coordinator has a key role in assessing eligibility and trial end points, but questions whether we have provided the tools for them to do so effectively. What would it look like if the Study Coordinator could designate with greater flexibility the data collected? If their role was redesigned to provide more input, and we provided more training and tools for data assessment, what would that look like? I suspect this far greater role in protocol conduct would also be great fun.

The Study Coordinator is vital to the conduct of our trials, but I would challenge you to consider how the landscape might change, and perhaps even the satisfaction of the job might increase, if we rethought the role of the Study Coordinator. I value your thoughts on this topic.

Best wishes,

Laurence H. Baker, D.O.
Group Chair, Southwest Oncology Group

Please direct your thoughts and comments to the Group Chair's Office

Phone: 734-998-7130

E-mail: SWOGHQ-Office@med.umich.edu

S0230/POEMS: Prevention of Early Menopause Study

The Other Side of SOFT!

By Kelly Phillips, M.D. and Halle Moore, M.D.

Several non-randomized Phase II studies have suggested that LHRH analogues may be effective in reducing the risk of premature chemotherapy-induced menopause in women receiving chemotherapy. **S0230 – Phase III trial of LHRH analog administration during chemotherapy to reduce ovarian failure following chemotherapy in early stage, hormone-receptor negative breast cancer** is a randomized study which will determine whether this is indeed the case. Most types of standard chemotherapy (including herceptin containing regimens) are allowed on the study. Patients randomized to the experimental arm receive goserelin 3.6 mg subcutaneously every 28 days during chemotherapy, starting at least 1 week prior to the first chemotherapy dose. The goserelin is provided free of charge. **CCOP institutions will receive a full Cancer Control credit for each patient.**

This study should be considered for all pre-menopausal women with hormone receptor negative breast cancer who are planning to receive adjuvant chemotherapy. The study is NOT limited to women who wish to preserve fertility. Reducing the chance of chemotherapy-induced menopause, even in women who have completed their childbearing is important in order to optimize their long-term quality of life. There are large numbers of women in their forties with hormone receptor negative breast cancer that might benefit from this study.

Premature menopause, a common side effect of chemotherapy, is not thought to have any therapeutic benefit in women with hormone receptor negative breast cancer, but can lead to major long-term health implications, such as osteoporosis and cardiovascular disease. For younger women who have not completed childbearing, infertility is also an important issue.

This is an intergroup study in cooperation with the International Breast Cancer Study Group (IBCSG). As of October 1, 2007, 99 patients were enrolled from North America. **Target Accrual is 416.**

If this study demonstrates that goserelin reduces the risk of chemotherapy induced menopause, **it will change the standard of care for pre-menopausal women with hormone receptor negative breast cancer.**

Interested in seeing your study highlighted in a future edition of the Group Newsletter?
Contact the Group Chair's office at (734) 998-7140 or let any member of the Group Chair's office know and Karen Giles, Public Relations Representative will contact you.

Message from the Outgoing OCN Chair Lisa Hansen, R.N., M.S.

I am amazed that three years have literally galloped by since I was appointed Chair of the Nurse Oncologist Committee (NOC) in January 2005. Based on our committee's plan for a 3-year rotation for the chair position, it is time to pass the reins on to the next leader. I am very pleased to announce that the committee is now in the extremely capable hands of the new chair, Marge Good, RN, BSN, MPH, OCN[®] and new vice-chair, Rose Ermete, RN, BSN, OCN[®], CCRP. Marge is well known to SWOG nurses and CRAs as the manager of the Wichita CCOP. Rose recently relocated to Michigan Cancer Research Consortium CCOP. Both nurses have dedicated years to SWOG's mission and to the care of clinical trial participants. They continue to play key roles in the NOC educational programs, nurse audit program, recruitment and adherence, and cancer control. I will continue to work closely with Marge and Rose as we prepare for the 2009 SWOG Competitive Grant Renewal. In addition, I hope to expand my contributions to the Cancer Control and Prevention Program. Remember that the NOC welcomes your participation in our committee activities. Please contact any NOC Executive Committee member if you are interested in contributing to projects such as education program planning, nurse auditor program, nurse-pharmacy committee (investigational drug information), or symptom management research (drop me an email at lhansen@lhs.org). Please consider contributing to SWOG and the national cancer clinical trial community!

Spring Group Meeting Nurse Oncologist Workshop

Saturday May 3, 2008

Registration: 1:00 PM

Program Starts: 2:15 PM

This spring the Nurse Oncologist Workshop will focus on Pharmacogenomics. Basic research discoveries about the genetic basis of drug response are currently being utilized in SWOG clinical trials. Pharmacogenomics attempts to correlate gene expression with a drug's efficacy or toxicity. This technology allows us to optimize treatment to a patient's genotype, therefore maximizing efficacy while minimizing adverse events. To learn more about this evolving field, come to the Nurse Oncologist Workshop on Saturday May 3, 2008.

The key note speaker is Christine Ambrosone, PhD. who will give an overview on what Pharmacogenomics is and how it is being utilized to develop new therapies. Other presentations will include a review of studies that utilize this technology, such as *TailorRx* & S0500, presented by Daniel F. Hayes, M.D. Siu Fun Wong, Pharm D. will also present.

Application has been made for contact hours to the ONS Approver Unit. ONS is accredited as an approver of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation. SoCRA attendance certificates will also be provided.

Pre-Workshop Sessions:

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|------------------|---|
| 1:30 – 1:45 a.m. | New SWOG Nurse Oncologist Orientation |
| 1:45 – 2:00 p.m. | Nurse Oncologist Business Meeting |
| 2:00 – 2:15 p.m. | NCI Educational Materials Update - <i>Sona Thakkar, MA</i> |

Breakout sessions for subcommittee meetings will be held on Sunday as follows:

| | |
|-------------------|---|
| 8:00 – 9:00 a.m. | A: Nurse QOL/D&D & Research Subcommittee |
| 9:00 – 10:00 a.m. | B: Education & Program Subcommittees |

New Public Relations Representative for SWOG

Effective February 4, Karen Giles has joined SWOG as the new public relations representative. The position has been expanded to include assistance in accrual enhancement for high priority Phase III trials. Please contact Karen if she can be of assistance in accrual enhancement for any of your trials. Also, please be sure to send her any newsworthy information coming out of your committees to ensure press coverage. Karen can be reached at the Group Chair's Office at 734-998-7140 or by email at kargiles@umich.edu.

Aventis Urologic Oncology Fellowship Announcement

The Genitourinary Cancer Committee of the Southwest Oncology Group is happy to announce a request for applications for the 2008 Aventis Urologic Oncology Fellowship Program.

This program is intended to support urologists finishing their residency program to pursue a fellowship program in GU oncology with an emphasis on clinical trials research. The applicant must have a mentor who is active in the GU Cancer Committee of the Southwest Oncology Group and has proven expertise in clinical trials recruitment and management. The program must be multi-disciplinary-based.

The fellowship provides \$50,000 for a one-year fellowship and a total of three awards will be granted. A progress report is required at the end of the fellowship program.

Interested institutions should submit a two-page application detailing the objectives of the program, resources available to the fellow, an outline of the fellowship program, and the name of the fellow if available. Please submit the applications to David P. Wood, Jr., M.D. by e-mail at davwood@med.umich.edu by April 15, 2008.

New Member Nomination Deadline Set

The next deadline for submitting membership nominations to the Operations Office is March 21, 2008. Prior to each Group meeting, nominations are considered for Member, CCOP, Affiliate, UCOP and Special Member investigators. Nominations are reviewed by the Membership Committee and recommendations are made to the Board of Governors. For a complete outline of the nomination process, refer to Southwest Oncology Group Policy Memorandum No. 7 at the Group's web site, swog.org. All application forms can be downloaded and printed.

HONORS

Richard I. Fisher, M.D. to Lead National Lymphoma Research Board

Richard I. Fisher, M.D., director of the James P. Wilmot Cancer Center, was elected chair of the Lymphoma Research Foundation's Scientific Advisory Board. Dr. Fisher will work with leading national lymphoma experts to provide strategic direction for the Foundation's scientific agenda.

"Lymphoma research is considered the 'Rosetta Stone' of cancer research because it helped unlock the mysteries of several other types of cancer," Fisher said. "On a personal and professional basis, it is very rewarding to be actively involved with an organization that funds cutting-edge research with such far reaching applications."

The Lymphoma Research Foundation is the nation's largest voluntary health organization devoted to funding lymphoma research and providing patients and health care professionals with critical information on the disease.

Carolyn Hoban, D.Sc. Named Chair of National Cancer Institute's Group Banking Committee

SWOG Executive Officer **Carolyn Hoban, D.Sc.** was named Chair of the National Cancer Institute Group Banking Committee (GBC) at their February meeting.

The purpose of the GBC is to improve the operation of the clinical oncology cooperative group human specimen banks and to coordinate banking activities among groups conducting Phase III and large Phase II clinical trials, develop and implement common collection and storage practices and guidelines for use and distribution of biospecimens. The GBC has oversight of all aspects of the management and use of clinical oncology cooperative group human specimen banks and their resources and assumes coordination of processes by which the NCI or the individual cooperative groups choose which investigators are approved to access the specimens. Specific areas of focus are to develop a Best Practices manual, Material Use Agreement, Informed Consent guidance for specimen collection and Informatics Initiative to improve access and distribution of samples for scientific research.