

Southwest Oncology Group

THE GROUP NEWSLETTER



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Southwest Oncology Group 2005 Spring Group Meeting Denver, Colorado April 6 - 10, 2005



Southwest Oncology Group Meeting section begins on page 7.
Register online on the Group Meetings page at <http://swog.org>



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The Group Newsletter

The purpose of THE GROUP NEWSLETTER is to facilitate Groupwide communication. You may submit articles by mail or e-mail to the Operations Office to the attention of the editor, Rosanne Fohn, (newsletter@swog.org). The deadline for the May 2005 issue is April 22, 2005. Copyright 2003.

Message from the Chairman

Thank you for your support!

By Charles A. Coltman, Jr.
Chairman

I was just 34 years old and a captain in the United States Air Force when I attended my first Southwest Oncology Group meeting in Houston in 1964. Fresh out of Ohio State University, where I completed my Internal Medicine and Hematology/Oncology Fellowship with an M.M.S. in internal medicine, I was a staff hematologist stationed at Wilford Hall USAF Medical Center in San Antonio. The idea of joining a cooperative group dedicated to clinical trials in cancer greatly appealed to me. The Southwest Cancer Chemotherapy Study Group, as our Group was called then, had been founded just eight years before as one of the very first cooperative groups instituted by the National Cancer Institute.

Once a member of the Group, I quickly became involved, serving on the Executive Committee from 1966 through 1981 and chairing the Lymphoma Committee from 1966 to 1977. I headed the Disease and Discipline Committee and the Leukemia Committee from 1977 through 1981. And in March 1981 the membership elected me Chairman of the Southwest Oncology Group. It has been my privilege to serve in this capacity for 24 years.

Together we have accomplished many great things. For example, in the past 17 years, the Food and Drug Administration has issued new drug approvals for nine cancer therapies as a result of our research. Over the years we have grown to be one of the largest cooperative groups in the world to study adult cancer. Here are just a few of our many accomplishments:

The 1980s

- In 1981 we refocused the Group to study only adult cancer after the pediatric



arm of the Group sought independent status in 1980.

- 1983 was an especially eventful year. We started the Community Clinical Oncology Program (CCOP) so institutions that had access to large minority populations could join the Group. We initiated the Quality Control Program to ensure we had the highest quality data. And we overcame seemingly insurmountable obstacles to

establish our new Statistical Center in Seattle, after the previous Statistical Center received a disapproval rating.

- During the 1980s we developed the Cancer Control Research Committee (CCRC) to address the need for chemoprevention, symptom management and quality of life programs.

- In 1988, I was impressed with the desire of urological oncologists to enter patients into clinical trials. This prompted me to establish the Urologic Cancer Outreach Program (UCOP) to attract new urologists to the Group and to increase patient enrollment to genitourinary trials.

The 1990s

- In 1990 we initiated the Minority-Based CCOP Program to include even more patients from minority groups in our research.

- In 1991 we established the Southwest Oncology Group Foundation to bring in private funds to support our research. We also started the Committee on Women's Health to focus on the special concerns of women.

- Another significant event of 1991 was the beginning of the United States-Japan Summit. I met Dr. Masanori Fukushima, Professor of Pharmacoepidemiology at Kyoto University in Japan, at an American Society of Clinical Oncology meeting in 1989. He wanted our guidance on how to improve clinical trials in Japan and so we formed a partnership and have met 11 times

(Continued next page)



It's easy to add the priority list to your PDA

The Southwest Oncology Group Priority List of open studies can now be downloaded to your Palm Pilot, Pocket PC or other personal digital assistant.

"This is just wonderful!" said Stephen K. Williamson, M.D., Director of Hematology/Oncology at the University of Kansas. "Since the listing is divided by disease committee, once you see a protocol you are interested in, you just click on the eligibility criteria and review it without ever having to use the computer."

Downloading is being provided through AvantGo® mobile internet service. There are two ways to begin the service:

- You can add the new channel automatically by clicking on the special AvantGo subscription page link on the PDA Bulletin Board page of swog.org. If you're not already an AvantGo subscriber, you can sign up for the free service



and get the instructions for installing it on your PDA. If you are an AvantGo subscriber, the SWOG channel will be added when you sign in.

- Or, existing AvantGo subscribers can log in to the site at the sign-in page, <https://my.avantgo.com/login/index.html>, and either do a search for "southwest," or go to the Health » Healthcare Professionals section and add our channel to your list.

We are beginning this service at a basic level, with just the Priority List for each disease committee, including open studies by title, drugs, eligible participating institutions, activation date, and a link to a separate eligibility criteria page by protocol. Depending on usage, we plan to add other options such as ability to select only diseases

of interest, only protocols approved by local IRB, etc.

If your PDA has wireless internet access, you can still get the PDA version of the Priority List directly by going to <http://swog.org/pda/>. This will only work if you have access to the Internet at the time you need the information, and will be slower than the pre-downloaded AvantGo pages, but if PDA storage space is an issue and you have a respectable transfer speed, it may be a viable alternative.

Send your comments, questions and suggestions about the service to webmanager@swog.org.

Web site notes Group's PDA listings

The Southwest Oncology Group's priority listing of open studies on personal digital assistants recently was noted on the ectopicbrain Web site. The Web site keeps medical professionals up to date on the latest technologies that help them become better organized and efficient, and help reduce errors and improve patient care. You can visit the organization's Web site at <http://pbrain.hypermart.net>.

Message from the Chairman

(Continued from previous page)

since the first summit in 1992. Over the years we have exchanged information on urological, gynecological, esophageal, gastric, lung, head and neck, colorectal and breast cancers, as well as osteosarcoma and lymphoma. This month we will meet in Hawaii to discuss gastric and colorectal cancer.

- In 1993 we launched the Prostate Cancer Prevention Trial, the largest study of its kind at that time. The intergroup trial involved nearly 19,000 participants.

- In 1998 the Southwest Oncology Group Foundation was renamed The Hope Foundation.

- In 1999 we established the Young Investigators Training Course to encourage young physicians to enter the field of cancer research through our Group. This program has had exceptional success. Thirty-one investigators have graduated since we established the program and they have submitted 35 protocols. At this point, 11 protocols have been activated across the United States, three are near activation and another 12 in various stages of development.

A new century of cancer research

- In 2001, the Southwest Oncology Group launched the Selenium and Vitamin E Cancer Prevention Trial, the largest-ever prostate cancer prevention trial. When accrual closed last summer, we exceeded our goal of 32,400 men by 10 percent to enroll 35,534 participants in 34 months. This included 15 percent participation by African Americans, a significant participation by the minority group most affected by the disease.

Even though we have made tremendous strides during the past quarter century, the best is yet to come! As I step down as Chairman and assume my new duties as Associate Chair for Prevention, I know the Southwest Oncology Group will continue to flourish under the chairmanship of Laurence H. Baker, D.O., who will accept the gavel at the Spring 2005 Group Meeting in April.

As a phlebotomist working for the great Dr. Jonas Salk during his randomized clinical trial to discover a cure for poliomyelitis back in 1956, I never dreamed that someday I would be conducting scientific research with the best of the best. Thank you all for your support over these many years. Together we will continue to search for new ways to eradicate cancer.

It's Quick & E-Z! Online GROUP MEETING Registration
<http://swog.org>



NCI adds more changes to Serious Adverse Event reporting

In the December edition of The Group Newsletter you read about the expansion of Adverse Event Expedited Reporting System (AdEERS) to include Serious Adverse Event (SAE) reporting on non-investigational drug protocols, and a new format for the SAE reporting guidelines in Southwest Oncology Group protocols. That newsletter had hardly gone out when the National Cancer Institute revised its guidelines for reporting SAEs. According to the NCI, the reason for the changed guidance (“CTEP, NCI Guidelines: Expedited Adverse Event Reporting Requirements,” dated December 15, 2004) is “so that CTEP can continue to meet [its] obligations to pharmaceutical collaborators as well as to the FDA.”

The new guidelines contain three major changes:

- *AdEERS reports must be submitted sooner.* Historically, NCI has required SAE reports to be submitted within 10 working days following an event. As discussed in the December newsletter, that was recently shortened to seven working days for Southwest Oncology Group studies, to assure adequate time for resolving any issues internally before forwarding on to NCI. The new NCI guidelines set up a two-tier reporting system:

- *For those events that require 24-hour AdEERS notification, the completed AdEERS report must be submitted within **five calendar** days.

- *Other reportable SAEs must be submitted via AdEERS within **10 calendar** days.

This means that, depending on the day of the week an event occurs and whether a holiday is involved, the amount of elapsed time for submitting a report can be as little as two and seven working days, respectively.

- *Some additional events that occur more than 30 days after last protocol treatment will now be reportable.* For patients

who received an investigational drug, Grade 3 events requiring hospitalization, and Grade 4 events, which occur more than 30 days after last protocol treatment must be reported via AdEERS if they are thought possibly related to the investigational agent. This expands the long-standing requirement to report all deaths thought possibly related, even if more than 30 days after last protocol treatment.

- *All commercial agent SAE reporting must be done via AdEERS.* The Group already initiated this change last fall, so it will have little new effect for our members. Thus far more than 20 Group commercial drug protocols have already been revised to require AdEERS reporting.

Until a given protocol is amended to include the new reporting time frames, adherence to them is voluntary for SAEs occurring to patients on that protocol. As always, the guidelines in Section 16 of the current protocol at the time of an SAE are the ones that must be followed in reporting that event.

Below this article is the new Guidelines Reporting Requirements Table for a patient who has received investigational drug on a Phase II or III study.

This table will be incorporated into the new Group format for SAE guidelines (covered in the December newsletter). All new Investigational New Drug (IND) studies will contain these new guidelines, and already-open IND drug studies will be amended to include these guidelines over the next five months.

The new guidelines also clarify and codify some other SAE reporting issues, including:

- Secondary malignancies, i.e., a cancer caused by treatment for a previous malignancy, are not reportable as SAEs in AdEERS. There is no change, however, in reporting occurrences

(Continued on next page)

Reporting Requirements for Adverse Events that occur within 30 days of the Last Dose of the Investigational Agent on Phase 2 and 3 trials									
	Grade 1	Grade 2	Grade 2	Grade 3		Grade 3		Grades 4 & 5 ²	Grades 4 & 5 ²
	Unexpected and Expected	Unexpected	Expected	Unexpected		Expected		Unexpected	Expected
				with Hospitalization	without Hospitalization	with Hospitalization	without Hospitalization		
Unrelated Unlikely	Not Required	Not Required	Not Required	10 Calendar Days	Not Required	10 Calendar Days	Not Required	10 Calendar Days	10 Calendar Days
Possible Probable Definite	Not Required	10 Calendar Days	Not Required	10 Calendar Days	10 Calendar Days	10 Calendar Days	Not Required	24-Hour; 5 Calendar Days	10 Calendar Days

¹ Adverse events with attribution of possible, probable, or definite that occur greater than 30 days after the last dose of treatment with an agent under a CTEP IND require reporting as follows:
 AdEERS 24-hour notification followed by complete report within 5 calendar days for:
 * Grade 4 and Grade 5 unexpected events
 AdEERS 10 calendar day report:
 * Grade 3 unexpected events with hospitalization or prolongation of hospitalization
 * Grade 5 unexpected event

² Although an adeers 24-hour notification is not required for death clearly related to progressive disease, a full report is required as outlined in the table.

December 15, 2004



QA Corner

Insights into Quality Assurance audits and regulatory review

With the new year comes a new cycle of audits for some institutions. You can help prevent audit deficiencies at your site by following the guidance below regarding informed consent and institutional review board (IRB) approval guidelines.

Informed consent

- All risks included in the model consent form, both life threatening and non-life threatening to the patient, must be listed in the site's local patient informed consent form. Each patient must be fully informed of all possible risks. Omission of any of these risks constitutes a major deficiency.

- All required elements must be in the site's local patient informed consent form, as per 21 CFR 50.25. Omission of any of these elements is a major deficiency.

- 21 CFR 50.25 also requires a statement that describes the extent to which confidentiality of patient records will be maintained. Omitting the Food and Drug Administration, National Cancer Institute, the study sponsor, the Southwest Oncology Group or Cancer Trials Support Unit, if applicable, is considered a major deficiency.

IRB approval guidelines

- All protocols must be approved by the IRB before patients can be registered.



Failing to obtain initial full board approval and to provide documentation of this approval is a major violation.

- An IRB must conduct a continuing review of research at least once per year. The deadline for this renewal is one year from the date of the previous review. Completing the review within 30 days after the deadline is considered a lesser deficiency, but completing a review 30 or more days after the deadline is considered a major deficiency. Registering patients during a lapse in approval is a major violation.

- All Serious Adverse Events must be

reported to the Southwest Oncology Group and the IRB. Failing to do so is a major deficiency.

- All protocol modifications that require full board review and all safety reports must be reviewed by the IRB within 90 days of the date of issue by the Southwest Oncology Group. Delaying the review more than 90 days is considered a major deficiency.

- It is a lesser deficiency if an administrative or editorial revision, which allows for expedited review, is not approved within 90 days.

If your site has determined that an oversight has occurred or if you simply are unsure about how the regulatory guidelines pertain to a particular situation, please call the Southwest Oncology Group Quality Assurance Department for guidance. We are here to help.

Do you have suggestions for future QA topics? If so, please contact Elaine Armstrong, Quality Assurance Manager, at qa@swog.org or 210-677-8808.

CCRC presents poster at breast symposium

The Cancer Control Research Committee and other Group investigators are very involved in breast cancer prevention and control research. During the Charles A. Coltman, Jr., San Antonio Breast Cancer Symposium held in San Antonio, Texas, in early December, the early results of **S9832** were presented in a poster entitled "Enhancing well-being during breast cancer recurrence: Preliminary findings from a Phase III study" (Gotay CC, Moinpour CM, Jiang CS, Ankerst D, Coleman D, Martino S, Taylor B, Bearden J, Daktil J, Gross H, and Albain KS).

NCI adds more changes to SAE reporting

(Continued from previous page.)

of AML or MDS; these must be reported as before.

- Persistent AEs must be reported only once unless the grade becomes more severe.

- Likewise, recurring AEs must be reported only once unless the grade increases or hospitalization is subsequently required.

- The long-standing Group policy requiring an SAE report on all deaths within 30 days of last treatment is now NCI policy also.

NCI Nurse Consultant Ann Setser will present more information on NCI's new SAE policy at the CRA Plenary Session of the Spring Group meeting. For more details now, a link to the new NCI guidelines policy is on the Serious Adverse Events page of swog.org.



A Letter from the Cancer Control Research Committee

Each SELECT Workshop during the Southwest Oncology Group meeting includes an update on matters of scientific interest to SELECT, the Selenium and Vitamin E Cancer Prevention Trial. At the Fall 2004 Group meeting, Dr. Scott M. Lippman, M.D., Chair-

man of the Cancer Control Research Committee, presented a scientific update about a new study involving red wine and prostate cancer. Following is an article based on the study results and Dr. Lippman's presentation.

A glass of wine with your PSA?

Researchers find red wine can reduce risk of prostate cancer

By Rosanne D. Fohn
Communications Coordinator

Wouldn't it be nice if something as simple as a glass of wine could help prevent prostate cancer? That's what a study from the International Journal of Cancer suggests.

"We found that men who consumed four or more glasses of red wine per week reduced their risk of prostate cancer by 50 percent," said Janet L. Stanford, Ph.D. Stanford is senior author of "Alcohol consumption and risk of prostate cancer in middle-aged men." The study appeared in the September 2004 edition of the journal.

Red wine seemed to be most effective in preventing aggressive types of cancer, Stanford said. Researchers found about 60 percent fewer cases of the aggressive types of cancer in men who drank four or more 4-ounce glasses of wine a week. Stanford's comments come from a press release issued by the Fred Hutchinson Cancer Research Center where the study was conducted.

Dr. Scott Lippman, Study Coordinator for the Selenium and Vitamin E Cancer Prevention Trial (SELECT), discussed the red wine study at the Fall 2004 Southwest Oncology Group Meeting. "This is one of only a few studies that show a strong connection between drinking liquor and the prevention of prostate cancer," he said. "This was a small study. While the results are preliminary they do show some promise, especially if other studies confirm the results."

The study compared red wine, white wine, beer and hard liquor, but only red wine seemed to prevent cancer. Researchers think the beneficial ingredient in red wine is *resveratrol*. There are high levels of resveratrol in the skins of red grapes. Smaller amounts also are found in white grapes, peanuts and raspberries.

The study showed that the chance of prostate cancer went



down 6 percent with each glass of red wine the men drank during a given week. However, the results were not as positive when the men drank more than a moderate amount of red wine. Stanford said that it is hard to encourage people to drink more than a small amount of alcohol because of problems that can come from heavy drinking. These problems can include a higher overall risk of cancer, the chance of an injury and social problems.

"But for men who already are consuming alcohol, I think the results of this study suggest that modest consumption of red wine, about four to eight 4-ounce drinks per week, is the level at which you might receive benefit. Clearly other studies show that more than that may have adverse effects on your health."

What is resveratrol?

According to the National Cancer Institute (NCI), resveratrol is a type of antioxidant compound found in the skin and seeds of grapes. This compound helps the grapevine defend itself against disease, infection, stress and injury.

Red wine contains higher levels of resveratrol than white wine. When white wine is made, the grape skins are removed after the grapes are crushed. This is not the case when red wine is made. When the red wine ferments, the antioxidant compounds from both the skin and seeds become concentrated in the wine.

Scientists are still in the early stages of testing the effects of red wine on cancer in humans. The types of cancer being studied include leukemia, skin, breast and prostate cancer.

The NCI cautions that drinking large amounts of alcoholic beverages may increase the overall risk of some types of cancer.



Southwest Oncology Group Spring 2005 Group Meeting

April 6-10
Grand Hyatt Denver
Denver, Colorado

SELECT Workshop kicks off Group Meeting

April 5 - 7, 2005

- Registration for the Southwest Oncology Group Meeting and SELECT Workshop and Poster Session begins **February 1**. Please register via the Southwest Oncology Group Web Site, <http://swog.org>, and click on the "Group Meeting" link. Faxed registrations and/or on-site registrations for the SELECT Workshop and Poster Session **will not** be accepted. Only 400 registrations will be accepted. **PLEASE NOTE:** You must register separately for the SELECT Workshop.

- We recommend that one staff member from each SELECT Study Center and Site attend the SELECT Workshop. Each SELECT Workshop offers new information and the opportunity for discussion of current issues.

- The Southwest Oncology Group Operations Office will pay \$850 for one clinical research associate from each approved study center and site to attend this meeting. This financial support can be used for coach airfare, hotel room expense, meals and/or ground transportation to attend the meeting. Registration and hotel information is available on the the Southwest Oncology Group Weg page, <http://swog.org>. A travel reimbursement form is located on the SELECT Workbench under Administration/Finance at the bottom of the page. For questions concerning designated attendees, funding or reimbursement, call the Operations Office at 210-677-8808.

- If you register by **noon (CDT) March 14**, you will receive a meeting packet with a name badge that you should wear to all Group Meeting sessions, including the SELECT Workshop and Poster Session. (If you register after noon (CDT) on March 14, your meeting packet and name badge will be available at the Southwest Oncology Group Meeting Registration Desk.)

See page 9 for the SELECT meeting agenda.

Myeloma Committee will not convene

Due to a conflict with the International Workshop on Myeloma in Sydney, Australia, the Myeloma Committee will not meet at the Spring 2005 Group Meeting in Denver.

IATA certification available online

While training for the International Air Transport Association certification will not be offered at this Group meeting, you can earn your certification online. This training is for people who ship study specimens.

Follow these three steps to earn certification:

1. Contact Barry Johnston (see below) to order a manual.

2. Order the IATA training video from the Clinical Research Associates video library (See page 26.)

3. Take the online test. (Cost is \$35.) Once you have successfully completed the test, Johnston will send you the certificate of training.

Note: There are only two sets of training videos, but if they are checked out you can be placed on a waiting list.

For more information, contact Anita Crosena, CCRP, acrosena@prodigy.net, 586-493-3426; Barry Johnston, HighQ LLC, highq@adelphia.net, 412-997-0555; or Jacqueline Hilger, hilger@breastlink.com, 562-933-7861.

It's Quick & E-Z! **Online** GROUP MEETING Registration
<http://swog.org>



Spring 2005 Southwest Oncology Group Meeting

You Are Cordially Invited
to attend a

Celebration Toast & Roast

honoring

**Charles A. Coltman, Jr., M.D.
Chairman
Southwest Oncology Group
March 1981 - April 2005**

*Saturday evening, April 9, 2005
Grand Hyatt Denver
Denver, Colorado*

6:00 - 6:30
Pre-Dinner Champagne
Imperial Foyer

6:30 - 8:30
Seated Dinner
Roast & Toast
Imperial Ballroom

featuring

Guest Presenters
Video Presentation

All Registered Group Meeting Attendees are invited to be a part of this evening recognizing Dr. Coltman's 24 years of service as Chairman of the Southwest Oncology Group

Please RSVP with your Group Meeting Registration via the Internet

It's Quick & E-Z! **Online** GROUP MEETING Registration
<http://swog.org>



Workshop & Poster Session

April 5 - 7, 2005

Preliminary Agenda

Tuesday, April 5

New Staff Check-in: 3:00 p.m. – 4:00 p.m.

New Staff Session: 4:00 p.m. – 6:30 p.m.

This session will give you the information you need to get started on SELECT. We strongly encourage *new* SELECT Staff to attend this session as well as the workbench demonstration.

SELECT Early Check-In and Workbench Demonstrations: 4:00 p.m. – 7:30 p.m.

All staff from SELECT Centers/Sites can check in at this time.

Wednesday, April 6

General Staff Check-In: 7:00 a.m. – 7:50 a.m.

Continental breakfast will be provided.

SELECT Workshop General Session: 8:00 a.m. – Noon

The General Session focus is “Retention and Adherence, Participant Follow-up, and Endpoint Ascertainment.” Updates from the SELECT Statistical Center and the National Cancer Institute will be presented.

Breakout Sessions: 1:30 p.m. – 6:00 p.m.

The Breakout Sessions are designed to be informal and smaller sessions than the morning presentations. You will be given the opportunity to choose between a variety of topics. Panel members will be available to answer questions.

Snacks and beverages will be provided.

Thursday, April 7

SELECT Poster Session: 8:00 a.m. – 11:00 a.m.

No food or beverages provided.

This is a great opportunity to ask questions of Southwest Oncology Group staff, as well as SELECT staff and committee members, who will accompany each poster. We encourage all SELECT study site staff to attend the poster session, as it provides one-on-one time with the SELECT Staff. Posters presented at this session contain updated or new information.

Please bring any new retention and adherence materials or items you have developed at your study site to share ideas with other SELECT study site staff. The materials can be handouts to participants, local newsletters, coupons, or event announcements and invitations. The items may be hats, measuring tapes, pens, etc. Remember to put a contact name, phone number and your study site ID number on the materials or items or attach a business card. You can drop them off anytime at the SELECT registration desk or at the beginning of the poster session. These materials and items will be put on display at the poster session. They will not be returned to you but will continue to be displayed at future workshops.



Clinical Trials Training Course For Southwest Oncology Group Clinical Research Associates

April 6 - April 7, 2005

Who should attend?

- ❖ **New** Southwest Oncology Group Clinical Research Associates (CRAs)
- ❖ Southwest Oncology Group CRAs who have never attended the course
- ❖ Senior Southwest Oncology Group CRAs who want to brush up their skills

CTTC important goals:

- ❖ To introduce the fundamentals of the Southwest Oncology Group and the National Cancer Institute's (NCI) policies and procedures.
- ❖ To provide the foundation to efficiently perform your responsibilities as a CRA. (The course includes a practicum session with demonstrations and hands-on practice.)

Cost:

- ❖ Thanks to The Hope Foundation, the Southwest Oncology Group members are **not** charged a registration fee for this course.
- ❖ **Non-group members must contact the Southwest Oncology Group Data Operations Center (206-652-2267) for space availability. Fee for non-Group members is \$500.**

IMPORTANT:

- ❖ **Register early on <http://swog.org>.** Space is strictly limited to **115** participants.
- ❖ **Note:** *Registering for the Southwest Oncology Group Meeting does not automatically enroll you in the CTTC.*
- ❖ **REGISTRATION DEADLINE: Noon (CDT), Monday, March 14, 2005.**
- ❖ Participants must attend the entire course to receive a certificate of completion.
- ❖ Registration to concurrent workshops is not permitted.

For more information, call the Southwest Oncology Group Data Operations Center at 206-652-2267.

Register online at <http://swog.org>

See page 11 for the course agenda.

FUTURE GROUP MEETINGS

2005

— September 28 - October 2, 2005 —

New Orleans, Louisiana

2006

— April 19 - 23, 2006 —

Salt Lake City, Utah

— October 4 - 8, 2006 —

Seattle, Washington

2007

— May 2 - 6, 2007 —

Chicago, Illinois

— October 3 - 7, 2007 —

Huntington Beach, California

It's Quick & E-Z! [Online](http://swog.org) GROUP MEETING Registration
<http://swog.org>



Clinical Trials Training Course For Clinical Research Associates

Wednesday, April 6, 2005

Morning Session

7:00-7:55	Registration	
7:55-8:05	Introduction	Diana Lowry, B.A.
8:05-8:30	The Cooperative Group Concept	Marjorie A. Godfrey
8:30-9:00	Clinical Trials and Protocol Development	Dana Sparks, M.A.T.
9:00-9:25	Data Flow with Special Emphasis on Electronic Data Submission	
9:25-9:40	The Expectation and Institutional Performance Review Reports	
9:40-9:55	BREAK	
9:55-10:25	Long Term Follow-up	Debbie Christie, M.B.A.
10:25-10:50	Adverse Event/Toxicity Assessment	
10:50-11:10	Pathology and Specimen Submission	
11:10-11:45	Q&A Session	Panel of Speakers
11:45-1:15	LUNCH (on your own)	

Afternoon Session

1:15-5:00	Practicum Session	Data Operations Center Staff and Group CRAs
	Patient Registration Process	Phyllis Stein, B.S., C.C.R.P.
	SWOG Web Registrations	

Thursday, April 7, 2005

Morning Session

7:45-8:20	Scientific Challenges and the Role of the CRA	
8:20-9:00	Ethics in the Conduct of Clinical Research	Charles A. Coltman, Jr., M.D.
9:00-9:25	Audits/Quality Assurance	Elaine Armstrong, M.S.
9:25-9:55	Serious Adverse Event Reporting	Nickey McCasland, R.N., M.H.A.
9:55-10:10	BREAK	
10:10-10:55	Drug Ordering and Record Maintenance	
10:55-11:25	The IRB and Informed Consent	
11:25-11:50	Quality of Life Assessments	Carol Moinpour, Ph.D.
11:50-12:00	Closing Remarks	Rodney Sutter

Other Clinical Research Associates Committee activities

Thursday, April 7

1:00 p.m.-4:00 p.m.	Clinical Research Associates Plenary Session
4:15 p.m.-6:00 p.m.	Clinical Research Associates Open Forum
6:00 p.m.-7:00 p.m.	Nurse Oncologist and Clinical Research Associates Hospitality Reception

It's Quick & E-Z! Online GROUP MEETING Registration
<http://swog.org>



Study Coordinators Workshop prepares physicians to lead protocols

Are you a Southwest Oncology Group physician interested in conducting a Southwest Oncology Group-coordinated research trial? If so, the Study Coordinators Workshop is for you!

Physician investigators who have never served as a Southwest Oncology Group Study Coordinator and who wish to coordinate a Group protocol must attend the Study Coordinators Workshop. The course provides you with the foundation necessary to perform

your responsibilities as a Southwest Oncology Group study coordinator. There is no registration fee.

Participants must attend the full course to receive approval to coordinate a Southwest Oncology Group research trial. For more information, contact Camille White or Scott Kurruk at 206-652-2267, or Dana Sparks at 210-677-8808.

STUDY COORDINATORS WORKSHOP

For Physician Investigators Planning to Conduct a Southwest Oncology Group Trial

Thursday, April 7, 2005

Noon – 4:30 p.m.

Tentative Agenda

Noon-12:30 p.m.	Check In
12:30p.m.-12:45 p.m.	Introduction / Role of a Study Coordinator John J. Crowley, Ph.D. Director, Southwest Oncology Group Statistical Center
12:45 p.m.-1:20 p.m.	Ethics in the Conduct of Clinical Research Charles A. Coltman, Jr., M.D. Chairman, Southwest Oncology Group
1:20 p.m.-1:55 p.m.	Protocol Development Dana B. Sparks, M.A.T Protocol Product Line Manager, Southwest Oncology Group Operations Office
1:55 p.m.-2:05 p.m.	Study Coordinator Responsibilities Diana K. Lowry, B.A. Data Operations Technical Manager, SWOG Data Operations Center
2:05 p.m.-2:15 p.m.	— Break —
2:15 p.m.-2:35 p.m.	Reality Session: Lessons from a Current Study Coordinator Julie R. Gralow, M.D. Seattle Cancer Care Alliance
2:35 p.m.-3:00 p.m.	Statistical Considerations Kenneth J. Kopecky, Ph.D. Biostatistics, Southwest Oncology Group Statistical Center
3:00 p.m. -4:30 p.m.	Practicum Session Statistical Center faculty and staff Laurence H. Baker, D.O. , Moderator Chair-elect, Southwest Oncology Group



Hilger new chair of CRA Executive Board

By Debra Christie, MBA, CCRP

Jacqueline Hilger is the new chair of the Clinical Research Associates Committee, replacing Angela Allred, who served as chair for three and one-half years.

Hilger joins the committee with more than 24 years of oncology experience in academic, community and pharmaceutical research. She holds a Masters of Science degree in Health Sciences, a Bachelor of Science in Business Management and is certified as a Certified Clinical Research Professional by the Society of Clinical Research Associates. Hilger has worked with the Southwest Oncology Group in various roles since 1991.

CRA Executive Board Committee Members

Jacqueline Hilger, B.S., M.S., C.C.R.P.	Chair
Debra Christie, M.B.A., C.C.R.P.	Vice Chair
Phyllis M. Stein Beal, B.S., C.C.R.P.	Subcommittee Chair-Head CRA
Beth Davis, C.C.R.P.	Subcommittee Chair-Communications
Lynn Campbell	Subcommittee Chair-Open Forum
Anita Crosena, C.C.R.P.	Subcommittee Chair-Education
Meredith Dawson, R.N., M.A.	At-Large Member 2003-2005
Stephanie Elsbury, B.S.H.	At-Large member 2004-2006
Jennifer Katz, C.C.R.P.	At-Large member 2004-2006
Gail Lerkins	At-Large member 2005-2007
Noboro Oishi, M.D.	Physician Advisor
Virginia McMahon, C.C.R.P.	Subcommittee Chair-Program
Marj Godfrey	Operations Office
Evonne Lackey, C.C.R.P.	Statistical Center
Rodney Sutter	Data Operations Center

Older Adult Sensitivity Training Nurse Oncologist Dinner Meeting

Dinner sponsored through the generous support of Pfizer Inc.

Thursday, April 7, 2005

7 p.m. – 9 p.m.

This program will help identify the unique needs of older adults and enhance communication skills that are necessary for improved understanding between clinicians and their older adult patients, thereby improving quality of care.

Objectives:

- Describe the unique medical challenges that impact the functional status of older adults.
- Identify strategies to improve the clinical outcomes of older adult patients
- Describe communication techniques that may be used to effectively partner with older adult patients in their healthcare.
- Explain the importance of quality improvement/performance measures for older adult patients.

Target Audience:

- Physicians
- Research Nurses
- Clinical Research Professionals
- Pharmacists

Faculty:

- **VICKI L. SCHMALL, Ph.D.**
Gerontology and Training Specialist and President of Aging Concerns West Linn, Oregon
Ph.D. from Oregon State University in Family Studies/Gerontology

Important:

- Registration is required. There is space for 50 registrants. Others will be placed on a waiting list.
- Registration to the general Southwest Oncology Group meeting does not automatically enroll you in this session.
- Certificates for continuing education (CE) credit will be provided by *Postgraduate Institute for Medicine* for physicians, nurses and pharmacists. You may use your CE certificate as proof of attendance for SoCRA credit.
- Questions? Please contact Rose Ermete at ermeter@aol.com.

It's Quick & E-Z! **Online GROUP MEETING Registration**
<http://swog.org>



Nurse Oncologist Workshop

New Frontiers in the Treatment of Cancer

Friday, April 8

Synopsis

This program will address innovative care for the oncology patient. This will include a discussion on molecular changes and various molecular targets in the treatment of solid tumors. How drugs are discovered in nature will be explored. New patient educational material from the National Cancer Institute will be presented. The program will close with an update on new drugs.

Application has been made for continuing education credit with the Oncology Nursing Society, which is an approver of continuing education by the American Nurses Credentialing Center's Commission on Accreditation. Attendance certificates will be given for credit by the Society of Clinical Research Associates.

Schedule

Morning Session

6:45 a.m.-8:00 a.m.	Registration
7:00 a.m.-8:00 a.m.	Continental Breakfast
7:30 a.m.-7:45 a.m.	CTSU Presentation
7:45 a.m.-8:00 a.m.	New Nurse Oncologist Orientation
8:00 a.m.-8:15 a.m.	Business Meeting
8:15 a.m.-9:15 a.m.	The Biology of Cancer <i>Judy Degroot, R.N., M.S.</i>
9:15 a.m.- 9:30 a.m.	Break
9:30 a.m.-10:30 a.m.	Drug Development, Diving for Answers <i>David H. Sherman, Ph.D.</i>
10:30 a.m.-11:30 a.m.	NCI Patient Education Material <i>Rose Mary Padberg, R.N., M.S.</i>
11:30 a.m.-Noon	New Drugs Update <i>Matt Boron, R.Ph.</i>
Noon-12:10 p.m.	Questions and Evaluations*

* Certificates for Continuing Education Credits will be distributed to attendees who complete and turn in their evaluation sheets. Application has been made for 9.2 hours to the Oncology Nursing Society (ONS) Approver Unit: ONS is accredited as an approver of continuing education by the American Nurses Credentialing Center's Commission on Accreditation.

Afternoon session

1:00 p.m.-2:00 p.m.	Session A	Nurse QOL/Disease & Discipline Subcommittee
1:00 p.m.-2:00 p.m.	Session B	Research 101
2:00 p.m.-3:00 p.m.	Session C	Nursing Research Subcommittee
2:00 p.m.-3:00 p.m.	Session D	Education and Program Subcommittees: Auditor Training
2:30 p.m.-3:30 p.m.	Session E	Breast Self-Exam Workshop
3:00 p.m.-4:00 p.m.	Session F	CCOP Subcommittee

Speakers

Judy Degroot, R.N., M.S.

Degroot is an oncology clinical coordinator for Genetech Inc. Sponsored by Genetech.

Rose Mary Padberg, R.N., M.S.

Padberg works at the National Cancer Institute of the National Institutes of Health. She is involved in the development and distribution of patient education material.

David H. Sherman, Ph.D.

Dr. Sherman is Professor of Medicinal Chemistry at the University of Michigan and holds appointments in the Department of Chemistry and the University of Michigan Medical School Department of Microbiology and Immunology. He focuses on isolation and analysis of new natural products from diverse source materials.

Matt Boron, R.Ph.

Boron manages the Treatment Referral Center at the National Cancer Institute, a resource for medical professionals looking for treatment options for their patients. He received his R.Ph. from Duquesne University.

Need a mentor ?

Turn to page 25 to sign up for
The Clinical Trials Nurse Mentorship Program!

It's Quick & E-Z! Online GROUP MEETING Registration
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Breast Self-Examination Workshop set for Friday

According to the American Cancer Society (ACS), about 1,372,910 new cancer cases are expected to be diagnosed in 2005 (excluding carcinoma in situ of any site except urinary bladder, as well as basal cell and squamous cell skin cancers). Among this number will be an estimated 211,240 new cases of invasive breast cancer in U.S. women. Breast cancer is the most frequently diagnosed non-skin cancer in women. Additionally, about 1,690 new cases of breast cancer are will be diagnosed in men.

Isn't it about time you learned BSE?

Breast self-examination (BSE) is an easy ten-minute procedure that can be conducted in the privacy of the home. BSE along with mammography and physical examination, can give women the best opportunity of detecting breast abnormalities at the earliest possible time. The earlier breast cancer is diagnosed and treated, the better the prognosis. Many abnormalities are discovered by women and/or their partner, making it all the more important for women to learn how to appropriately examine their breasts.

A one-hour workshop that is open to anyone interested will be conducted by Patra K. Grevstad, RN, MN, during the Spring 2005 Group Meeting in Denver on **Friday, April 8, 2005, from 2:30 to 3:30 p.m.**

The workshop objectives are:

- To understand the importance of conducting regular breast self-examination.
- To demonstrate a knowledge of the steps and methods for effective breast self-examination.
- To distinguish healthy breast tissue from abnormal breast tissue.

Objectives will be met by viewing a video, utilizing discussion and a hands-on examination of breast models having examples of abnormal tissue.

If you just want to refresh your knowledge or learn the technique for the first time, this workshop is for YOU! Don't miss this opportunity...we know you'll be glad you attended!

CRA Continuing Education Workshop to focus on sarcoma

Sarcoma will be the topic for the Clinical Research Associates Workshop at the Spring 2005 Group Meeting. The workshop will be held from 8 a.m. to noon on Thursday, April 7. Check-in will be held from 7:30 a.m. to 8 a.m.

In order to attend and receive continuing education units, you must register online before the March 31 deadline at <http://swog.org>. This registration is in addition to the Group Meeting registration.

There is no fee to attend the workshop, courtesy of The Hope Foundation.

Holiday Schedule

All CRAB Offices

Presidents' Day, February 21, 2005
 Memorial Day, May 30, 2005
 Independence Day, July 4, 2005

Operations Office

Battle of Flowers, April 22, 2005
 Memorial Day, May 30, 2005
 Independence Day, July 4, 2005

Statistical Center Staff

at Fred Hutchinson Cancer Research Center

Presidents' Day, February 21, 2005
 Memorial Day, May 30, 2005
 Independence Day, July 4, 2005

Opportunities for women, minorities, persons with disabilities

The Southwest Oncology Group is committed to an appropriate representation of all members at all Group-sponsored meetings. Therefore, all factions of the Group, including both genders and all races or ethnicities, as well as persons with disabilities, are encouraged to attend and participate in these meetings.

The Southwest Oncology Group offers committee meetings of particular interest to women and minorities, including the Committee on Special Populations. There are also frequent symposia and Plenary Session presentations featuring gender and minority research issues.

Group members with disabilities may wish to contact the Operations Office when they register for the meeting to ensure that arrangements are made for appropriate accommodations and accessibility to all Group functions. To assist in this effort, we have revised our meeting registration forms to include an area in which persons with disabilities may identify any special needs required for their meeting attendance.



COME ON... LET'S GET MOVING!



“CRUSH THE CRAB”

5K Run

- When:** Saturday, April 9.
Where: Meet in the hotel lobby before 6 a.m.
Departure time: We will depart the lobby at 6 a.m. sharp for the starting point of the race.
Entry Fee: Free!

The Crush the Crab 5K Run will be held on Saturday morning, April 9. Participants will be transported to the beautiful 314-acre City Park, located five minutes east of downtown. The park is home to the Denver Zoo, a variety of fountains, a newly renovated Martin Luther King Jr. statue, the Denver Museum of Nature and Science, as well as an 18-hole golf course. After the race and a brief awards program, you will be escorted back to the hotel in ample time to freshen up and attend the Group Meeting Plenary Session.

The “Crush the Crab” 5K Run features first-, second- and third-place trophies awarded to the first three men and first three women to cross the finish line in the following age categories: **Age 40 and younger, 41 to 54, and 55 and older.** In addition, trophies will be awarded for the **Overall Best Time - Female, and the Overall Best Time - Male.**

PLEASE NOTE: Trophies will be awarded only to registered members of the Southwest Oncology Group, registered Group Meeting attendees or others affiliated with the Group and their family members.

— Model Consent and Release - Crush the Crab 5K Run —

In consideration of my participation in the Crush the Crab 5K Run, on behalf of myself, my heirs, legatees, personal representatives and all those claiming by or through me, I consent to, and do hereby discharge and release and forever hold harmless the Southwest Oncology Group; the Grand Hyatt Denver; Destination Services of Colorado, Inc.; and the City of Denver, Colorado, and their affiliates, agents, servants, employees, successors, and heirs and any facility at which events are held, from any and all claims, actions, losses, damages, or expenses for personal and bodily injury (including death) and property loss or damage of whatever the nature or cause, incurred by me or arising out of or in any way in conjunction with my participation in the aforementioned competition.

I agree that any photographs taken of me are the property of the Southwest Oncology Group and I waive any right of inspection or review. I am of legal age and capacity and have read and understand the content of this consent and release.

Register online now!

Come by the Group Meeting Registration/Information Desk before Saturday morning to pick up your run number and sign the consent form. You will receive your free T-shirt at the event.

It's Quick & E-Z! **Online** GROUP MEETING Registration
<http://swog.org>



SOUTHWEST ONCOLOGY GROUP
Spring 2005 GROUP MEETING
Hotel Room Reservation Information

HOTEL ROOM RESERVATION
INFORMATION

Make your HOTEL ROOM RESERVATIONS for your stay
at the Grand Hyatt Denver
Denver, Colorado
Wednesday, April 6 - Sunday, April 10

ONLINE: <http://swog.org>

Be sure to request the Southwest Oncology Group rate.

	SINGLE or DOUBLE
Southwest Oncology Group Rates:	\$169
Business Plan Rates:	\$189
Regency Club Rates:	\$199

Group Rate cutoff date is **March 7, 2005**

IMPORTANT! Business Plan and Regency Club accommodations are based on availability.
Rates shown **DO NOT** include tax -- currently the rate is 13.85%.

The above rates are guaranteed until **March 7, 2005**, or until the reserved block is SOLD OUT, *whichever comes first*. Reservations received after the deadline will be accommodated on rate and space availability only.

RESERVE EARLY!

Note: There is NO printed reservation form in this edition of The Group Newsletter. You may make your hotel room reservations online as noted above and at the bottom of this page.

It's Quick & E-Z! **Online** GROUP MEETING Registration
<http://swog.org>



Alberts appointed director of Arizona Cancer Center

David S. Alberts, M.D., was appointed director of the Arizona Cancer Center effective January 1. Alberts is an active member of the Southwest Oncology Group Cancer Control Research Committee, Committee on Special Populations and Gastrointestinal Cancer Committee. He served the Group as Chair of the Gynecologic Cancer Committee for 20 years.

Alberts, who was deputy director of the Arizona Cancer Center before his appointment, has been at the University of Arizona since 1975 and served as head of the Division of Cancer Prevention and Control since 1989. In addition, he serves as regents professor of medicine, pharmacology, nutritional science and public health at the University of Arizona College of Medicine.

His four major areas of research include retinoids in cancer treatment and prevention, biomarkers of skin carcinogenesis, prevention of colon cancer and nuclear karyometric analysis as a biomarker of early neoplasia.

The Southwest Oncology Group thanks the following sponsors for their support of the Spring 2005 Group Meeting

PATRON

Abbott Pharmaceuticals
Eli Lilly & Company
Genetech BioOncology
Novartis Oncology
Pfizer Inc.

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CENTURION

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Roche Laboratories

SUPPORTER

AstraZeneca

Berlex Oncology

GlaxoSmithKline

Lippincott Williams & Wilkins

MedImmune Oncology

Merck & Co.

Pharmion Corporation

SuperGen

Dr. Anthony Shields to receive Distinguished Scientist Award

Anthony Shields, M.D., Ph.D., a member of several Southwest Oncology Group committees, will receive the prestigious Peter Valk Distinguished Clinical Scientist Award from the Academy of Molecular Imaging at its annual conference in March.

Dr. Shields is Professor of Medicine and Oncology at Wayne State University and the associate director of clinical research at Karmonos Cancer Institute. He is also chief of the Gastrointestinal Oncology section of the Division of Hematology/Oncology and the program leader of Developmental Therapeutics.

In the Southwest Oncology Group, Dr. Shields is a member of the Gastrointestinal, Lung Pathobiology, Radiation Therapy and Early Therapeutics committees. He is being honored for his research on the development of new imaging technologies in therapy, particularly using position emission tomography. He also is involved in developing new drug therapies for the treatment of solid tumors.

Important notice regarding Group publications

Please remember to share the current status for all Southwest Oncology Group publications with the Publications Specialist at the Operations Office, whether they are abstracts or manuscripts, submitted or published. One of the primary responsibilities of the Southwest Oncology Group is to report the results of completed trials. All studies, whether the results were positive or negative, must be published to assure continued funding of Group activities by the National Cancer Institute. Therefore, keeping this information up to date is of paramount importance.

All phases of the publication process with a journal or society meeting should be reported to the Operations Office. This includes submissions, resubmissions, acceptances, acceptances pending revisions, as well as publications not accepted. This will ensure that complete and accurate publication information is reported on all Group studies for grant and progress report submissions, in all newsletters published by the Group, and on the Group Web page. It will also ensure that investigators and their respective institutions are correctly credited for the various stages of publication on their Investigator Contribution Sheets.

Copies of submissions or correspondence received from the journal can be faxed to the Operations Office at 210-677-0006 or e-mailed to pubs@swog.org.



Manuscripts and Abstracts Published

The publications listed below are those that have been received in published form by the Operations Office Publications Specialist from October 27, 2004 through January 6, 2005.

MANUSCRIPTS PUBLISHED

- 9318/9405** Recombinant human erythropoietin as an adjunct to radiation therapy and cisplatin for stage IIB-IVA carcinoma of the cervix: a Southwest Oncology Group study. RS Lavey, PY Liu, BE Greer, WR Robinson, PC Chang, RB Wynn, ME Conrad, C Jiang, M Markman, DS Alberts. Gynecologic Oncology 95:145-151, 2004.
- S9916** Docetaxel and estramustine compared with mitoxantrone and prednisone for advanced refractory prostate cancer. DP Petrylak, CM Tangen, MHA Hussain, PN Lara Jr, JA Jones, ME Taplin, PA Burch, D Berry, C Moinpour, M Kohli, MC Benson, EJ Small, D Raghavan, ED Crawford. New England Journal of Medicine 351(15):1513-1520, 2004.

ABSTRACTS PUBLISHED

- *8736** Histologic subtypes do not confer unique outcomes in early-stage lymphoma: long term follow up of SWOG 8736. CM Spier, M LeBlanc, EM Chase, RI Fisher, TP Miller. Blood 104(11): #3263, 2004.
- *8819** Chromosomal imbalances in germinal center B-cell like and activated B-cell like diffuse large B-cell lymphoma influence gene expression signatures and improve gene expression-based survival prediction. A Zettl, S Bea, G Wright, I Salaverria, P Jehn, G Ott, WC Chan, E Jaffe, D Weisenburger, T Greiner, J Armitage, R Gascoyne, J Connors, T Grogan, T Miller, R Fisher, J Delabie, S Kvaloy, HK Mueller-Hermelink, V Moreno, E Montserrat, W Wilson, L Staudt, A Rosenwald, E Campo. Blood 104(11): #415, 2004.
- 8819** Gene expression profiling, frozen and paraffin section immunohistochemistry, and in situ hybridization for determination of monoclonality in diffuse large B-cell lymphoma. MW Andres, RA Roberts, DJ Mustacich, RD Gascoyne, DA Fuchs, MX Wang, RM Braziel, WC Chang, TM Grogan, LM Rimsza. Blood 104(11): #4553, 2004.
- *8819** HLA-DR protein status predicts survival in patients with diffuse large B cell lymphoma (DLBCL) treated with the MACOP-B chemotherapy regimen. LM Rimsza, P Farinha, DA Fuchs, H Masoudi, JM Connors, RD Gascoyne. Blood 104(11): #3273, 2004.
- *9321** Comparable survival in newly diagnosed multiple myeloma (MM) after VAD induction with high dose therapy using Melphalan 140 mg/m² + TBI 12 Gy (MEL + TBI) versus standard therapy with VBMCP and no benefit from interferon (IFN) maintenance: final clinical results of Intergroup trial S9321 in the context of IFM 90 and MRC VII trials. J Crowley, R Fonseca, P Greipp, J McCoy, B Barlogie. Blood 104(11): #539, 2004.
- *9321** Genetic polymorphisms associated with clinical outcome in the Intergroup trial S9321, comparing high dose therapy with standard dose therapy for myeloma, on behalf of ECOG, SWOG, CALGB, and the Bank on a Cure. R Santana-Davila, J Crowley, B Durie, B Barlogie, P Greipp, B Van Ness. Blood 104(11): #1495, 2004.
- * Presented**

(Continued page 21)



Southwest Oncology Group Protocols

A Recap of Recent Protocol Activity from December 1, 2004- January 15, 2005

The PROTOCOL UPDATE is meant to be a handy reference of protocol activity during the time stated. When noting Temporary Closures and Re-Activated Protocols, bear in mind that temporarily closed studies are often reopened after observation of some degree of anti-tumor activity in the initial cohort of patients. Other reasons for reopening studies could include revision of the protocol to enhance the margin of safety for patients, or resolution of administrative problems, such as with drug supply or drug distribution. If you have any questions about a temporary closure or a re-activation, you may wish to contact the Study Coordinator for more information.

ACTIVATIONS

S0312, A Phase II Study of IV Gemcitabine and Oral Capecitabine in Patients with Advanced Renal Cell Cancer. Study Coordinators: Drs. P.J. Van Veldhuizen, Jr., P.N. Lara, Jr., and P.H. Gumerlock. **Activation 12/01/04.**

S0344, A Phase II Surgical Trial of Intralesional Resection of Low-Grade Intracompartmental Chondrosarcoma of Bone. Primary Study Coordinator: Dr. L.R. Randall. **Activation 12/01/04.**

S0347, A Randomized Study of Weekly Vinorelbine (Navelbine®) Alone or in Combination With Trastuzumab (Herceptin®) (NSC-688097) for Patients With Her-2 Positive Metastatic Breast Cancer Whose Tumors Have Progressed

After Taxane + Trastuzumab Combination Therapy – Phase III. Study Coordinators: Drs. L. Puztai and F. Esteva. **Activation 12/15/04.**

S0413, Phase II Study of GW572016 (NSC #727989) as First Line Therapy in Patients with Advanced or Metastatic Gastric Cancer. Study Coordinators: Drs. Iqbal and H.J. Lenz. **Activation 12/15/04.**

S0329, Phase II Study of Biweekly Gemcitabine and Paclitaxel (Gemtax) Combination in Patients with Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck (SCCHN). Study Coordinators: Drs. O. Kucuk R. Wheeler and F. Worden. **Activation 1/01/05.**

CLOSURES

CTSU/E3201, Intergroup Randomized Phase III Study of Postoperative Irinotecan, 5-Fluorouracil and Leucovorin vs Oxaliplatin, 5-Fluorouracil and Leucovorin vs 5-Fluorouracil and Leucovorin for Patients with Stage II or III Rectal Cancer Receiving Either Preoperative Radiation and 5-Fluorouracil or Postoperative Radiation and 5-Fluorouracil. **Temporary Closure effective 11/26/04.**

S9630, A Randomized Comparison of Medroxyprogesterone Acetate (MA) and Observation For Prevention of Endometrial Pathology in Postmenopausal Breast Cancer Patients Treated with Tamoxifen. Study Coordinators: Drs. R. Potkul, K. Albain, C. Salomon and S. Wilczynski. **Permanent Closure effective 12/15/04.**

S0200, A Phase III Randomized Study of Pegylated Liposomal Doxorubicin Plus Carboplatin Versus Carboplatin in Platinum-Sensitive Patients with Recurrent Epithelial Ovarian or Peritoneal Carcinoma After Failure of Initial Platinum-Based Chemotherapy. Study Coordinators: Drs. D.S. Alberts, A.M.

Lopez and S. Wilczynski. **Permanent Closure effective 12/15/04.**

CTSU/E1899, A Phase III Randomized Trial for Evaluating Second Line Hormonal Therapy (Ketoconazole/Hydrocortisone) versus Docetaxel/Estramustine Combination Chemotherapy on Progression Free Survival in Asymptomatic Patients with a Rising PSA after Hormonal Therapy for Prostate Cancer. **Permanent Closure effective 12/28/04.**

E8897, Correlation of Histopathology, Immunohistochemistry and Quantitative Radiology With Outcome in Early Stage Nonseminomatous Germ Cell Tumor. Southwest Oncology Group Study Coordinator: Dr. C.R. Nichols. **Permanent Closure effective 12/28/04.**

S0211, A Phase II Trial of STI571 for the Treatment of Platinum and Taxane Refractory Stage III and IV Epithelial Ovarian

(Continued on page 21)



Manuscripts and Abstracts Published

(Continued from page 19)

- *9438** Impact of increased body weight on acute toxicity and outcome of autologous stem cell transplantation for non-Hodgkin's lymphoma: a Southwest Oncology Group analysis. P Stiff, J Unger, S Forman, M LeBlanc, T Miller, O Press, J Thompson, R Fisher. Blood 104(11): #352, 2004.
- *S9800** FC receptor polymorphisms do not influence progression free survival (PFS) of follicular NHL patients treated with CHOP followed by rituximab (SWOG 9800). DG Maloney, B Pender-Smith, JM Unger, RM Braziel, J Radich, OW Press, TP Miller, TM Grogan, M LeBlanc, RI Fisher. Blood 104(11): #589, 2004.
- *S0014** Effect of adding rituximab to three cycles of CHOP plus involved-field radiotherapy for limited-stage aggressive diffuse B-cell lymphoma (SWOG-0014). TP Miller, JM Unger, C Spier, B Stea, E Cantu, M LeBlanc, RI Fisher. Blood 104(11): #158, 2004.
- *S0108** Expression of VEGF, VEGF receptors, and other angiogenic markers in relapsed aggressive non-Hodgkin's Lymphoma: Correlative studies from the SWOG S0108 trial. A Stopeck, M Iannone, L Rimsza, T Miller, R Fisher, W Bellamy. Blood 104(11): #2288, 2004.
- *E4494** Rituximab-CHOP versus CHOP with or without maintenance rituximab in patients 60 years of age or older with diffuse large B-cell lymphoma (DLBCL): an update. TM Habermann, E Weller, VA Morrison, PA Cassileth, J Cohn, S Dakhil, RD Gascoyne, B Woda, R Fisher, BA Peterson, SJ Horning. Blood 104(11): #127, 2004.
- *N9741** N9741: Oxaliplatin (Oxal) + CPT-11 or 5-fluorouracil (5FU)/leucovorin (LV) in advanced colorectal cancer (CRC): final efficacy data from an intergroup study. RM Goldberg, RF Morton, DJ Sargent, CS Fuchs, RK Ramanathan, SK Williamson, BP Findley. American Society of Clinical Oncology Gastrointestinal Cancers Symposium #215, 2004.
- *Multiple Studies** Acute myeloid leukemia (AML) with t(6;9)(p23;q34) defines a very poor risk leukemia subgroup with distinguishing Clinicopathological features: a United States (US) cytogenetics Intergroup study of 62 AML and MDS cases. ML Slovak, CD Bloomfield, H Gundacker, G Dewald, FR Appelbaum, RA Larson, MS Tallman, C Willman, Y Ravindranath, TA Alonzo, A Carroll, B Hirsch, S Raimondi, NA Heerema. Blood 104(11):#567, 2004
- *Multiple Studies** New treatment options have changed the natural history of follicular lymphoma. RI Fisher, M LeBlanc, OW Press, DG Maloney, TP Miller. Blood 104(11): #583, 2004.
- * Presented**

Southwest Oncology Group Protocols

(Continued from page 20)

Cancer and Primary Peritoneal Cancer. Study Coordinators: Drs. D.S. Alberts, A. Jang and S. Wilczynski. **Temporary Closure effective 1/15/05.**

S0030. Protocol for Assessment of Capecitabine for Advanced Colorectal Cancer in Patients Aged 70 years and Older (and in a Cohort of Patients Younger than 60 Years), Phase II and

Parmacology. Southwest Oncology Group Study Coordinator: Dr. H.J. Lenz. **Permanent Closure effective 2/1/05.**

S0300. Randomized Placebo-Controlled Biomarker Modulation Trial using Celecoxib in Premenopausal Women at High Risk for Breast Cancer. Study Coordinators: Drs. P.H. Brown, G.T. Budd, J. Gralow, K.S. Albain, A.M. Gown and K. Powell. **Temporary Closure effective 1/15/05.**

It's Quick & E-Z! **Online** GROUP MEETING Registration
<http://swog.org>

**CTSU News****Cancer Trials Support Unit begins QA program**

As the number of patients being enrolled through the Cancer Trials Support Unit (CTSU) continues to increase, a more formalized process of surveillance was needed to assure data quality. The CTSU Quality Assurance (QA) Program has been implemented to provide metrics regarding the quality of data on case report form data submitted by clinical sites enrolling patients. Since the CTSU plays a central role receiving and tracking forms and queries, the development of a structured QA program was a logical step to address data quality. When developing this Quality Assurance program, the CTSU QA Committee reviewed Group practices and industry standards. One practice standard adopted by the QA Committee was to enforce a 60-day response time for pending queries.

Currently, queries regarding case report form data are

obtained from the cooperative groups, processed in the CTSU, and forwarded to the sites for response. The CTSU receives the responses back from the sites and forwards them to the Cooperative Group. The CTSU tracks query response time, discrepancy information and delinquency rates which are incorporated into individualized reports that are distributed to each of the sites.

QA information will be reported quarterly using a rolling distribution method. Approximately one-third of site reports will be sent out each month. Tracking for these reports is done through Oracle Clinical. In the future, Remote Data Capture (RDC) query information will also be reported on the QA reports. The first of these reports is the *Site Summary Report*, which outlines query rates for the site, including response times for queries delineated by protocol. The Site Summary Report contains the number of protocols the site has active, total patients accrued by protocol, total CRFs received for each protocol, total number of queries, query responses received, average response time (days) and the oldest pending query. *Query Categories* will also be reported. These categories include inconsistent data (discrepant or incorrect data), missing data (incomplete form, areas left blank, missing or wrong key information), Adverse Event (AE)/Serious Adverse Event (unreported toxicity, AE), and data verification (confirmation, clarification, wrong form version and additional source documentation). This report provides sites with information about what types of errors are generating the queries.

The *Site Summary Detail Report* provides sites with more detail on all the queries. For example, the patient ID number, specific Case Report Form (CRF), and the date the query was generated are outlined in this report. This report will assist sites in determining exactly which queries are pending, as well as where to go to resolve them. Finally, the *Delinquency and Expectancy* report outlines what forms are expected as well as which forms are currently delinquent for that site for the Full Data Entry studies only (e.g. BR19, MA 27, B-34 and N0147.) For all other studies, the groups are responsible for distributing Delinquency and Expectancy reports.

Reports are currently being sent out by e-mail to all sites submitting CRFs to the CTSU. For those who have no email access, the reports are being sent by surface mail. If the principal investigators would rather these reports be sent directly to the study coordinator, then please call the CTSU Help Desk to make this request. (Password-protected Site Summary Report access through the CTSU Web site is being explored). For more information, please contact the CTSU at CTSUContact@westat.com or call the CTSU Help Desk at 1-888-823-5923.

CTSU studies endorsed by Southwest Oncology Group

Protocol

ACOSOG Z9000

ACOSOG Z9001

CALGB 30102

CALGB 40101

CALGB 49907

CALGB 80101

CALGB-90202

ECOG 1899

ECOG 2100

ECOG 2603

ECOG 2902

ECOG 3201

ECOG 4501 (*study disapproved*)

IBCSG 24-02

IBCSG 25-02

MDA 3410

NCIC CTG BR.19

NCIC CTG MA.20

NCIC CTG MA.21

NCIC CTG MA.27

N0147

NSABP B-30

NSABP B-33

NSABP B-34

NSABP B-35

NSABP-B-39

RTOG 0214

RTOG P-0014

RTOG 98-04

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Kathy S. Albain, MD

Lori J. Pierce, MD

Laurie E. Gaspar, MD

Gregory P. Swanson, MD

and Primo N. Lara, MD

Lori J. Pierce, MD

More CTSU news

Southwest Oncology Group - Led Studies

Congratulations to VIA Christi Regional Medical Center in Kansas, which enrolled the most patients (154) via the Cancer Trials Support Unit from all of

the Southwest Oncology Group sites. The chart below 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 Southwest Oncology Group trials on the CTSU menu.

SWOG - Led Studies – Target/Current/CTSU Accruals and Site Registrations through the CTSU				
Protocol	Target Accrual	Current Accrual (as of 12/20/04)	CTSU Accrual (as of 12/20/04)	Sites Registered for Trial (approved as of 12/20/04)
S0012	350	275	75	133
S0023	840	579	48	45
S0106	568	7	0	29
S0124	620	322	121	198
S0205	704	196	33	112
S0221	4500	448	174	192
S0226	690	22	10	115
S0432	296	6	4	26
S9910	NA	NA	0	36
S9921	1360	580	19	63
S9925	NA	NA	114	113
SWOG-9007	NA	NA	0	17

SWOG Endorsed Studies-Target/Current/CTSU Accruals and SWOG Enrollments through the CTSU				
Protocol	Target Accrual	Current Accrual (as of 12/20/04)	CTSU Accrual (as of 12/20/04)	SWOG Enrollments through the CTSU (as of 12/20/04)
ACOSOG-Z9001	380	331	160	47
CALGB-30102	530	64	12	4
CALGB-40101	4646	1339	782	328
CALGB-49907	720	262	129	42
CALGB-80101	824	104	77	28
CALGB-90202	680	19	5	1
E1899	590	18	4	4
E2902	139	1	0	0
E3201	3000	228	79	39
IBCSG-24-02	3000	101	84	15
IBCSG-25-02	1845	206	115	15
MDA-3410	680	57	19	12
N0147	4800	326	326	68
NCIC-CTG-BR.19	1242	429	354	77
NCIC-MA.20	1822	1120	36	4
NCIC-MA.21	2100	1880	317	159
NCIC-MA.27	6830	1510	1238	405
NSABP-B-35	3000	1307	222	40
RTOG-98-04	1790	483	16	2
RTOG-P-0014	1050	19	5	4
RTOG-0214	1058	98	7	4

It's Quick & E-Z! Online GROUP MEETING Registration
<http://swog.org>



Statistical Center Staff News

Goodbyes

Donna Pauler Ankerst, Ph.D., has accepted a position with the International Multiple Sclerosis Foundation in Munich, Germany, where her husband's family lives.

James Faulkner, M.S., statistician on the Genitourinary Committee, has decided to pursue his longtime interest in ecology. He has left the Statistical Center to take a job with the National Oceanic and Atmospheric Administration in Seattle.

Changes

Nadia Howlader, M.S., joins the statistical team on the Genitourinary and Cancer Control committees. Howlader, who received her master's degree in biostatistics from the University of Washington, has been working at the Fred Hutchinson Cancer Research Center on a variety of projects involving SEER-Medicare and other large databases, as well as longitudinal analyses of PSA data.

March 11 next deadline to submit membership nominations

The next deadline for submitting membership nominations to the Operations Office is March 11, 2005. 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.

To process a new investigator nomination, all of the following information must be received by the Operations Office by March, 11, 2005:

- Application for New Investigator Form
- Nomination letter from the Principal Investigator
- Copy of the nominee's most recent curriculum vitae stating whether or not the nominee is board certified
- Certification of Education in the Protection of Human Subjects
- New investigator pharmacy information
- Affirmation of Integrity Statement
- Purchase Service Agreement (Affiliate investigators only)

Incomplete nominations will not be processed until a complete packet is received. For a complete outline of the nomination process, refer to Southwest Oncology Group Policy Memorandum No. 7 at the Group's Web site, <http://swog.org>. All application forms can be downloaded and printed.

Southwest Oncology Group Addresses & Phone Numbers

Southwest Oncology Group Operations Office

14980 Omicron Drive, San Antonio, TX 78245-3217
Phone: 210-677-8808 FAX: 210-677-0006
Web page: <http://swog.org>

Southwest Oncology Group Chair-Elect Office

Laurence H. Baker, D.O.
c/o Mary Vestich
University of Michigan Medical Center
1500 E. Medical Center Drive, 7216 CCGC
Ann Arbor, Michigan 48109-0948
Phone: 734-936-3983 FAX: 734-0948

Cancer Research And Biostatistics (CRAB)

Phone: 206-652-9711
FAX: 206-652-4612



Therapeutic Data Operations Center at CRAB

c/o Cancer Research and Biostatistics
1730 Minor Avenue, Suite 1900
Seattle, WA 98101-1468
Fax Data Submission: 800-892-4007 or 206-342-1680
Phone: 206-652-2267

Correspondence 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



Selenium and Vitamin E

Cancer and Prevention Trial (SELECT)

1730 Minor Avenue, Suite 1900
Seattle, WA 98101-1468
Deliveries: Same address as above.
Phone: 206-652-1338
Correspondence Fax: 206-652-1339
Fax Data Submission: 888-652-2940 or 206-839-1726

Prostate Cancer Prevention Trial (PCPT)

Southwest Oncology Group Statistical Center
Fred Hutchinson Cancer Research Center
1100 Fairview Avenue North, M3-C102
P. O. Box 19024, Seattle, WA 98109-1024
Phone: 206-667-6868 FAX: 206-667-6869



Clinical Trials Nurse Mentorship Program Application

(Circle) I am requesting a mentor I wish to become a mentee

Name/credentials: _____

Institution/affiliation: _____

Address: _____

City: _____ State: _____ Zip Code: _____

Telephone: _____ Fax: _____ E-mail: _____

Mentee: If you would like us to contact your supervisor, provide the name and contact information:

Name: _____

Address: _____

City: _____

State/Zip: _____

E-mail: _____

Best time to contact: _____

_____ Do not contact my supervisor.

Circle the type of institution in which you are employed:

University CCOP Private office Clinic Satellite institution Other

What is your current position?

Clinical trial nurse Nurse practitioner CRA Administration Patient care

Other: _____

Time in current position: _____

Time involved in clinical trials: _____

Circle the areas in which you would like support (protégé) or have experience (mentor):

- | | |
|-----------------------------------|---|
| Audit preparation | Maintaining source documentation |
| Coordinating a research team | Managing satellite institutions |
| Budgeting | Patient education |
| Drug accountability | Patient monitoring |
| Educating staff/staffing issues | Organizing records/source documentation |
| Institutional Review Board issues | Recruiting/informed consent/eligibility |
| Maintaining long-term follow up | Toxicity reporting |
| Other support areas: _____ | |

Circle the type of trials in which you are involved:

Nursing research Cooperative Group Pharmaceutical Prevention

Treatment Investigator initiated Phase I Phase II & III

Phase IV Other: _____

Send application to:
CTN Mentorship Program
c/o Rose Ermete
9820 Levan
Livonia, MI 48150
Ermeter@aol.com
FAX: 313-916-8270

If you work with cooperative group trials, circle the groups with which you are affiliated:

SWOG ACOS CALGB COG CTSU ECOG GOG NSABP NCCTG NCIC NWTSG RTOG

Other: _____

Please list some interests you enjoy outside of work: _____



VIDEOTAPE ORDER FORM CLINICAL RESEARCH ASSOCIATES COMMITTEE

- Everything You Need to Know About Radiotherapy...But, Were Afraid to Ask (4/98)
 Side Effects and Toxicities of Radiation Therapy (4/98)
 GU Diseases: Renal Cancer Overview (4/98)
 GU Diseases: Locally Advanced Bladder Cancer Overview (4/98)
 GU Diseases: Advanced Bladder Cancer Overview (4/98)
 Adrenal, Prostate & Testicular Cancer: Surgical Overview; Pathological Overview (10/98)
 Adrenal, Prostate & Testicular Cancer: Radiation Therapy; Medical Oncology; Introducing CAPRI (Cancer of the Prostate Risk Index); Panel Discussion (10/98)
 Head & Neck Cancer: Preneoplasia, Chemoprevention, Organ Preservation (10/99)
 Head & Neck Cancer: Resectable Carcinoma, Adjuvant Therapy, Unresectable Disease (10/99)
 Immunologic Therapy: Vaccine Therapy (4/00)
 Immunologic Therapy: Antibody Based Therapies (4/00)
 Immunologic Therapy: Intermediate Endpoints in Cancer Immunotherapy (4/00)
 IRB Basics & Beyond (4/00)
 Brain Tumors: Surgical management; Pathology (10/00)
 Brain Tumors: Radiotherapy; Chemotherapy (10/00)
 Federal Guidelines Governing Research and IRBs: Trends in Research Ethics; Historical Perspectives to Current Climate of Research; OHRP Changes and New Directions (4/01)
 Quality Improvement; Achieving Compliance; Hot Spots & Various Sundries (4/01)
 Handling Misconduct in Clinical Research (4/01)
 Common SWOG Audit Deficiencies; The IRB Decision Process (4/01)
 Breast Carcinoma: Surgical Intervention & New Techniques, Role of Immunohistochemistry in Cancer Diagnosis (4/02)
 Breast Carcinoma: Biomarker Studies; What's New in Adjuvant Therapy for Breast Cancer (4/02)
 CRA Plenary Session: Surviving Breast Cancer; Dealing with a Diagnosis of Breast Cancer (4/02)
 CRA Plenary Session: Surviving Prostate Cancer; Reconstructive Surgery After a Mastectomy (4/02)
 HIPAA: The HIPAA Privacy Rule and Research (10/02)
 HIPAA: HIPAA Compliance in the Research Setting (10/02)
 Leukemia: CRAs Perspective on Leukemia Trials; AML in Younger Patients (10/03)
 Leukemia: Pathology of Leukemia; AML in Older Patients (10/03)
 Radiation Therapy and New Imaging Techniques: RT101 and RT/QA; QARC; Cranial/Extracranial Radiosurgery Techniques -- First Half (4/04)
 Radiation Therapy and New Imaging Techniques: Cranial/Extracranial Radiosurgery Techniques -- Second Half; Imaging Techniques -- PET, Cone Beam CT, Spect, MRS; Panel Discussion (4/04)
 IATA Training for Shipping Dangerous Goods (10/04)

NAME: _____

ADDRESS: _____ DEPARTMENT: _____

CITY: _____ STATE: _____ ZIP CODE: _____

TELEPHONE: (____) _____ AFFILIATION/INSTITUTION: _____

E-MAIL: _____

_____ I assume responsibility for the prompt and safe return of all tapes requested. There will be a \$10 replacement fee for damaged or lost tapes. Tapes must be returned at the end of one month.

SIGNATURE: _____ DATE: _____

NOTE: If several tapes are ordered, it may take up to several months to complete the order due to demand.

MAIL ORDER FORM TO: Jacqueline Hilger, B.S., M.S., CCRP, Research Director, Breastlink Medical Group,
701 East 28th Street, Suite 412, Long Beach, CA 90806.