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Happy Holidays
from All of Us
to All of You!

The purpose of The Group Newsletter is to facilitate Group-wide communication. Articles are welcome; typed hard copy, computer disc and electronic transmission are all acceptable formats for submission. Please send articles to the Operations Office to the attention of Dee Daniel. Article submission date is January 9, 2004, for February 2004 publication. Copyright 2003.

Message from the Chairman

Six More Years of Funding!

The Statistical Center Competitive Renewal Grant Site Visit was conducted on June 10, 2003, in Seattle, Washington, and a little less than a month later, on July 7 and 8, 2003, the Operations Office Reverse Site Visit was conducted in Bethesda, Maryland. Outstanding presentations involving disease and discipline committees were subjected to stringent review. I am pleased to report that the Group’s Statistical Center received a rating of “Excellent to Outstanding” (Adjectival Merit Descriptor) and was awarded 6 years funding and the Operations Office received an “Excellent” rating (Adjectival Merit Descriptor) also with funding for another 6 years.

The Group’s CCOPs Recognized for 20 Years of Excellence in Clinical Research

The twentieth anniversary of the National Cancer Institute Community Clinical Oncology Program was celebrated during the Fall Group Meeting. At the initiation of the program in 1983, there were concerns regarding the potential decrement in the quality of research data generated by the CCOP physicians; however, a hallmark of the Southwest Oncology Group CCOP program has been the extraordinary quality of the data generated by these clinical investigators in busy private practices. The Group’s CCOP program began with 19 institutions and over the past 20 years it has grown, not only in numbers, but also in scope, including creation of the Minority-Based CCOP institutions. There are now 61 NCI CCOP and MB-CCOP institutions in 34 States across our country; of these 29 are affiliated with the Southwest Oncology Group, 6 of which are MBCCOPs.

Nine of the Group’s CCOP institutions were part of the original 19 and they were honored during the Plenary Session. Receiving a commemorative plaque marking the occasion were: Columbus CCOP – J. Philip Kuebler, MD, PhD, Principal Investigator; Dayton CCOP – Howard M. Gross, MD, Principal Investigator; Grand Rapids CCOP – Kathleen J. Yost, MD, Principal Investigator; Kansas City CCOP – Jorge C. Paradelo, MD, Principal Investigator; Northwest CCOP – Lauren K. Colman, MD, Principal Investigator; St. Louis – Cape Girardeau CCOP – Patrick H. Henry, MD, Principal Investigator; Virginia Mason CCOP – Andrew D. Jacobs, MD, Principal Investigator; Western Regional CCOP – David K. King, MD, Principal Investigator; and Wichita CCOP – Shaker R. Dakhil, MD, Principal Investigator.

These nine institutions are the foundation upon which the entire Group CCOP program was built; on behalf of the Southwest Oncology Group Board of

Continued on the next page.
Message from the Chairman (Continued)

...CCOPs Recognized...(continued)

Governors, I extend our thanks and appreciation to all of the CCOP and Minority-Based CCOP institutions and their staff members, who work so diligently to serve their communities across our nation.

PCPT Results Were Focus of 2003 Fall Plenary Scientific Program

As I pointed out in the July 2003 Group Newsletter, we are still exploring “the rest of the story” regarding the results of the Prostate Cancer Prevention Trial (PCPT). The scientific portion of the Plenary Session was devoted to PCPT beginning with a detailed history of development of the study and concluding with comments from a study participant. The program was moderated by Group Chair Elect Dr. Laurence H. Baker, DO, and included the following presentations:

Ian M. Thompson, Jr., MD, Study Coordinator of the Prostate Cancer Prevention Trial (PCPT) and Professor and Chair of Urology at The University of Texas Health Science Center at San Antonio, presented, “Where Were We in 1992? Randomize the First Patient!”

Phyllis Goodman, MS, Lead Statistician for the Prostate Cancer Prevention Trial at the Southwest Oncology Group Statistical Center in Seattle presented, “Design of the Prostate Cancer Prevention Trial (PCPT).”

Dr. Thompson then continued with, “Results of the Prostate Cancer Prevention Trial (PCPT).”

M. Scott Lucia, MD, a Co-PI for PCPT, Assistant Professor and Chief, Renal Pathology Service at the University of Colorado Health Sciences Center. His topic was “Pathology and the Prostate Cancer Prevention Trial (PCPT).”

Scott M. Lippman, MD, Professor of Medicine and Cancer Prevention and Chair, Department of Clinical Cancer Prevention at The University of Texas M.D. Anderson Cancer Center. He is Chair of the Southwest Oncology Group Cancer Control Research Committee, and a member of the PCPT Steering Committee. He is also a Primary Study Coordinator for the Selenium and Vitamin E Cancer Prevention Trial (SELECT). He presented “The Promise of Translational Results in the Prostate Cancer Prevention Trial (PCPT).”

Leslie G. Ford, MD, Associate Director for Clinical Research in the National Cancer Institute Division of Cancer Prevention, presented “Public Health Implications of the Prostate Cancer Prevention Trial (PCPT).”

Peter Greenwald, MD, Director of the National Cancer Institute Division of Cancer Prevention, presented “Comments from a Participant in the Prostate Cancer Prevention Trial.”

The final presentation of the Plenary Session was an informative panel presentation of “How Can the Central Institutional Review Board (CIRB) Benefit You?” It was moderated by Jacqulyn Goldberg, JD, of the National Cancer Institute and featured physicians and research staff from some of the Group’s institutions who recounted their experience in utilizing the CIRB.

Young Investigators Program Graduates Four With Varied Research Interests

The Young Investigators Training Course was conceived in 1999 and the first class was held in 2000. Twenty-three (23) Young Investigators have graduated the program since its inception, including the four this past April. They are: Lupe G. Salazar, MD, Acting Instructor at the University of Washington in Seattle. Her research interest is immunotherapy. Angela M. Davies, MD, Assistant Professor of Medicine, University of California Davis Cancer Center in Sacramento. Her research focus is treatment of advanced non-small lung cancer (NSCLC). Susanne M. Arnold, MD, Assistant Professor of Medicine, Markey Cancer Center, University of Kentucky in Lexington. Her research interest is focused on taking an innovative approach to cancer treatment – that of using low-dose radiation to increase the effectiveness of chemotherapy for treatment of squamous cell cancers of the head and neck. Deborah A. Lehrich, M.D., assistant professor of medicine at the University of New Mexico and the acting chief of hematology and oncology at the Veterans Administration Hospital in Albuquerque. She focused on a research protocol using intravesical gemcitabine for patients with superficial bladder cancers.

The next session of the Hope Foundation/OrthoBiotech Young Investigators Training Course is scheduled for March 2004.
The current Phase III trial for patients under age 66 with a diffuse aggressive NHL with either a High-Intermediate or High IPI classification is the US and Canada Intergroup trial (S9704) that compares CHOP(R) x 8 to CHOP(R) x 6 with an autologous transplant.

The trial is based on the French LNH-87 trial subgroup analysis that suggested both a PFS and survival advantage for early transplant vs transplant at the time of progression or relapse; i.e., about 20% more patient survive if transplant is part of their initial therapy. Based on the GELA trial data, Rituxamab has been added (as of June 1) to this protocol for CD20 positive NHLs, making the standard therapy arm the current state-of-the-art therapy for these patient groups.

The important features are:

1. Any patient with a diffuse aggressive NHL (excluding mantles and lymphoblastic NHLs) with any 2 or all 3 of the following factors are eligible:
   a. LDH > ULN
   b. Stage III or IV disease
   c. SWOG/ECOG PS 2-i.e., able to provide self care but able to work

2. While all eligibility tests need to be done pre-cycle 1 (all routine for this disease), registration can occur either before cycle 1 or 2, making it easier to treat a sick patient quickly without protocol enrollment.

3. All conventional chemotherapy can be given close to home (75% of the therapy on the BMT arm and 100% on the control arm). In addition, an additional stipend is being paid to the enrolling center/physician.

To date, enrollment is approximately one half of the anticipated number to complete the trial and nearly 100 have been randomized. This is the first US-led up-front randomized transplant trial for any lymphoma and in order to complete in a timely fashion, we would appreciate your participation. Feel free to e-mail the PI, Dr Patrick Stiff with any questions and/or concerns at: pstiff@lumc.edu.

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**Nurse Oncologist Committee Honors Outgoing Chair**

A tribute to outgoing Nurse Oncologist Committee Chair, Marcia Grove-Conrad, RN, MSN, MPH, OCN, was held during the Nurse Oncologist Workshop on October 2, 2003, in Seattle. Lisa Hansen, RN, MS, AOCN, reviewed highlights of Ms. Grove-Conrad’s accomplishments over the past 4-1/2 years and presented her with a crystal plaque of appreciation from the Nurse Oncologist Committee. Among her accomplishments, Ms. Grove-Conrad fostered an expanded role for Nurse Oncologists in clinical trial development, review, and education. She successfully represented the Nurse Oncologist Committee at the Reverse Site Visit in Bethesda, procuring six years of funding and a score of “Excellent.”

Carolyn Schmidt, RN, MS, from Henry Ford Health System has been appointed as the new chair of the Committee.
The smart money in Seattle was on the Cancer Control Research Committee (CCRC), which raced to the finish line of another Group Meeting, leaving the hoofbeats of confusion, doubt and angst in its dust. Attendance to the various CCRC meetings was strong, demonstrating the members’ gratifying commitment to the Committee’s important work.

Thursday, October 2, 2003, was a busy day for the CCRC, starting with the two-hour Molecular Epidemiology Subcommittee meeting at 8:00 a.m. Chair Dr. Regina M. Santella opened the meeting with her customary request of interested guests among the 15-20 people in attendance to become members of the Subcommittee through their institutional Group PIs. Next Dr. Santella summarized the exciting Intergroup application for a NCI P01 to study the biology of the Prostate Cancer Prevention Trial (PCPT) (also discussed below in this column) (Dr. Santella is Leader of P01 Project 5 and Co-Leader Co-Director of P01 Cores A and C). She also led a discussion of the results of a P01 pilot study of DNA preparation and genotyping. Lively working discussions of the ongoing projects SELECT (e.g., new questions on medication usage added to the medications questionnaire and the Subcommittee’s work on a justification for collecting additional blood samples), sample banks for other clinical trials, Dr. Christine Ambrosone’s R01-funded study of genotype and response to breast cancer treatment, the Group-funded pilot study of genotype in association with the treatment of acute myeloid leukemia, and lung cancer in women and of the new proposal “Sulfotransferase Polymorphisms and Survival after Tamoxifen Therapy” rounded out the Molecular Epidemiology agenda.

Chair Dr. Gary E. Goodman welcomed 40-45 members and guests to the Chemoprevention Subcommittee (10:00 a.m. to 1:00 p.m.), which included a jam-packed agenda of 5 active and 3 closed studies and slide presentations and/or lively working discussions of 10 proposed studies (e.g., S0300, “Chemoprevention of Breast Cancer with the COX-2 Inhibitor Celecoxib: Randomized Placebo-Controlled Biomarker Mulation Trial, Phase II,” and “Calcium, Aspirin, and Selenium [CASE] Colorectal Cancer and Polyp Recurrence Prevention: Phase IIa”). Dr. Goodman closed this meeting with the comment that the full slate of exciting chemoprevention proposals will require careful CCRC scrutiny for protocol-development prioritization.

CCRC Chair Dr. Scott M. Lippman chaired the 3-hour educational presentations, a lively interactive panel discussion (panelists Drs. Klein, Moinpour and Minasian and PCPT Lead Statistician Phyllis Goodman) moderated by CCOP Symposium Chair Dr. J. Philip Kuebler raised animated discussions of many PCPT-related topics, such as finasteride-related guidelines for high-grade-disease and PSA screening and multivariate analyses to ascertain profiles of men most likely to benefit from finasteride prevention of prostate cancer. No CCRC Open Meeting would be complete without the concise, brief reviews of the current business of the CCRC subcommittees, which were provided by Subcommittee Chairs Drs. Santella (Molecular Epidemiology), Goodman (Chemoprevention) and Carolyn C. Gotay (Behavioral and Health Outcomes [BAHO]), who was in the unusual position of previewing her upcoming, rather than recapping her concluded, meeting.

Dr. Gotay’s three-hour BAHO Subcommittee met promptly on the heels of the Open Meeting at 6:00 p.m. Twenty-five members and guests participated actively in the always full, information-packed agenda of working discussions of 11 studies, including the closed study SWOG-9342, “A Study of the Late Cardiac Effects of Two Different Adjuvant Chemotherapy Regimens in Women with Node Negative Breast Cancer Treated on SWOG-8897,” the open S0029, “Single Agent Docetaxel for Metastatic Breast Cancer in Patients Aged 70 Years and Older (and in a Cohort of Patients Younger than 60 Years), Phase II,” and the temporarily closed S9908, “A Double-Blind, Placebo-Controlled Trial to Study the Efficacy and Safety of L-Glutamine (in AES0014 Delivery Vehicle) Upon Radiation Therapy-Induced Oral Mucositis in Head and Neck Cancer Patients, Phase III.” Also on the agenda were 13 studies in advanced or early development, including S0229, “A Randomized Trial Assessing the Effects of Exercise on Patients with Locally Advanced Non-Small Cell Lung Cancer (NSCLC) Undergoing Curative Intent Combined Modality Therapy (Ancillary to S0023)” and “Mindful Meditation’ to Enhance the Quality of Life for Cancer Chemotherapy Patients,” respectively.

The three Subcommittee and one Open meetings of the CCRC crowded into the winner’s circle, a trifecta plus one, at the end of the long day of Thursday, October 2. The late, great Seattle Slew must have smiled down on the exhausted CCRC crews as they packed away their racing silks until the next Group Meeting in Huntington Beach, CA, (alluringly close to Santa Anita Park) in Spring 2004.
Cancer Control Research Committee (continued)

PCPT P01 Update

The P01 application entitled *Biology of the Prostate Cancer Prevention Trial (PCPT)* (last discussed in this column in July 2003) was submitted to the NCI by the October 1, 2003, grant application deadline. The Intergroup P01 investigative team headed by PI Dr. Scott M. Lippman and Co-PIs Drs. Charles A. Coltman, Jr., Alan R. Kristal, Regina M. Santella, and Ian M. Thompson, Jr., submitted the following six projects and three cores (and key personnel) in the P01 application:

* **Project 1:** “5a-Reductase, CYP3A4 and CYP3A5 Gene Variants in the PCPT.” Juergen Reichardt, PhD (Leader); Ashraful Hoque, MD, PhD (Co-Leader); Robin J. Leach, PhD; Ron Ross, MD; William D. Figg, PharmD; and Ian M. Thompson, MD.

* **Project 2:** “Androgen Receptor and HSD3b2 Gene Variants and Serum Hormones in the PCPT.” Dr. Figg (Leader), Douglas K. Price, PhD (Co-Leader); Dr. Reichardt, Demetrius Albanes, MD; Dr. Leach; and Frank Stanczyk, PhD.

* **Project 3:** “Insulin-like Growth Factor Axis and Insulin Resistance in the PCPT.” Michael N. Pollak, MD (Leader); Marian Neuhouser, PhD (Co-Leader); and Alan Kristal, DrPH.

* **Project 4:** “Diet and Diet-related Factors in the PCPT.” Dr. Kristal (Leader); Irena King, PhD; and Dr. Neuhouser.

* **Project 5:** “Oxidative Damage, Estrogens and DNA Repair in the PCPT.” Regina M. Santella, PhD (Leader); Christine B. Ambrosone, PhD (Co-Leader); and Dr. Hoque.

* **Project 6:** “Genotypic and Phenotypic Studies of Inflammation in the PCPT.” Elizabeth A. Platz, ScD (Leader); Angelo M. DeMarzo, MD, PhD (Co-Leader); M. Daniele Tangen, DrPH (Director); John Crowley, PhD (Co-Director); Donna Pauler, PhD; Michael LeBlanc, PhD; and Phyllis Goodman, MS.

* **Core A:** “Administration.” Scott M. Lippman, MD (Director), Drs. Kristal, Santella, and Thompson.

* **Core B:** “Biostatistics/Data Management.” Cathy Tangen, DrPH (Director); John Crowley, PhD (Co-Director); Donna Pauler, PhD; Michael LeBlanc, PhD; and Phyllis Goodman, MS.

* **Core C:** “Pathology and Genotyping.” M. Scott Lucia, MD (Director), Dr. Santella (Co-Director), and Dr. Albanes (Co-Director).

Although the clinical analyses and results of the PCPT have been published (Thompson et al, *New Engl J Med* 2003), the complicated, time-consuming work of interpreting these results through biological analyses has just begun. The CCRC congratulates the outstanding team of PCPT P01 investigators for their hard work on, and wishes them Godsspeed in their forthcoming site visit for, this massive, complex application, which was 538 pages long, not counting appendices (to be sent later per NCI P01 guidelines).

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Common Terminology Criteria for Adverse Events v3.0 (CTCAE)

The new version of the Cancer Therapy Evaluation Program Criteria expands upon version 2.0 to include adverse events applicable to all oncology clinical trials regardless of modality. The new Criteria contains 1,048 terms while version 2.0 consisted of only 348. Not only are the Criteria expanded to describe events that may be related to all treatment modalities, but supra-ordinate terms are provided to group events based on disease process, signs, symptoms or diagnosis. An example is “Stricture/Stenosis GI” for which there are 14 site terms for gastrointestinal stricture or stenosis from the anus to the stomach. Similarly, there are 54 site codes for “Pain.”

CTCAE v3.0 is fully implemented as of October 2003; protocols approved by CTEP on or after October 1, 2003, will use CTCAE v3.0. Protocols initially submitted for review by April 2, 2003, will also use v3.0, regardless of approval date. Version 2.0 is not discontinued, but, will remain active for older studies.

You can ascertain which Criteria is to be used for your patient by consulting section 8.0 of your Southwest Oncology Group protocol “Toxicities to be Monitored and Dosage Modifications.”

You can access CTCAE v3.0 at [http://ctep.cancer.gov/reporting/ctc.html](http://ctep.cancer.gov/reporting/ctc.html). Supporting documentation and educational tools will be posted on that website and on [http://swog.org](http://swog.org) in the months to come. The spiral-bound pocket-size CTCAE v3.0 booklets published by the National Cancer Institute (NCI) were distributed to institutions by the Operations Office in the November 1 mailing.

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Cancer Symptom Management and Palliative Care News

Symptom management and palliative care research opportunities can now be found in one place on the National Cancer Institute Web site, [cancer.gov](http://cancer.gov). A new page contains announcements of funding opportunities and areas of encouraged research. Find announcements from multiple NIH Institutes and Centers. The NCI’s Palliative Care Working Group has provided the site that includes topics such as:

* Biobehavioral and mind-body interactions
* End-of-life
* Pain and other symptoms
* Mental health
* Translating research to practice

Following are URLs that will get you to the information: [http://www.cancer.gov/researchfunding/announcements/symptommanagement/](http://www.cancer.gov/researchfunding/announcements/symptommanagement/). (Be sure to note the two m’s in the last section of the URL.) Or, access the web page via the NCI’s cancer.gov research funding portal at [http://www.cancer.gov/researchfunding/announcements](http://www.cancer.gov/researchfunding/announcements).
Role Of Surgeons In Cancer Prevention

Cancer prevention holds promise to significantly decrease the numbers of cancers diagnosed and the mortality caused by cancers in general.

As surgeons treating the cancer patient, we are keenly aware that cancer prevention is an emerging discipline, and yet, we must stress the reasons why cancer prevention should take a larger role in our every day activities of cancer management.

1. Early diagnosis and treatment has been the surgeon’s motto; we should extend this practice into the pre-cancerous stages of carcinogenesis. This will result in better cure rates and quality of life.
2. Primary and secondary prevention (i.e., chemoprevention and cancer screening) will have effective treatments and strategies as result of advances in science and technology.
3. Surgeons can take on important roles in promoting cancer prevention: education, participation in trials, risk assessment, and reduction in individuals with genetic or other predisposition.
4. Surgeons can develop and conduct key Phase II studies based on tissue surrogate markers.
5. Cancer prevention is the ideal venue for improved communication between surgeons and patients, referring physicians and community.

If the above reasons have given you some motivation to join the action, then the following current and proposed trials in the Southwest Oncology Group will interest you:

1. **BREAST**
   
   **S0300 (Proposed)** – Chemoprevention of Breast Cancer with the COX-2 Inhibitor Celecoxib: Randomized Placebo-Controlled Biomarker Modulation Trial, Phase II.
   
   **Powel H. Brown, MD, PhD**
   
   High-risk post-menopausal women randomized to one year of celecoxib, with end-point of mammographic density and breast core biopsy.

2. **LUNG**
   
   **E5597 (Active)** – Phase III Chemoprevention Trial of Selenium Supplementation in Persons with Resected Stage I Non-Small Cell Lung Cancer.
   
   **Omer Kucuk, MD**
   
   Completely resected T1 and T2 N0 non-small cell lung carcinoma, NED, randomized to yeast selenium or placebo.

3. **PROSTATE**
   
   **S0000 (Active)** – SELECT: Selenium and Vitamin E Cancer Prevention Trial for Prostate Cancer.
   
   **Scott Lippman, MD**
   
   This study accrual surpassed initial predictions and will close by end of 2004. Proposed companion studies will have longer accrual window.

4. **MELANOMA**
   
   
   **Marie-France Demierre, MD**

5. **GYNECOLOGY**
   
   **S0212 (Proposed)** — Phase IIb Randomized Placebo-Controlled Trial of Oral Celecoxib for High-Grade Squamous Intraepithelial Lesions of the Cervix.
   
   **William R. Robinson, MD and David S. Alberts, MD**
   
   CIN grade 2 and 3 with pathological confirmation randomized to treatment of celecoxib or placebo for three months followed by LOOP or CONE excision. Response rate and COX-2 and HPV expressions are primary and secondary endpoints, respectively.

6. **GI**
   
   **CASE Study (Proposed)** — A Phase III trial of Calcium, Aspirin and Selenium (CASE) to prevent colorectal cancer and polyp recurrence.
   
   **David S. Alberts, MD; James R. Marshall, PhD, and David ZJ Chu, MD**

In the protocols under development and scheduled to be activated in the near future, interested surgeons can contact the Study Coordinators to obtain more information or offer help in refining and implementation of the protocols. In addition, surgeons who have ideas for correlative science studies for any of these protocols are encouraged to discuss the subject with the investigators or with the chairpersons of the Disease Committees.

David ZJ Chu, MD
City of Hope Medical Center
News from QARC

At the Quality Assurance Review Center (QARC), we have seen a dramatic shift since the beginning of the year in the number of institutions providing diagnostic imaging and RT materials in electronic files. We are pleased to see this change and while we do continue to support film submission, we want to encourage more institutions to send data to QARC electronically. This can be done several ways. Below are some guidelines and helpful hints. Please note that there are important differences between Diagnostic Imaging Scans and Radiation Therapy Data.

**Diagnostic Imaging Scans**

Most CT and MRI scanners produce image files in DICOM (Digital Imaging and Communications in Medicine) format. DICOM is a standard that can be easily read by several commercial viewers. The DICOM files can be transferred to QARC either by CD or e-mail. If burned to a CD we prefer that only one patient is included on each CD; however, multiple studies for the same patient may be on the same CD. These are large files; therefore, at many sites the e-mail system are not able to send these files as attachments. However, we do not have restrictions at QARC, so if you can send the DICOM file as an attachment, it can be received.

DICOM files, whether received via e-mail or CD, have lots of information stored with the image. The images can be windowed and leveled by the reviewers at QARC allowing them to find the optimal contrast for reading the images. The scale embedded in the image remains intact allowing the reviewers at QARC to make accurate measurements from the images. When a digital picture of an image is taken and sent to QARC as a .jpg or dropped into a PowerPoint file, that type of information in the image is lost. Electronic pictures, such as jpg, bmp and tif, are fine for some data transfer, but cannot be used for CT or MRI when a diagnostic review of those scans is required.

**Radiographs/Plain Films**

Plain films such as chest x-rays or bone x-rays are required by some studies. The x-ray machines that produce these images are less frequently digital machines that can produce DICOM files, although, this is a changing paradigm. If your institution’s x-ray machines can produce DICOM images, you can send those to us those either by CD or Dicom Communicator as explained above. Good quality digital pictures of x-rays taken with a digital camera or a saved screen shot from a digitized film may be adequate for the review. However, if accurate measurements are required a picture will not substitute for a DICOM file or a film.

**Radiation Therapy Data**

Much of the RT data required by protocol can be submitted electronically to QARC. Most radiation therapy planning today is done with treatment planning computers. The patient’s diagnostic CT or MRI is sent to the planning system. The planning system uses the data from the diagnostic study to present a digital reconstruction of the patient on which the physician identifies tumor and tissue at risk as well as critical structures. Using the planning system the physician and dosimetrist plan how the patient will be treated to deliver the prescription dose to the treatment volume while preventing the dose to critical structures from exceeding normal tissue tolerance criteria in the protocol. Documentation of the treatment plan is displayed in various formats including Digital Reconstructed Radiographs (DRR), Beam’s Eye Views (BEV), Dose Volume Histograms (DVH) and isodoses. These types of data can be saved as screen captures (.jpg or .bmp) and sent to QARC on CD or as attachments to an e-mail. Screen captures from the treatment planning system should be distinguished from DICOM RT files. At this time, we do not want DICOM RT files submitted to QARC. One final note about treatment planning, a treatment planning CT is different than a diagnostic CT. When studies require the diagnostic CT, a treatment planning CT cannot be substituted.

Many Radiation Oncology Departments no longer produce verification films from the treatment machines (linear accelerators). Real-time portal imaging has replaced verification films. These systems display an image of the beam portal on a monitor for the time that the patient is receiving treatment. A “screen-shot” of the portal imaging can be taken and saved as a digital picture (.jpg or .bmp). This can be submitted to QARC on CD or by e-mail.

All e-mails can be sent to tborchardt@QARC.org. If you have any questions, please contact Tracy Borchardt or any of us at QARC:  [http://www.qarc.org/qarcstaff.htm](http://www.qarc.org/qarcstaff.htm)

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**Quality of Life Survivorship Findings for SWOG-9208/SWOG-9133**

This study of survivorship and late effects follows patients annually for seven years; it is one of the few prospective, randomized trials to examine quality of life and late effects in patients with Hodgkin’s disease. As a result of the early closure of SWOG-9133, we will have a smaller quality of life sample than originally planned. Therefore, the follow-up assessments for those patients we did enroll take on even more significance.

Submission rates for quality of life forms beyond Year 3 are below acceptable levels. Quality of life at Year 5 was designated as the primary endpoint for SWOG-9208 so it is particularly important to obtain follow-up data at 5 years.

Thank you all for the terrific effort made to date. Please give extra attention to obtaining this important survivorship information. Remember -- there is funding for collecting follow-up data.
Published

The publications listed below are those that have been received in published form by the Operations Office Publications Specialist from July 3 through November 12, 2003.

C Since Last Newsletter


Manuscripts Published (Continued)

Abstracts Published Since Last Newsletter

*9035 HLA D3(7) confers a poor prognosis in intermediate thickness (1.5-4.0 mm) melanoma: serotyping of 553 patients on SWOG 9035. JA Sosman, J Unger, JE Lee, P Liu, L Flaherty, VK Sondak. Proc of the American Society of Clinical Oncology. 22:710 (#2856), 2003.


S0000 Form and function: PDF+ versus HTML form design. KB Gower, B Kleinman. Controlled Clinical Trials. 24(3S) Suppl:188S (#P186), 2003.


*Presented

The Hope Foundation Platinum Association Drawing Makes Georgia Investigator A Very Happy Guy!

Mark R. Keaton, MD, said he and his wife had a “feeling” that they would soon be driving a new Porsche. Even at that, when Dr. Keaton’s name was called during the Platinum Association Prize Drawing, it still took a few moments to sink in. Dr. Keaton is a Medical Oncologist in private practice in August, Georgia. He was given a choice of a 2004 Porsche Boxster or Cayenne SUV — there’s a Cayenne parked in his driveway these days!

Andrew D. Jacobs, MD, from Virginia Mason Medical Center in Seattle, and Anthony F. Shields, MD, PhD, Karmanos Cancer Institute in Detroit won roundtrip Southwest Airline tickets and Hyatt accommodations in New Orleans and San Antonio, respectively.

The next Porsche drawing for members of the Foundation’s Platinum Association will be held at the 2004 Fall Group Meeting in Kansas City scheduled for October 20-24.
S0202. A Phase II Trial of Gemcitabine (NSC-613327) and Capcetabine (NSC-712807) in Patients With Unsectable or Metastatic Gallbladder or Cholangiocarcinoma. Study Coordinators: Drs. S. Iqbal and H.J. Lenz. Activation Revision, 09/01/03.


S0230. Phase III Trial of LHRH Analog Administration During Chemotherapy to Reduce Ovarian Failure Following Standard Adjuvant Chemotherapy in Early Stage, Hormone-Receptor Negative Breast Cancer. Study Coordinators: Drs. H.C.F. Moore, K.S. Albain. Activation, 10/01/03.

S0301. A Phase II Study of Induction With Daunorubicin, Cytarabine, and Cyclosporine All By Continuous IV Infusion for Previously Untreated Non-M3 Acute Myeloid Leukemia (AML) in Patients of Age 56 or Older. Study Coordinators: Drs. T.R. Chauncey, A.F. List, C.L. Willman, M.L. Slovak and D.R. Head. Activation, 10/01/03.


S0322. Single Agent ZD-1839 in Patients With Advanced Head and Neck Carcinoma or Non-Small Cell Lung Cancer Aged 75 Years and Older (and in a Cohort of Patients 50 Years Old and Younger), Pharmacology. Study Coordinators: Drs. J. Doroshow and T. Synold. Activation, 08/15/03.

S0327. A Phase II Trial of PS-341 (NSC-681239) in Patients with Platinum-Treated Extensive Stage Small Cell Lung Cancer. Study Coordinators: Drs. P.N. Lara, Jr., A.M. Davies, P.H. Gumerlock and W.A. Franklin. Activation, 09/01/03.

S0331. A Phase II Trial of STI-571/Imatinib (Gleevec®) in Neuroendocrine Carcinoma of the Skin (Merkel Cell Carcinoma). Study Coordinators: Drs. W.E. Samlowski, R.J. Tutfill and M.C. Heinrich. Activation, 10/01/03.

S0355. A Phase I Pharmacokinetic Study of Epothilone B Analogue BMS-247550 (NSC-710428D) in Patients with Advanced Malignancies and Varying Levels of Liver Dysfunction. Study Coordinators: Drs. A. Davies. Activation, 11/01/03.

AEWS0031. Trial of Chemotherapy Intensification Through Interval Compression in Ewing Sarcoma and Related Tumors, Phase III Intergroup. Study Coordinator: Dr. Karen H. Albritton. Activation 09/01/03.

CLOSURES (No Closures 10/01/03, 10/15/03, and 11/15/03)


S0926. Phase II Study of Temozolomide in Unsectable or Metastatic Gastrointestinal Stromal Tumors (GIST). Study Coordinators: Drs. M.M. Zalupski and R.A. Kempf. Permanent Closure, 09/01/03.


S0013. Evaluation of In Vitro Assays as Predictors of Clinical Outcome in Patients With Locally Advanced (Stage IIIB-IVA) Cervical Carcinoma, Biologic. Study Coordinator: Dr. R.A. Burger. Permanent Closure, 11/15/03.


S0127. A Phase II Study of OSI-774 (NSC 718781) in Unsectable or Metastatic Adenocarcinoma of the Stomach and Gastroesophageal Junction. Study Coordinator: Dr. T. Dragovich. Permanent Closure, 08/15/03.

S0227. Phase III Randomized Trial of Cisplatin/Paclitaxel Versus Cisplatin/Gemcitabine in Recurrent, Persistent or Metastatic Carcinoma of the Cervix. Study Coordinators: Drs. H.J. Long and M. Markman. Permanent Closure, 7/28/03.

C80002. A Phase II Study of Local Excision Alone or Local Excision Plus Adjuvant Chemoradiation Therapy for Small Distal Rectal Cancers. Study Coordinator: Dr. Morton S. Kahlenberg. Permanent Closure, 8/29/03.

E4397. A Phase II Trial of Preradiation in Multiagent Chemotherapy For Adults With “Poor Risk” Medulloblastoma, PNET, and Disseminated Ependymoma. Southwest Oncology Group Study Coordinator: Dr. G.R. Barger. Permanent Closure, 11/15/03.

G0175. A Randomized Phase III Trial of IV Carboplatin (AUC 6) and Paclitaxel 175 mg/m2 Q 21 Days X 3 Courses Plus Low Dose Paclitaxel 40 mg/m2/wk Versus IV Carboplatin (AUC 6) and Paclitaxel 175 mg/m2 Q 21 Days X 3 Courses Plus Observation in Patients With Early Stage Ovarian Carcinoma. Southwest Oncology Group Study Coordinators: Drs. D.S. Alberts and C. Johnston. Permanent Closure, 8/15/03.
A special PCPT-CRA Evening Session was held on the evening of October 1 during the 2003 Fall Group Meeting in Seattle to honor and thank research staff who have contributed to the success of this study. A poster was presented recognizing all Study Center and Site staff, past and present, who have worked on this study.

In addition, the following Study Center and Site staff were recognized for their 10 year commitment to the PCPT:


—Highest Number of Participants Randomized to PCPT—

**TOP 6 SITES**

<table>
<thead>
<tr>
<th>Site</th>
<th>Number of Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site 260 Wilford Hall Medical Center</td>
<td>1,444</td>
</tr>
<tr>
<td>Site 227 Upstate Carolina CCOP</td>
<td>538</td>
</tr>
<tr>
<td>Site 206 Mayo Clinic</td>
<td>448</td>
</tr>
<tr>
<td>Site 149 Sentara Cancer Institute</td>
<td>395</td>
</tr>
<tr>
<td>Site 435-311 Stanford Univ/VAMC San Francisco</td>
<td>386</td>
</tr>
<tr>
<td>Site 224 Sutter Health Cancer Research Group</td>
<td>332</td>
</tr>
</tbody>
</table>

—Highest Percentage of End-of-Study Biopsies—

**Number of potential biopsies (**) **

<table>
<thead>
<tr>
<th>Range</th>
<th>Site</th>
<th>Number of Biopsies</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>15 – 25</td>
<td>Site 305 Presbyterian Hospital</td>
<td>15&lt;sup&gt;th&lt;/sup&gt; percentile (≈ 82%)</td>
<td></td>
</tr>
<tr>
<td>26 – 75</td>
<td>Site 137 Decatur Memorial Hospital</td>
<td>26&lt;sup&gt;th&lt;/sup&gt; percentile (≈ 90%)</td>
<td></td>
</tr>
<tr>
<td>76 – 125</td>
<td>Site 248 Vermont Cancer Center</td>
<td>76&lt;sup&gt;th&lt;/sup&gt; percentile (≈ 90%)</td>
<td></td>
</tr>
<tr>
<td>126 - 200</td>
<td>Site 229 MeritCare Hospital CCOP</td>
<td>126&lt;sup&gt;th&lt;/sup&gt; percentile (≈ 85%)</td>
<td></td>
</tr>
<tr>
<td>200+</td>
<td>Site 172 Grand Rapids CCOP</td>
<td>200&lt;sup&gt;th&lt;/sup&gt; percentile (≈ 80%)</td>
<td></td>
</tr>
</tbody>
</table>

(* *) “Potential Biopsies”: Men who died prior to Contact 80 or men who refused further contact were not included.
NO147: Remote Data Capture Training

At the North Central Cancer Treatment Group (NCCTG) meeting in October, 2003, the feasibility and advantages of centralized data collection (within the Cooperative Group environment) was demonstrated through Remote Data Capture (RDC) Training Sessions, introduced jointly by the CTSU and NCCTG. The CTSU (in collaboration with NCCTG) developed a web-based study database using Oracle Clinical for the NO147 study, which must be accessed via the CTSU for all sites. The NO147 study is a randomized Phase III trial of Irinotecan (CPT-11) and/or Oxaliplatin (OXAL) plus 5-Flourouracil (5-FU) / Leucovorin (CF) after curative resection for patients with Stage III Colon Cancer. When NO147 is activated in November 2003, all sites will perform data entry and updates using the RDC system. RDC permits the online resolution of queries, it allows data transfers to occur from CTSU to NCCTG using the Clinical Data Transfer System, and the CTSU will be able to randomize all enrollment information, and the CTSU will be able to provide delinquency reports and data quality reports to NCCTG and sites. In this new system, the CTSU will compile all enrollment information, and the CTSU will be able to randomize patients in the NCCTG database using online randomization procedures. Also, the CTSU will verify the credentials of investigators and sites by using the Regulatory Support System (RSS).

Educational Tools: eCourse and Operations Manual

The CTSU offers a series of web-based educational programs and materials that promote and assist with the enrollment of patients on cancer studies. The CTSU offers an on-line educational program from the public side of the web site (www.ctsu.org) called eCourse that provides both novice and experienced research staff with a convenient method of learning about participation in clinical trials through the CTSU.

The eCourse consists of 4 modules: learn, register, review, and manage. The LEARN Module provides an overview of the CTSU for physicians and research team members. The REGISTER Module provides instructions for member, site, and patient registration. The REVIEW Module demonstrates the menu of available protocols and details protocol communications regarding activations, amendments, updates, and closures. The MANAGE Module offers guidelines for CTSU processes and protocol implementation, including study record maintenance, regulatory and patient record documentation, data submission, study agent procedures, adverse event reporting procedures, radiation therapy guidelines, and auditing procedures.

The CTSU also offers a detailed Operations Manual. Full text or individual chapters are available for download and printing on the members’ side of the CTSU website (http://members.ctsu.org) under the Education and Training Tab. The CTSU Operations Manual includes information about the Physician Credentialing Process, Protocol-Specific Site Registration, Patient Enrollment / Registration, Financial Reimbursement, Data Submission & Study Record Maintenance, and Audits

Both the eCourse and the Operations Manual are updated semi-annually. The newly updated Fall 2003 versions of the eCourse and the Operations Manual are currently available. Please visit the CTSU web site to access these educational tools and resources. For those who have additional questions, please contact the CTSU help desk at 1-888-823-5923 or by email at CTSUcontact@westat.com.

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**SWOG Lead Studies – Target/Current/CTSU Accruals and Site Registrations through the CTSU (as of 9/26/03)**

<table>
<thead>
<tr>
<th>Protocol</th>
<th>Target Accrual</th>
<th>Current Accrual</th>
<th>CTSU Accrual</th>
<th>Site Registered for Trial (Approved)</th>
</tr>
</thead>
<tbody>
<tr>
<td>S0012</td>
<td>300</td>
<td>103</td>
<td>16</td>
<td>47</td>
</tr>
<tr>
<td>S0023</td>
<td>840</td>
<td>336</td>
<td>20</td>
<td>47</td>
</tr>
<tr>
<td>S0124</td>
<td>620</td>
<td>80</td>
<td>13</td>
<td>80</td>
</tr>
<tr>
<td>S0200</td>
<td>900</td>
<td>21</td>
<td>3</td>
<td>50</td>
</tr>
<tr>
<td>S9900</td>
<td>600</td>
<td>320</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>S9921</td>
<td>1360</td>
<td>359</td>
<td>3</td>
<td>39</td>
</tr>
<tr>
<td>S9925</td>
<td>NA</td>
<td>NA</td>
<td>79</td>
<td>91</td>
</tr>
</tbody>
</table>

The above chart illustrates the target accrual for the study, the current accrual for the study, the CTSU accrual for the study, and the number of approved site registrations for all SWOG trials on the CTSU menu as of 9/26/03.
Endorsed Studies indicate collaboration between the disease committees of the Endorsing Groups and the Group sponsoring the study. Enrollments are via the CTSU for those members who do not already have access to the study via affiliations with the sponsoring Group or participating InterGroups. These protocols were included in the August 01- November 15, 2003, mailings.

**CTSU/IBCSG 24-02.** A Phase III Trial Evaluating the Role of Ovarian Function Suppression and the Role of Exemestane as Adjuvant Therapies for Premenopausal Women With Endocrine Responsive Breast Cancer (SOFT). Southwest Oncology Group Study Coordinator: Dr. S.M. Martino. **Activation, 08/15/03.**

**CTSU/IBCSG 25-02.** A Phase III Trial Evaluating the Role of Exemestane Plus GnRH Analogue as Adjuvant Therapy for Premenopausal Women With Endocrine Responsive Breast Cancer (TEXT). Southwest Oncology Group Study Coordinator: Dr. S.M. Martino. **Activation, 08/15/03.**

**CTSU/NCIC-MA.27.** A Randomized Trial of Exemestane Versus Anastrozole With or Without Celecoxib in Postmenopausal Women With Receptor Positive Primary Breast Cancer. Southwest Oncology Group Study Coordinator: Dr. G.T. Budd. **Activation, 08/15/03.**

**CTSU, Z9000.** A Phase II Study of Adjuvant STI571 (Gleevec™) Therapy in Patients Following Completely Resected High-Risk Primary Gastrointestinal Stromal Tumor (GIST). **Permanent Closure, 09/30/03.**

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**CCRP Exam To Be Offered At Spring 2004 Group Meeting**

Twenty-eight clinical research associates took the Society of Clinical Research Associates (SoCRA) clinical research associate certification examination at the 2003 Fall Group Meeting in Seattle. We will offer the examination again at the Spring 2004 Group Meeting in Huntington Beach. Please check the SoCRA web page (www.socra.org) or contact SoCRA at 1-800-SOCRA92 or 215/345-7749 for information about the application deadline. A minimum of 10 is required for the exam to be conducted.

The purpose of the certification program is to create an internationally accepted standard of knowledge, education, and experience by which clinical research associates will be recognized as professionals in medical research. Individuals achieving a passing score on the examination may use the title “Certified Clinical Research Professional” or the initials “C.C.R.P.” after their name.

Applicants must be current members of SoCRA in good standing or apply for membership and the certification examination simultaneously. Applicants also must have been employed two of the last five years as a clinical research associate.

The certification examination consists of five major areas of content: 1) conduct of clinical trials; 2) institutional review boards and regulations; 3) ethical issues; 4) ability to follow directions; and 5) abstracting information from medical records. Applications for the certification examination and membership in SoCRA may be obtained by calling 1-800-SOCRA92 or 215/345-7749. Information may also be obtained from the Web site at the following address: [www.socra.org](http://www.socra.org)

The Southwest Oncology Group contact persons are Angela Allred (501-686-8274) and Debbie Christie (601-984-1099).

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**Laughter is the Best Medicine!**

Don’t let anyone tell you that Group Meetings are always “all work and no play.” Here’s proof that it simply isn’t so! Elaine Lundberg, M.A., Humor Therapist, engaged the funny bones of 26 Southwest Oncology Group nurses during a special dinner program sponsored by GlaxoSmithKline during the 2003 Fall Group Meeting. *(Turn to pages 16-18 in this newsletter for more news about the activities of the Nurse Oncologist Committee.)*
Clinical Research Associates Committee Update

The October 2003 CRA Committee meeting in Seattle was very successful. Radiation Therapy and New Imaging Techniques is planned as the Continuing Education Workshop topic for the Spring 2004 Group meeting in Huntington Beach, California. The CRA Plenary Session will likely include a presentation on Cetuximab due to the new pancreatic study.

October 2003 marked the 20th anniversary of the Southwest Oncology Group CRA Committee. CRAs were recognized with certificates identifying the number of years they have worked with the Group.

I would again like to thank everyone who took the time to complete an Evaluation Form at the end of each CRA function during the Seattle meeting. The evaluation forms are invaluable tools for the CRA Committee. They allow us to determine if we are meeting the needs of the CRAs, and allow you to give feedback about the meetings you attend and what topics and/or presenters you would like to see in the future. Please help us steer the direction of the CRA Committee by taking the time to complete evaluations at the Huntington Beach meeting. If you have suggestions for future meeting topics, please contact one of our Subcommittee Chair:

Communications: Beth Davis  
Continuing Education: Anita Crosena  
Head CRA: Phyllis Stein  
Open Forum: Linda Balla  
Posters: Marilyn Turner  
Program: Virginia McMahon  
Survivor Program: Courtney Terry

Plans are to offer the SoCRA (Society of Clinical Research Associates) CCRP examination again at the Huntington Beach meeting. If you are interested in taking the exam, please refer to the information about the examination included elsewhere in this newsletter. A minimum of 10 people taking the exam is needed to conduct the exam.

The Survivor Recognition Program will officially return during the Spring 2004 meeting in Huntington Beach, California. Three survivors from that area will be honored; we are looking for hosts/hostesses. Courtney Terry is heading up this initiative; please volunteer for this very worthwhile and rewarding program.

We will also be unveiling a new program called the Partnerships for Life Program. An introduction to the program was made during the Head CRA Meeting in Seattle. You will be learning more about this valuable program after the first of the year. This is a joint effort between the CRA Committee and the Nurse Oncologist Committee to increase patient compliance decrease lost to follow-up rates.

Thanks to everyone for helping to make the CRA Committee a success and an important part of the Southwest Oncology Group. I look forward to seeing you in Huntington Beach.

Angela Allred, BS, CCRP  
Chair, SWOG CRA Committee

It’s Here Now — Online Specimen Tracking!

The Southwest Oncology Group is proud to announce that an important new feature of the CRA Workbench has been added: The Online Specimen Tracking system. This new system allows both the CRAs (who are responsible for submitting specimens) and the Labs and Repositories (which receive those specimens) to log and track individual specimens via the Internet. We hope it will provide a greater convenience and ease of use while maintaining a clear record of individual specimens.

The system will be initially used only on specific new studies; the first will be the Adjuvant Breast trial S0221, activated on November 1, 2003. All other studies will continue to employ the standard specimen submission guidelines as listed in their protocols. Other new studies will begin using the system as appropriate when they are activated; there is currently no plan as yet to apply the system to current, active studies. Be sure to check each protocol for its specific specimen submission requirements.

To access the Online Specimen Tracking system, simply navigate to the CRA Workbench at https://gill.crab.org/txwb/Logon.aspx to log on as usual. There will be a new link in the sidebar called “Specimen Tracking,” which when clicked will open a new window for Online Specimen Tracking.

As with Web Registration (“WebReg”), we will offer options for either “live” data — which will connect to our actual database — as well as for “test” data, which will allow users to explore the new system in a test environment to become comfortable with the program before using it for actual patient data.

We recognize that this is brand new for everyone — that includes us! That’s why, as always, we strongly encourage feedback, positive or negative, from our users. We are eager to incorporate any suggestions that would help strengthen the system or make it a more useful tool in the CRA Workbench. Email us any time at technicalquestion@crab.org with comments, problems or suggestions!

9th Annual Clinical Trials Management in Oncology Training Program
February 23-26, 2004
at City of Hope National Medical Center
Duarte, California

Presented by City of Hope National Medical Center

Includes lectures covering topics from study design to reporting adverse events, and everything in between. Hands-on exercises allow you to work interactively with others in a supportive atmosphere to solve problems relevant to the lectures heard that day. The goal is to give you skills to take back to your place of employment, allowing you to contribute high-quality data and protocol management to the research process.

For complete information: http://crrtraining.coh.org
Contact: Jennifer Simpson at 626-359-8111 x65087
CRA Plenary Session Fills Information Needs for CRAs/Nurses

One hundred fifty-nine Clinical Research Associates/Nurses attended the CRA Plenary Session on October 2, 2003. Of those present, 63 percent completed the evaluation sheets. Thank you, all of you, who took the time to complete the evaluation sheets and offer suggestions for the next Group Meeting in April ’04. As a reminder, the Society of Clinical Research Associates approved this program for 1.5 Continuing Education Credits.

Based on the evaluation sheets, this was a very informative meeting. As always, the Southwest Oncology Group Operations Office/Statistical Center Update provided important information on changes that are taking place, not only within the Group, but also in the Data Operations Office, including electronic data submission and tracking.

Renee Robinson, CCRP, gave excellent examples and suggestions on how to conduct clean, safe and more efficient clinical trials in her presentation of “Good Clinical Practice – The Pitfalls and Perils.” The Code of Federal Regulations and ICH Guidelines provided by Renee through the support of Amgen will be useful tools for all CRAs.

“Interpreting the Bone Marrow Report – 101,” presented by Dr. Jeffrey Berenberg, provided everyone with basic information needed to read and understand the bone marrow report. Thanks to Dr. Berenberg’s informative presentation, cellularity, sudan black, non-specific esterase, bone marrow aspirate and biopsy are no longer just words that are found in reports and rarely understood.

As in past meetings, Siu-Fun Wong, PharmD, Pharmacy Committee Chair, did an excellent job in explaining growth factors in, “What is the Role of the Granulocyte Growth Factors in the Management of Leukemia.” Not only did Dr. Wong give a great overview of AML, but she also gave excellent examples of how chemotherapy induced neutropenia would be handled with the support of growth factors. If you had little or no experience with the growth factor Neulasta?, this was the meeting to attend. After this presentation, Neulasta’s use, administration, dosing and side effects were well understood.

Thanks are extended to Jacqueline Benedetti, PhD, Southwest Oncology Group Statistical Center; Marjorie Godfrey, Southwest Oncology Group Operations Office; Renee Robinson, CCRP, UCLA; Jeffrey Berenberg, MD, University of Hawaii MBCCOP; and Siu-Fun Wong, PharmD, Chair of the Pharmacy Committee, for their support of the Group’s CRAs and their continuing efforts to improve their skills and education. Also, a special “Thank you!” is extended to Amgen for their support.

CRA Workbench – On-Line Data Query Tracking!

Have you ever wondered...

Why you keep receiving queries which you could swear you’ve already responded to?

What the status is of your reply – for example whether it has been reviewed yet by the DC?

Whether your reply was deemed adequate or if additional information is necessary?

You’re in luck, because the Statistical Center is working on developing an on-line data query monitoring system whereby data requests and the status of those requests will be better tracked in the Statistical Center database.

CRAs who attended the STARS seminar during the Fall Group Meeting in Seattle were shown the prototype of this query tracking system, which the Statistical Center hopes to deploy within the next 2-4 months. Once deployed, access will be via the CRA Workbench. The system won’t replace the current paper system already in place – at least not initially. CRAs will still continue to receive paper copies of data requests on the Patient Evaluation Status Reports, just as you are used to receiving now. Instructions on the paper report will be changed to lead you to the CRA Workbench, should you choose, to review and indicate online that you’ve responded to the query.

Several unique features will exist with the on-line system, including a query-specific “Review Status” as well as checkboxes that will allow you to indicate that you’ve submitted the requested data or indicate the reason why you cannot. Another new feature of the on-line system will be the ability for the CRA to print a current version of the Patient Evaluation Status Report.

Queries generally pertain to incomplete or conflicting data relevant to key study endpoints such as eligibility, adverse events, or tumor response or status of disease. Queries help us obtain thorough and non-contradictory data, which are necessary for reliable statistical analysis. So, it is to everyone’s advantage to develop a tool which helps us all better manage these important queries.

Stay tuned to the “What’s New” section of the CRA Workbench for further information regarding our new Query Tracking System!

Disease Committee Representatives Needed...

The Clinical Research Associate (CRA) Committee has openings for CRA representatives to the Committee on Special Populations and to the Surgery Committee. As a committee member, the representatives attend closed sessions where new protocols are discussed, review protocols in development and work on special projects with the committee chair.

Please contact Beth Davis at Alta Bates Comprehensive Cancer Center (510-204-3428) or e-mail bdavis@salick.com.
Nurse Oncologist Committee News — Notes from the Nurse Oncologist Committee Chair

Report from the Nurse Oncologist Committee Chair

As I briefly expressed at the Nurse Oncologist Workshop at the recent Southwest Oncology Group Meeting, I am both honored and humbled to accept the position of Chair of the Nurse Oncologist Committee. Having been involved with the workings of this Committee for the last several years, I know firsthand what gifted and dedicated nurses there are under the umbrella of the Group, working to make a difference in the lives of our patients through clinical trials – and it is truly amazing. For that, I want to thank each and every one of you who are committed to this work.

It is especially rewarding for me to be able to follow in the footsteps (so to speak) of our very own “oncology nurse pioneer” at my institution, Norma Oberhauser. As noted in our SWOG Nursing Manual (a copy of which can be found on the Group’s website), way back in 1966 when the Group was known as the Southwest Cancer Chemotherapy Study Group, “Ms. Oberhauser from Henry Ford Hospital in Detroit participated with the Principal Investigator and attended group meetings.” From the one nurse who attended then to the 150+ who attended our Nurse Oncologist Workshop at this meeting, and in everything else that has been accomplished by means of the Nurse Oncologist Committee throughout these years, “we’ve come a long way baby,” as the saying goes.

I am humbled because, in spite of the many achievements of this Committee, there are still many challenges. In the following excerpts from each of our Subcommittee chairs, you will get a sense of where we are and where we hope to go. Please read through them carefully, and if you would like more information or if you feel there might be an opportunity for you to become more involved, please do not hesitate to contact us.

And, most importantly, keep up the outstanding work that you are doing…as I am reminded quite frequently, it truly does make a difference.

Carolyn

Disease and Discipline: Deborah Ward and Rose Ermete

There were 20 attendees at the Subcommittee meeting, approximately half of whom were liaisons. Deborah Ward reported that there remain issues among the liaisons as to timing of nursing review of protocols and creation of fast fact sheets. The timing of these processes will need to be clarified with the Operations Office. Discussion further centered on the quality-of-life component to treatment protocols. Many present at the Subcommittee meeting were interested and requested an educational session at the next meeting related to this topic. The remainder of the meeting was a presentation by Rose on SOP’s for clinical research activities.

Due to Carolyn Schmidt’s acceptance of the NOC chair position, she will no longer be the co-chair to this Subcommittee. Through the next meeting, Rose Ermete will be transitioning from the Program Subcommittee to this Subcommittee as a co-chair, and Deborah Ward will transition to the Program Subcommittee.

Education: Dorothy Coleman, Pamela Williams and Juanita Garrison

There were 12 attendees, which was low and possibly attributable to the auditing meeting that was held at the same time. At the subcommittee meeting, Dorothy Coleman reviewed the SWOG auditing data quality sheet that listed deficiencies for treatment studies. Three people volunteered to work on the audit manual; however, this project has been temporarily placed on hold until further discussion with the Operations Office.

There were two poster presentations at this meeting: Lisa Hansen/Marcia Grove-Conrad from the reverse site visit and Rose Ermete on mentorship.

Pam Williams discussed the drug manual. Thirty-eight monographs have been submitted to the Operations Office, and they should be on the Group website within the next 1-2 weeks. All forms will have a last review date on the bottom to assure that the most current version is being utilized. Pam requested that a table of contents be added to the manual. Zevalin and Oxaliplatin have been updated, and three drugs have been reviewed. An electronic template has been created. Three additional monographs are in draft and are due to Pam by November 1. Four are currently not assigned, as well as five new ones. These 12 monographs are scheduled for completion by the next Group Meeting.

Program Committee: Karen Mack and Rose Ermete

One hundred fifty-six nurses and CRAs attended the Fall Nurse Oncologist Workshop “Care of the Lung Cancer Patient: Applications for Practice” on October 3, 2003. The workshop was very well received with many positive comments on the evaluations. Robert A. Chapman, MD, presented “Lung Cancer 101.” He gave a very informative talk on the epidemiology of lung cancer as well as information on how to stage this disease. Elizabeth Waxman, MSN, RN, AOCN spoke on “Management of the Lung Cancer Patient,” and discussed the use of referral services in the care of the lung cancer patient. “Exercise & Cancer” was presented by Keri Winters, PhD., with a review of various studies supporting the use of exercise to decrease fatigue in the patient receiving chemo-
Nurse Oncologist Committee News (Continued)

therapy. Information was presented on a new study to be activated, evaluating benefits of exercise in the chemotherapy patient. “New Drugs in the Treatment of Lung Cancer,” offered by Siu Fun Wong, PharmD, focused on Cytotoxic and Target Agents.

The Nursing Disease and Discipline Committee again offered Continuing Education Units for the presentation of “Standard Operating Procedures (SOPs)” from Rose Ermete, RN, BSN, OCN, CCRP, with discussion on the importance of SOPs and how to begin writing them. “Research 101,” presented by Maggie Ramsey, RN, MS, AOCN, from the Nursing Research Committee also offered Continuing Education Units, and an overview of research in the cooperative group setting.

A special dinner program featured Elaine Lundberg, MA., Humor Therapist. The twenty-six nurses in attendance were treated to a delightful evening of humor along with ways to incorporate humor into daily practice and relieve some of that stress that we all seem to have. (Check out the photograph on page 13 to see some stress-less nurses!)

Continuing Education Units for all programs were provided through the Oncology Nursing Society (ONS) and The Society of Clinical Research Associates (SoCRA). The program committee is always open to your suggestions. Please contact Rose Ermete (Ermeter@aol.com) or Karen Mack (mackkarenl@uams.edu) if you have an educational topic that you would like to present at the Spring Meeting.

Research: Maggie Ramsey

Research 101 was well attended. There appears to be a great deal of interest in a Research 102 class; this probably would involve identifying an idea and taking it through the process. Shirley Raltz has agreed to do the Research 101 next meeting, however, more individuals may need to be identified to support this Subcommittee in this manner.

Attendees at the Subcommittee meeting were enthusiastic about a number of potential tasks: setting up a chat room and identifying specific work groups with an emphasis on symptom management, psychosocial, and cancer control. Other ideas expressed were exercise and neuropathy studies. It was also noted that Disease & Discipline should work more closely with this Subcommittee to help identify and further support nursing research activities.

CCOP: Marge Good

Marge Good stated that there were about 18 members present at the session. Patient satisfaction was reviewed and two tools were discussed. There is a strong interest in doing a study on patient satisfaction on clinical trials. Marge Good is speaking with a physician who has conducted patient satisfaction evaluation as part of another study and working on ideas. There also was discussion related to devising a system for reporting SAE’s.

Committee on Special Populations Liaison report: Marcia Grove-Conrad

Congratulations were extended to Dr. Albain and committee for the “outstanding” award at the reverse site visit. Building upon its accomplishments, the committee is involved in some new breast protocols/concepts on ovarian salvage, effect of exercise on fatigue and weight gain, and relief of metastatic disease bone pain. Work continues with multi-variant analyses of various special populations registered to Group trials in looking for patterns that might need further investigation, and submitting articles for publication concerning the patterns. New initiatives include survival issues, tracking special populations for long term toxicities, and interventions for specific treatment-related symptoms.

Cancer Control Liaison Report: Lisa Hansen

Multiple trials and projects are under development in the Cancer Control Research Committee. The Molecular Epidemiology Subcommittee is launching pharmacogenetics studies in breast cancer, prostate cancer, and acute myelogenous leukemia. These studies will utilize existing biologic specimens to help elucidate how individual variations in chemotherapy metabolism might affect tumor response. $S9908, the Glutamine Trial for Oral Mucositis, was temporarily closed due to drug supply issues. These issues are in the process of resolution and a protocol revision is forthcoming.

Chemoprevention news included the astounding accrual to SELECT, encouragement to enroll patients on the companion trial (PREADVISE) for prevention of Alzheimer’s Disease, and practical strategies for promoting adherence to the SELECT protocol treatment assignment. Accrual to the high-grade PIN trial $S9917 has improved significantly over the past six months. Finally, members can look forward to a new trial in cervical cancer prevention.

Welcome to Our New Members!

Barry Boatman RN, MA, OCN, CCRN, CIM — Research Manager, Atlanta Regional CCOP, Atlanta, Georgia.

Betty Jurisich, RN, BSN, OCN — Director Tulane Cancer Center, Office for Clinical Research, New Orleans, Louisiana.

Lisa Justice, RN, OCN — Clinical Research Nurse, Columbia River Oncology Program, Portland, Oregon.

Ruth Chaplen, RN, MSN, AOCN, CS — Nurse Practitioner, Karmanos Cancer Institute, Detroit, Michigan.

Denise Reinke, APRN, BC, AOCN — Director Sarcoma Research, University of Michigan Cancer Center, Ann Arbor, Michigan.

Linda Vocila, RN, BSN, OCN — Oncology Research Nurse, Greater Phoenix CCOP, Phoenix, Arizona.

Denise Weiss, RN, CS, MSN — Nurse Practitioner, Karmanos Cancer Institute, Detroit, Michigan.

Interested in Joining? It’s easy, just fill out the application on the next page and mail it to Patra Grevstad RN, MN, at the address noted on the application.
SOUTHWEST ONCOLOGY GROUP
Nurse Oncologist Committee
MEMBERSHIP APPLICATION FORM

Date Submitted: ___________________________ Date Received: ___________________________

Please note it is highly recommended that you attend at least one out of every four meetings to become a member and maintain membership status. If you have questions regarding this application, please call Patra K. Grevstad, RN, MN, at (206) 386-2442 or email at: patra.grevstad@swedish.org.

Name and Credentials: ___________________________________________________________

Current Position: ___________________________ Specialty: ___________________________

Social Security Number: ___________________________ Business Address: ___________________________

Phone: ___________________________ Fax: ___________________________

E-Mail Address: ___________________________ Principal Investigator: ___________________________

Group Status  __ Member  __ CCOP  __ Affiliate  __ UCOP  __ Other: ___________________________

WOULD YOU BE INTERESTED IN HAVING A MENTOR? _____ YES  _____ NO

If you are interested in becoming a member of a specific Subcommittee, please check the appropriate box(es) below; information will be sent to you.

__ Disease and Discipline  __ Education  __ Research  __ Program  __ Membership

Required Information (must accompany application): Curriculum Vitae, Resume, or Biographical Sketch

I have reviewed the above application for membership in the nurse oncologist committee and recommend approval for the above applicant. My signature below affirms this recommendation plus my commitment to providing opportunities for attendance to SWOG meetings in order to maintain membership status.

_________________________________________________________________________

Principal Investigator

PLEASE MAIL COMPLETED FORM AND REQUIRED INFORMATION TO:
Patra K. Grevstad, RN, MN
Membership Chair, SWOG Nurse Oncologist Committee
Swedish Cancer Institute
1221 Madison, Suite #400
Seattle, WA 98104

Rev 04/03
Operations Office Staff News

September Baker and Valerie Salido have joined the Operations Office as Quality Assurance Auditors. Previously, September, a Certified Pharmacy Technician (CPht), served at an acute care hospital for five years. While there, she also served on multidisciplinary process improvement and quality assurance committees. Most recently, she completed an internship with the Cancer Therapy and Research Center. Valerie served as Director of Regulatory Affairs, as well as Clinical Research Coordinator at two local clinical research centers conducting Phase II, III, and IV clinical research trials in a wide range of therapeutic areas.

Statistical Center Staff News

Welcome, Babies!

Jim Faulkner, Statistician, and his wife Yuri, welcome their son, Nikolas, born October 3, 2003. Earlier this year, Statistician Cathy Tangen and husband Brent Hillard welcomed their daughter, Kelly Marie, born April 30, 2003. Our good wishes are extended to both families!

Welcome and Congratulations!

The SWOG Data Operations Center would like to take this opportunity to recognize a few additions to the department as well as some promotions. We welcome John Kendall and Julia Jackson, our most recent Data Control Technicians who joined us this September. Stephanie Edwards has been promoted to Data Operations Supervisor. Stephanie joins the Data Operations management team after having spent several years as Data Coordinator on the Breast and Sarcoma Committees. Christine McLeod, an avid “Trading Spaces” fan recently traded her space as a Data Control Technician for a promotion to Data Coordinator on the Breast Committee. In addition, Janice Leaman was promoted from Data Control Technician Lead to Data Coordinator. Janice will assume responsibility for some Lung and GU studies. Jennie Barrett has been promoted to Data Coordinator and will join the GI Committee. Jennie joins our department after serving as a Data Control Technician for SELECT for the past three years.

2003-2004 Holiday Schedule

—Operations Office—
Christmas Day, December 25, 2003
Day After Christmas, December 26, 2003
New Years Day, January 1, 2004

—Statistical Center Staff
at Fred Hutchinson Cancer Research Center—
Christmas Day, December 25, 2003
New Year’s Day, January 1, 2004
Martin Luther King Day, January 19, 2004
Presidents’ Day, February 16, 2004

—All CRAB Offices—
Christmas Day, December 25, 2003
Day After Christmas - Boxing Day, December 26, 2003
New Year’s Day, January 1, 2004
Day After New Year’s Day, January 2, 2004
Martin Luther King Day, January 19, 2004
Presidents’ Day, February 16, 2004

Cancer Research And Biostatistics (CRAB)
Phone: 206-652-9711 FAX: 206-652-4612

SELENIUM and VITAMINE CANCER PREVENTION TRIAL (SELECT)
1730 Minor Avenue, Suite 1900
Seattle, WA 98101-1468

Data Operations Center at CRAB
Data Operations Center
c/o Cancer Research and Biostatistics
1730 Minor Avenue, Suite 1900
Seattle, WA 98101-1468
PHONE: 206-652-2267 FAX: 206-652-4612

Delivery (FedEX, UPS, etc.): SWOG Data Operations Center
c/o Cancer Research & Biostatistics
1730 Minor Avenue, Suite 1900
Seattle, WA 98101-1468

DECEMBER 2003
Seattle Weather Can’t Dampen Spirits

One thing for sure, the SWOG Crab Crushers never let a little fog or chilly weather keep them off the beaten path! Sixty-plus runners and walkers boarded buses at the crack of dawn for a quick trip to one of Seattle’s most scenic trails, the Burke-Gilman Trail. Runners included: Karen H. Albritton, MD, Huntsman Cancer Institute; Michael F. Barber, PharmD, Aventis, 2nd Place Men 40 & Under; Michelle Bartholet, RN, Washington Hem/Onc Specialists, 3rd Place Women 40 & Under; James D. Bearden III, Upstate Carolina CCOP; Ruth Canamar, Arizona Cancer Center; Wendy A. Carr, Texas Tech University Medical Center; Helen K. Chew, MD, University of California - Davis; Warren A. Chow, MD, City of Hope National Medical Center, 3rd Place Men 41-54; Joseph I. Clark, MD, Loyola University Stritch School of Medicine, Overall Best Time Men (17:30:88) and 1st Place Men 41-54; E. David Crawford, MD, University of Colorado Health Sciences Center, 1st Place Men 55 & Over; Nora K. Galvin, RN, CTR, Grand Rapids Clinical Oncology Program CCOP, 2nd Place Women 55 & Over; Jennifer M. Hartley, RN, BSN, 3rd Place Women 41-54, Mobile Infirmary Medical Center, Gulf Coast MBCCOP; Brian F. Issell, MD, University of Hawaii, 3rd Place Men 55 & Over; Julie A. Kish, MD, H. Lee Moffitt Cancer Center, 1st Place Women 55 & Over: Ben Kleinman, Southwest Oncology Group Statistical Center, 1st Place Men 40 & Under; Amanda Knight, RN, BSN, Southwest Cancer Center; Alan P. Lyss, MD, Missouri Baptist Cancer Center; Daruka Mahadevan, MD, PhD, Arizona Cancer Center; Ross W. McFarland, MD, Wilford Hall Medical Center, Lackland AFB; Sandra Brown McKnight, RPH, AstraZeneca Pharmaceuticals; Vivek K. Mehta, MD, Swedish Cancer Institute NW; Halle C.F. Moore, MD, Overall Best Time Women (22:03) and 1st Place Women 40 & Under, Cleveland Clinic Foundation; Tanya Moore, RN, Alta Bate Comprehensive Cancer Center; Douglas A. Nelson, MD, Keesler Medical Center, Keesler AFB; Paul Okunieff, MD, University of Rochester Medical Center; David M. Peereboom, MD, Cleveland Clinic Foundation; Marilyn K. Peltier, RPH, Centocor; Maggie Ramsey, RN, MS, 2nd Place Women 41-54, Harrington Cancer Center; Denise Reinke, APRN, University of Michigan; Jane F. Ringlein, RN, MSN, Aventis Oncology; Vicki M. St. John, 1st Place Women 41-54, Merck & Company, Inc.; Susan B. Schulman, CCRA, University of Utah; Don W. Shaffer II, MD, Marietta, Georgia; Pramod K. Sharma, MD, University of Utah Huntsman Cancer Institute; Julie Stover, MIRT University of Arkansas; Erika J. Struble, MD, Wilford Hall Medical Center, Lackland AFB, 2nd Place Women 40 & Under; Gregory P. Swanson, MD, Cancer Care Northwest, 2nd Place Men 41 to 54; Sheela Tejuani, MD, Henry Ford Hospital; Mary Jo Uhen, RPH, Bristol-Myers Squibb Oncology; Richard O. Wein, MD 3rd Place Men 40 & Under, University of Mississippi; Kimberley R. Wells, CCRP, Southwest Cancer Center; Jeannette L. Wilcox, MD, Greenville CCOP; Jacqueline P. Williams, PhD, University of Rochester Medical Center; Michael G. Wortman, RN, 2nd Place Men 55 & Over, MSJ Cancer Services; Bennett W. Yu, MD, Eastern Virginia Medical School; and Jeffrey A. Zonder, MD, Wayne State University/Karmanos Cancer Institute.

We are grateful to the AstraZeneca for their continued sponsorship of the “Crush the Crab” 5K Run and Fitness Walk.

Top photo: Halle Moore accepts her award for Overall Best Time - Women, from E. David Crawford, he garnered 1st Place in the Mens division. Bottom photo, left to right: Womens 2nd Place winners Erika Struble, Nora Galvin, & Maggie Ramsey.

Top photo, left to right: Female 1st Place winners Halle Moore, Vicki St. John, and Julie Kish. Bottom photo, left to right: Mens 2nd Place winners Gregory Swanson and Michael Wortman.

Top photo, left to right: Paul Okunieff, Brian Issell and E. David Crawford take a water break. Issell was later awarded a 3rd Place in Mens division. Bottom photo, left to right: Mens 3rd Place winners Warren Chow and Richard Wein.
Mark Your Calendars!

Southwest Oncology Group Future Meeting Dates

— 2004 —
— April 28 - May 2, 2004 — Huntington Beach, California
— October 20 - 24, 2004 — Kansas City, Missouri

— 2005 —
— April 5 - 10, 2005 — Denver, Colorado
— September 28 - October 2, 2005 — New Orleans, Louisiana

— 2006 —
— April 19 - 23, 2006 — Salt Lake City, Utah
— October 4-8, 2006 — Seattle, Washington

Check the Southwest Oncology Group website for updates!
http://swog.org (Meetings & Training Section)

Fall 2003 Group Meeting Educational Grants

PATRON
Aventis Oncology GlaxoSmithKline

Centurion
Genentech, Inc. Eli Lilly and Company Novartis Oncology

Pacesetter
Amgen Bristol-Myers Squibb EMD Pharmaceuticals, Inc. OSI Pharmaceuticals SuperGen

Supporter
AstraZeneca Berlex Oncology Cell Therapeutics, Inc. Chiron BioPharmaceuticals DDOTS, Inc. IDEC Pharmaceuticals MedImmune Oncology, Inc. Merck & Company, Inc. MGI Pharma Pfizer, Inc. Sanofi Oncology

We appreciate their support!