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The microphone-shaped Reunion Tower dominates the Dallas skyline. Photo courtesy of the Dallas Convention and Visitors Bureau.

Group meeting heads to Dallas

The Fall 2005 Southwest Oncology Group Meeting has been moved to the Hyatt Regency Dallas, due to the extensive hurricane damage in the Gulf Coast area. The dates are the same: Sept. 28-Oct. 2.

Please check the [Fall Group Meeting bulletin board page](#) frequently for the most current information, including the meeting schedule, accommodations and airline information. The Crush the

Crab race has been cancelled.

Name tags and meeting folders will not be mailed in advance. Please pick them up at the SWOG Information Desk in Dallas. The meetings guide will be posted on the GroupWeb site when it is available.

See the [Group meetings section](#) of the newsletter, beginning on [page 5](#).

For more about things to do in Dallas, visit <http://visitdallas.com>.

The Group Newsletter

The purpose of THE GROUP NEWSLETTER is to facilitate communication among members of the Southwest Oncology Group. You may submit articles by e-mail to newsletter@swog.org or by mail to the address at the top of this page. The deadline for the November 2005 edition is Oct. 14, 2005. Copyright 2005.



Message from the Chairman

Southwest Oncology Group leaders hold summit in Michigan

By Laurence H. Baker, D.O.

On June 20-21, representatives of the Statistical Center and Operations Office joined us here at the Headquarters Office in Ann Arbor, Mich. The primary purposes of this initiative, called by its code name "The Summit," were to develop improved communication and understanding among us all, and to review the Clinical Trials Working Group report released a few weeks earlier. I, for one, felt the meetings were helpful and I learned a great deal.

Angela Ribble from Seattle has photos. Come to the plenary session in New Orleans to see your staff in action. (The photo of John Crowley is worth the price of admission.) Our next plenary session promises to be exciting and challenging as we begin to examine ways to improve the clinical trials process. John Crowley and I are co-planning the session.



Laurence H. Baker, D.O.

role, Dr. Fisher will chair our Scientific Advisory Board (SAB) and will be prepared to serve as interim chair if I become incapacitated. He would hold this position until the next Group meeting, when a special election would be held. However, please note, I have no plans for becoming incapacitated!

We also are delighted to announce a new external member of the SAB, David Harrington, Ph.D., from Harvard. Dr. Harrington is a leader in biostatistics and is familiar with cooperative group trials.

As some may have noticed, the House passed its version of the appropriations bill for fiscal year 2006. NCI is scheduled to receive a 0.3 percent increase, which we all understand is really a significant decrease in available funds. Our SAB members have their work cut out for them as they help shape our priorities in the coming years.

When Ronald Reagan was spokesperson for General Electric, he used to say, "Progress is our most important product." I thought it was light bulbs. For certain, however, clinical trial accrual is our most important product. We are on track for 7,000 cases accrued to our therapeutic trials in 2005, which represents a doubling over the past two years.



Announcements

I am very pleased that Richard I. Fisher, M.D., from the University of Rochester, has accepted the appointment as Deputy Group Chair of the Southwest Oncology Group. Dr. Fisher has been chair of the Lymphoma Committee since 1985. His appointment was heartily endorsed by our external advisors and the National Cancer Institute (NCI). In this

Upcoming Group Meetings

2005

September 28 - October 2
New Orleans, La.

2006

April 19 - 23
Salt Lake City, Utah
October 4 - 8
Seattle, Wash.



2007

May 2 - 6
Chicago, Ill.
October 3 - 7
Huntington Beach, Calif.

2008

April 30 - May 4
Atlanta, Ga.
October 29 - November 2
Chicago, Ill.



The Southwest Oncology Group

The primary mission of the Southwest Oncology Group is to make progress in the prevention and cure of cancer through clinical research.

Laurence H. Baker, D.O.
Chairman

Southwest Oncology Group Headquarters Office

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P.O. Box 483
Ann Arbor, MI 48106
Phone: 734-998-7130 Fax: 734-998-7118

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>

Cancer Research And Biostatistics (CRAB)

1730 Minor Avenue, Suite 1900
Seattle, WA 98101-1468
Phone: 206-652-9711
Fax: 206-652-4612

.....

Therapeutic Data Operations Center at CRAB

Send mail and deliveries to SWOG Data Operations Center
c/o the CRAB address above
Fax data submission: 800-892-4007 or 206-342-1680
Phone: 206-652-2267
Correspondence fax: 206-652-4612

.....

Selenium and Vitamin E Cancer and Prevention Trial (SELECT)

Send mail and deliveries to
SELECT c/o the CRAB address 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

Statistical Center news

Patients overdue for follow-up

Most recent therapeutic studies now have a final deadline for follow-up – either three years, five years or some other time period specified in the protocol. We have had a number of calls to the Southwest Oncology Group (SWOG) Data Operations Center in which a clinical research associate has a patient enrolled in a therapeutic study, the time for follow-up has passed, and the patient is still listed on the patient follow-up report.

Keep in mind that we still need to collect all the necessary data required for the trial. For example, if a patient was registered Jan. 1, 2002, on a study requiring three years' follow-up but the last date of contact provided to us was Dec. 1, 2004, this patient will continue to appear on the follow-up list until you provide us with a final contact date of Jan. 1, 2005, or later.

If you have questions about this, please contact the Data Operations Center at 206-652-2267.

Make note of correct address for Data Operations Center

Even though it has been more than three years since the Southwest Oncology Group (SWOG) Data Operations Center moved to its "new" address, mail for therapeutic studies is still being sent to the old address at the Fred Hutchinson Cancer Research Center. We are fortunate that the mail is still being forwarded to us; however, there is no guarantee how long this will continue.

In order to make sure that we receive your data in a timely matter and to prevent anything from being returned to you, please make sure that you and your affiliates have **the correct address as shown in the box to the left.**

We realize that some protocols have not been updated with this new information. We are working to correct them as amendments arise.

For SWOG-coordinated studies, we prefer that you submit data online whenever possible. If a particular form is not available for online submission, please fax your data to us without a cover sheet to 1-800-892-4007.

These faxes go directly into our database to be verified by our data control technicians. This greatly reduces the processing time involved in resolving issues and updating follow-up status.

Data for a different cooperative group should be sent directly to that group. We now have direct data submission among the other groups, with the exception of the Children's Oncology Group. For any questions regarding this, please contact us at 206-652-2267.



Group leaders meet for team-building at Michigan Summit

Leaders from the Southwest Oncology Group offices met June 20-21 in Ann Arbor, Mich., for a summit conference.

Led by Group Chairman Laurence H. Baker, D.O., the attendees spent half a day in activities at the University of Michigan challenge program, also known as the ropes course. These

activities were designed to help colleagues build trust in their team members and to solve problems as individuals and as part of a group. Among the activities were a rolling log challenge and a blindfolded maze activity.

The rest of the time was dedicated to exchanging information, educating

staff and setting goals for the Group.

Among the attendees from the Headquarters Office were two of the Group's three executive officers, Bruce G. Redman, D.O., and Anne F. Schott, M.D.; Denise Reinke, M.S., N.P., administrative director; Anna Schork, J.D., the Group's legal and fiscal administrator; Joy Reilly, fiscal administrator; and Mary Vestich, administrative assistant.

From the Operations Office were Marj Godfrey, director; Connie Barnes, programs manager/assurances; Nickey McCasland, R.N., M.H.A., Serious Adverse Events program manager and Web manager; and Dana Sparks, M.A.T., protocol product line manager.

Representing the Statistical Center were Director John Crowley, Ph.D., and Deputy Director Jackie Benedetti, Ph.D.

Attending from Cancer Research and Biostatics were Angela Ribble, project manager; and Evonne Lackey, C.C.R.P., coordinating center manager.



Rockin' and rollin' – Group Chairman Laurence H. Baker walks a swinging log suspended several inches above the ground with help from his teammates.



Lost souls convention – (From left) Marj Godfrey, Mary Vestich, Connie Barnes and Nickey McCasland run their hands along ropes tied between trees to find their way out of a maze. Participants could not talk and had to rely on their problem-solving skills to locate the way out through a narrow opening.



At the end of his rope – John Crowley takes a moment to consider the odds of getting out of the maze, while Denise Reinke ponders the same question.



Southwest Oncology Group Meeting September 28 - October 2 in the Hyatt Regency Dallas

Plenary session to feature the evolution of clinical trials

The scientific highlight of the Fall 2005 Southwest Oncology Group Meeting will be the plenary session, scheduled for 8:30 a.m. to 11 a.m. on Saturday, Oct. 1.

Organized and co-led by Group Chairman Laurence H. Baker, D.O., and Group Statistician John Crowley, Ph.D., the plenary session will focus on the evolution of cancer clinical trials, both nationally and internationally.

After opening comments by Dr. Baker, who is professor of Internal Medicine and Pharmacology at the University of Michigan in Ann Arbor, will be the featured speakers and their discussants:

- **Richard I. Fisher, M.D.**, deputy Group chair and chair of the Lymphoma Committee, will speak on "Clinical Trials in Europe: The Lymphoma Experience." Dr. Fisher also is chair of SWOG's Scientific Advisory Board and director of both the James P. Wilmot Cancer Center and Cancer Services for Strong Health. He also is the Samuel E. Durand Professor of Medicine at the University of Rochester Medical Center in Rochester, N.Y.

- **Richard Pazdur, M.D., F.A.C.P.**, will speak on "The Relevance of Clinical Trial Data Generated Outside the United States." Dr. Pazdur is director of the Division of Oncology Drug Products Center for Drug Evaluation and Research at the U.S. Food and Drug Administration in Rockville, Md.

- **Janet E. Dancey, M.D.**, senior

investigator of the Investigational Drug Branch of the NCI's Cancer Therapy Evaluation Program, in Rockville, Md., will speak on "Population and Design issues for Oncogene-Targeted Therapies."

- **David R. Gandara, M.D.**, chairman of the Southwest Oncology Group Lung Cancer Committee, will apply Dr. Dancey's presentation to lung cancer. Dr. Gandara is professor of medicine at the University of California Davis Cancer Center in Sacramento, Ca.

- **P.Y. Liu, Ph.D.**, biostatistician at the Group's Statistical Center in Seattle, Wash., will speak on "Electronic Data Capture: The SWOG Early Therapeutics System."

- **John J. Crowley, Ph.D.**, director of the SWOG Statistical Center, will speak on "SWOG's Future Plans," in relation to Dr. Liu's presentation.

- **Anne F. Schott, M.D.**, SWOG executive officer, will speak about "End Points for Phase II Trials." Dr. Schott is assistant professor of Internal Medicine at the University of Michigan at Ann Arbor, Mich.

- **Robert B. Livingston, M.D.**, chair of SWOG's Breast Cancer Committee, will apply Dr. Schott's presentation to breast cancer. Dr. Livingston is professor of medicine and oncology at Seattle Cancer Care Alliance in Seattle, Wash.

Questions will be accepted during designated question-and-answer periods throughout the plenary session.

SELECT sessions to open fall 2005 Group meeting

The Selenium and Vitamin E Cancer Prevention Trial (SELECT) Workshop will kick off the Fall 2005 Southwest Oncology Group meeting in Dallas.

SELECT sessions will be held Sept. 27 through Sept. 29.

The Operations Office will offer limited financial support for one clinical research associate (CRA) from each approved study center and site to attend the training. For information on how to take advantage of this stipend, go to the Group Meeting page on the SWOG Web site, <http://swog.org>, or call Marj Godfrey at 210-677-8808.

A travel reimbursement form is located on the SELECT Workbench under the Administration/Finance button. Click on the Reimbursements Forms link.

CRAs are encouraged to bring any new retention and adherence materials they have developed to put on display during the SELECT Poster Session, 8 a.m. to 11 a.m., Sept. 29. Just put your name, phone number and study site number on the item and bring it to the SELECT registration desk or the poster session. The items will be saved for display at future Group meetings.

Only 400 people can register for the SELECT workshop. Sign up by logging on to <http://swog.org>, click on Group Meeting and choose the SELECT workshop. See the tentative workshop schedule on [page 6](#).



CRA Open Forum set for Sept. 29

The Clinical Research Associates (CRAs) Open Forum will be held from 4:15 p.m. to 6 p.m. Sept. 29 in the Hyatt Regency Dallas hotel.

This forum, during the Fall 2005 Southwest Oncology Group Meeting, is for both new and experienced CRAs. "There is abundant information to help new CRAs get through the maze. The topics are geared to boost their self-confidence and retain their sanity," said Lynn Campbell, chair of the CRA Open Forum. "More experienced CRAs can refresh their memories on things they may not have done in a while. And there is always a need to be updated on things that have changed."

Topics to be discussed are:

- Research drug handling
- Quality assurance audits
- Financial reimbursement
- Tumor markers
- Reporting serious adverse events
- CRA workbench
- Forms completion
- Nurse oncology



This monument to the cowboy is located in Dallas' Pioneer Plaza. Photo courtesy of the Dallas Convention and Visitors Bureau.

Workshop & Poster Session Preliminary Agenda

Tuesday, Sept. 27

- 3 p.m. - 4 p.m.** **New staff check-in.**
- 4 p.m. - 6:30 p.m.** **New staff session.**
This session will give you the information you need to get started on SELECT.
- 4 p.m. - 7:30 p.m.** **Early check-in, workbench demonstrations.**
Workbench demonstrations are highly recommended for new SELECT staff.
- 4 p.m. - 7:30 p.m.** **Hospitality reception.**

Wednesday, Sept. 28

- 7 a.m. - 7:50 a.m.** **General check-in. Continental breakfast.**
- 8 a.m. - noon** **SELECT Workshop General Session.**
Theme: "Promoting Communication in a Long-Term Prevention Trial."
- 1:30 p.m. - 6 p.m.** **Breakout Sessions. Snacks and beverages.**
Choose from among several topics and expert panelists to get the answers you need to better conduct SELECT at your institution.

Thursday, Sept. 29

- 8 a.m. - 11 a.m.** **Poster session. No food or drinks provided.**
Ask questions of Southwest Oncology Group and SELECT staff and committee members as they present new and updated information. Remember to bring any new retention and adherence materials to this session to share with others. Attach your name, phone number and study site ID number. Materials will be kept for display at future Group meetings.
- 9 a.m. - 10:30 a.m.** **Respiratory Ancillary Study.**
For SELECT staff whose sites are participating in this ancillary study of SELECT.
- 10:30 a.m. - noon** **PREADVISE Normal Aging Cohort.**
For SELECT staff whose sites are participating in the PREADVISE Normal Aging Cohort.



Clinical Trials Training Course for Therapeutic Studies

A Workshop for Southwest Oncology Group Clinical Research Associates

Wednesday, Sept. 28 and Thursday, Sept. 29, 2005

Who should attend?

- ❖ **New** Southwest Oncology Group clinical research associates (CRAs).
- ❖ SWOG CRAs who have never attended the course.
- ❖ Senior SWOG CRAs who want to brush up on their skills.

Goals of the course:

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

Cost:

- ❖ Thanks to the Hope Foundation, the course is free for SWOG members.
- ❖ **Attendees who are not members of SWOG must contact the SWOG Data Operations Center (206-652-2267) for space availability and the fee.**

IMPORTANT:

- ❖ **REGISTER EARLY!** Space is strictly limited to **115** participants.
- ❖ This training course is intended for CRAs who work on SWOG *therapeutic studies*, **not** the Selenium and Vitamin E Cancer Prevention Trial (SELECT).
- ❖ **Note:** Registration to the general SWOG Group Meeting does not automatically enroll you in the CTTC.
- ❖ **REGISTRATION DEADLINE: Monday, Sept. 12, 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 SWOG Data Operations Center at (206) 652-2267.

To view the agenda, click on Clinical Trials Training Course when signing up for the Group meeting at <http://swog.org>.

A call for CRA posters!

Share your ideas and highlight your accomplishments by participating in the Clinical Research Associates (CRA) poster session during the Group meeting.

Some themes to consider are:

- One for all, all for HIPAA
- Using the short form to consent patients in other languages
- Clinical trial alternatives at your institution
- Support groups: sharing information
- Preparing for an audit
- Honoring research participants
- Successful tips for managing a research team

- Schedule tracking systems to manage patient follow-up
- Side effect management and education tools
- Finding alternative resources: working with uninsured or underinsured patients on clinical trials
- Paperless IRB
- Join the network: research chat
- New scientific areas of interest

For poster guidelines or to submit your poster, contact Amy.DeBlaise@chw.edu, by Aug. 15, 2005.



SoCRA to offer certification exam at the Group meeting

The Society of Clinical Research Associates (SoCRA) certification exam will be held from 8 a.m. to noon on Wednesday, Sept. 28, during the Fall 2005 Southwest Oncology Group Meeting. The registration deadline was Aug. 17.

Applicants must be members of SoCRA and have been working in clinical research for more than 24

months. Detailed eligibility criteria are listed on the SoCRA Web site, <http://www.socra.org>.

Individuals who pass the SoCRA exam may use the title of certified clinical research professional, or C.C.R.P., to indicate that they have met an internationally accepted standard of knowledge, education and experience as a professional in

medical research.

While the exam is offered during the Group meeting, applicants must register for the exam through the SoCRA. The application, fee information and sample exam questions are available at the SoCRA Web site.

The Southwest Oncology Group contact person for the SoCRA exam is Debra Christie, M.B.A., C.C.R.P., dchristie@crr.umsmed.edu, 601-984-1099.

CEU Workshop set for Sept. 29

Pancreatic and hepatobiliary carcinomas will be the focus of the Clinical Research Associates Continuing Education Workshop. The workshop will be held from 8 a.m. to noon on Thursday, Sept. 29, during the Fall 2005 Southwest Oncology Group Meeting. You must register in advance to attend this meeting and to obtain continuing education units from the Society of Clinical Research Associates.

To register, log on to the SWOG Web site at <http://swog.org>, choose Group Meeting and click on "Continuing Education Workshop."

Print just what you need from the Report of Studies

While printed copies of the Report of Studies (ROS) will be available at the Group meeting near the registration desk, it is also available online at the Southwest Oncology Group Web site.

Printing just the studies you need will avoid your having to carry around the hefty printed version and help the Group cut printing costs. To access the ROS online:

1. Log on to <http://swog.org>.
2. Click on "Clinical Trials."
3. Select "Report of Studies."

Correlative Sciences Committee to present minisymposium on pharmacogenomics

By Daniel F. Hayes, M.D.
Co-chair
Correlative Sciences Committee

You may have noticed that your patients don't look alike, nor do they respond to your therapies in the same way, either in terms of efficacy or toxicity.

For years, oncologists have used *somatic* changes in the tumor to individualize therapy. The use of tumor expression of estrogen-receptor content to select endocrine treatment for breast cancer patients is a classic example. However, little research has gone into studies of inherited, *germ-line* differences between individuals that might fundamentally affect the therapeutic risk-to-benefit ratio.

Pharmacogenomics is defined as the study of inherited, germ-line single nucleotide polymorphisms (SNPs) in genes that are important for drug activity. These genes may be involved in drug metabolism either to active or inactive metabolites, and/or they may be direct or indirect targets of the drug.

The Southwest Oncology Group is increasingly incorporating studies of pharmacogenomics into

prospective clinical trials. At the Fall 2005 Southwest Oncology Group Meeting in Dallas, the General Correlative Sciences Committee will present a minisymposium on "Pharmacogenomics of Cancer Therapy." This symposium, which will be held from 4 p.m. to 6 p.m. on Thursday, Sept. 29, is open to all SWOG members – laboratory and clinical investigators and clinicians.

Dr. David Flockhart, a clinical-molecular pharmacologist from Indiana University and a renowned expert in the field, will present a 30-minute overview of pharmacogenomics in general and specific to cancer. He will be followed by Dr. Christine Ambrosone of Roswell Park Cancer Institute, co-chair of SWOG's Molecular Epidemiology Subcommittee, who will discuss her ongoing studies in the Group. After these presentations, a 45-minute discussion of other ongoing studies will be presented by the respective disease correlative science chairs, accompanied by an "open mike" discussion of where we are and where we might wish to go in this exciting field.



Nurse Oncologist Workshop

Breast Cancer Treatment, Issues and Controversy

Friday, Sept. 30

Synopsis

This program will address the various aspects of caring for the breast cancer patient, including anatomy, physiology, staging, treatment and patient management within the clinical trial setting. It is designed for oncology research nurses and clinical research associates (CRAs) working with Southwest Oncology Group clinical trials.

Certificates for continuing education credits (CEUs) will be distributed to attendees who complete and turn in their evaluation sheets. Application has been made for CEUs 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. Certificates of attendance will be given for Society of CRA credit.

Schedule

Morning Session

6:45 a.m.-8:00 a.m.	Registration
7:00 a.m.-8:00 a.m.	Continental breakfast
7:45 a.m.-8:00 a.m.	New nurse orientation
8:00 a.m.-8:15 a.m.	Business meeting
8:15 a.m.-Noon	Program

Afternoon session

1:00 p.m.-2:00 p.m.	Session A	Nurse QOL/Disease and 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/Research 102
2:00 p.m.-3:00 p.m.	Session D	Education and Program Subcommittees
2:30 p.m.-3:30 p.m.	Session E	Breast Self-Exam Class
3:00 p.m.-4:00 p.m.	Session F	CCOP Subcommittee

Speakers

Ruth Chaplen, R.N., M.S.N., A.O.C.N.

Chaplen is an advanced-practice nurse at the Karmanos Cancer Institute in Detroit, Mich. She has spoken both nationally and internationally on various cancer nursing topics.

Jamie Myers, R.N., M.N.

Myers, a regional scientific associate director for Novartis, is responsible for healthcare professional education. She received her master's degree from the University of Kansas and has given many ONS-CEU-supported presentations. Her presentation is sponsored by Novartis.

Siu-Fun Wong, Pharm.D.

Wong is an associate professor of pharmacy practice at Western University of Health Science, where she instructs and mentors students in research. She chairs SWOG's Pharmacy Committee and reviews the pharmacy component of study designs. She received her Doctor of Pharmacy degree from the University of California, San Francisco.

Opportunities for women, minorities, persons with disabilities

The Southwest Oncology Group is committed to encouraging attendance of all its members to the semiannual Group meetings.

SWOG offers committee meetings of particular interest to women and minorities, including the Committee on Special Populations. There also are frequent symposia and plenary session presentations featuring

gender and minority research issues.

Group members with disabilities are encouraged to call the Operations Office (210-677-8808) after they register online for the Group meeting, if they need special arrangements or accommodations in order to participate fully in all Group functions.



Surgery Committee to discuss quality assurance in clinical trials

One of the main roles for surgeons in the Southwest Oncology Group is to make sure that the quality of SWOG's clinical trial results is not compromised by inadequate surgery. This quality assurance function begins at the earliest stages of protocol development and is carried through to the end of the data analysis. Quality enhancement, through education and dissemination of information regarding protocol requirements, is another key aspect in the process.

Recently, the Surgery Committee proposed and the SWOG Executive Committee approved the Surgical Quality Assurance Program. The purpose of the program is to uphold surgical quality for SWOG clinical trials and to assure that surgical credentialing and data review is performed. Any trial that includes qualifying or protocol-mandated surgery in its design is included in the program's scope.

The implementation of the Surgical Quality Assurance Program and other discussion regarding quality assurance in SWOG trials will be discussed during the Surgery Committee meeting at the fall 2005 Group meeting. The committee will meet on Friday, Sept. 30, from 3 p.m. to 4 p.m.

Reserving your hotel room for the Group Meeting in Dallas

Whether you have booked your hotel room for the Fall 2005 Southwest Oncology Group Meeting or are just now planning to do so, please go to the [SWOG Group Meetings page](http://swog.org/Visitors/GpMeeting.asp) for instructions. (<http://swog.org/Visitors/GpMeeting.asp>).



Hyatt Regency Dallas
300 Reunion Blvd.
Dallas, Texas 75207
214-651-1234

Group Rates for single or double accommodations:

Southwest Oncology Group rate	\$195*
Business Plan rates	\$215*
Regency Club rates	\$225*

Group rate is guaranteed through Sept. 8, 2005.

* Business Plan and Regency Club accommodations are based on availability. Rates shown do not include tax, which is 15 percent.

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

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The do's and don'ts of reporting serious adverse events

By Nickey McCasland, R.N., M.H.A.
Serious Adverse Events
Program Manager

The National Cancer Institute's (NCI) online **Adverse Event Expedited Reporting System (AdeERS)** is now the standard method for reporting serious adverse events (SAE) on Southwest Oncology Group studies.

SWOG uses AdeERS in the centralized mode: every AdeERS report on a SWOG study is first transmitted to the Operations Office for review before the report is submitted to the NCI. This gives the SAE staff the chance to catch errors, omissions or discrepancies and contact the submitter before the report goes to the NCI. But because reporting SAEs in AdeERS can be time-consuming, do not waste your time with unnecessary work or with repairing errors. Here are some guidelines to help you submit required AdeERS reports that are right the first time:

Do's:

- Follow the reporting guidelines in Section 16 of the protocol. If you are not sure about whether to submit a report, call the Operations Office at 210-677-8808. The SAE staff can help you interpret the guidelines.
- Submit the report as soon as you have enough solid information to list specific adverse events (AEs) and associated attributions. An expedited report should be, well, expedited. It can always be amended to add more detail or change incorrect first impressions as more information becomes available.
- Either complete and submit the report within 10 calendar days or withdraw it. If an event requires 24-hour reporting, complete and submit the report within five calendar days. AdeERS will withdraw and mark as "Initiated, Not Submitted" any report that was not submitted within the prescribed time – and this is not a good thing.
- Use the "Sections of Report" screen to switch off



any optional sections not applicable to a report.

- Report all deaths on study or deaths within 30 days of the last protocol treatment, regardless of attribution.

Don'ts

- Don't use the "Other: Specify" AE option unless it is truly a very rare but reportable event that is not adequately covered by one of the hundreds of AE descriptions on the criteria list.
- Don't create a new report if another reportable AE occurs on the same patient during the same cycle/course. In this case, you should amend the previous report to add the new information.

• Don't list concurrent medications (or other contributing causes) which are not at least possibly related to the AEs being reported. A "laundry list" of medications like antacids, laxatives, pain medications and supportive medications, none of which are related to why the AEs are being reported, is both time-consuming to enter and unhelpful in determining causality.

- Don't enter "None" or "N/A" in optional sections. Instead, go to "Sections of Report" and switch inapplicable sections to "No."
- Don't report non-reportable AEs. If you are submitting a report because of a Grade 3 AE that required hospitalization, for example, it is not necessary to report other, incidental AEs that are not themselves reportable. Those do need to be reported on the protocol's AE form; save them for that.
- Don't use the AdeERS 24-hour report option unless the protocol specifies it. A 24-hour report is only required for Grade 4 or 5 AEs at least possibly related to an investigational drug. And if you start a report via the 24-hour option, you must complete it within five calendar days, whether it actually needs to be reported in 24 hours or not.



Quality Assurance Corner

The importance of standardized source documentation

One of the primary objectives of quality assurance audits is to make sure that the data reported on the research records accurately reflect the data as it is reported in the source documents. In multisite clinical trials, it is important for source documentation to be standard across all sites to ensure consistent trial data. Adhering to the following recordkeeping requirements will ensure that quality data is collected to substantiate the integrity of the research process:

- All data submitted on case report forms or via electronic data submission must be supported by original source documents. Source documentation is usually the medical record, such as the clinic chart or hospital records, but may also include printouts of lab results, patient diaries, telephone logs, etc. The reported research data must match the source documents, data point to data point.
- Source documents must have appropriate identifiers to verify that they correspond to the specified subject, contain chronological entries and are filed in an organized fashion to facilitate review during an audit. Only dark ink should be used, never pencil. Notes and signatures must be legible. A Site Authority Log was recently distributed to all institutions to assist auditors in identifying research personnel signatures and initials.
- All source documentation must be signed/initialed and



dated. Multiple entries by the same person on the same day require only one signature and date on the page. Entries by different people must be signed/initialed and dated by the person making the entry.

- Source documentation must be relatively permanent and protected from unauthorized change. Original documents should never be destroyed if they require corrections due to errors. When changes are necessary, the original values should not be obscured by using correction fluid or by obliterating the original data. To make corrections, the old data should be lined through, the new value recorded, initialed and dated, and the reason for change recorded, if necessary.
- Post-dated documents should not be altered in an attempt to resolve deficiencies. When additional data needs to be inserted, it should not be squeezed between the lines or in the margins. Instead, an addendum that is signed and dated in present time should be placed in the chart. The deficiency and the circumstances surrounding the situation should also be documented, if necessary, to clarify the situation.

If you have questions about source documentation or a suggestion for a future QA topic, please contact Elaine Armstrong, SWOG QA manager, at qa@swog.org or 210-677-8808.

August 26 next deadline to submit membership nominations

The next deadline for submitting membership nominations to the Operations Office is Aug. 26, 2005. Prior to each Group meeting, nominations are considered for Member, Community Clinical Oncology Program, Affiliate, Urologic Cancer Outreach Program 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 Aug. 26, 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. 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.



How to download large files from the Group Web site

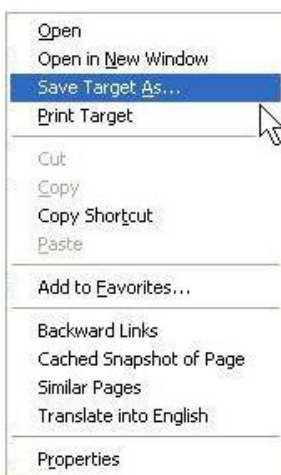
By Nickey McCasland, R.N., M.H.A.
Web Manager

Some document files that you must download from the Southwest Oncology Group Web site are very large. In particular, safety reports from the National Cancer Institute (NCI), which must be passed along for review by local institutional review boards (IRBs), can be extremely hefty. This is because of the way they are produced. Although SWOG receives them as PDF (portable document format) files, they are initially created by scanning, a process that can push files of more than a few pages to multimegabyte size.



You will soon see an improved method of handling safety report files on swog.org. They will be listed separately rather than combined into one large file, which will mean that each file is a much more manageable size. However, there will always be some large files. Sometimes even a protocol document or MRU file can take a lot of time to download. Here are some tips for downloading large PDFs:

- Don't give up too quickly when downloading a large file. If the icon in the upper right corner of your browser is still moving, the download is still in progress. It can take a matter of several minutes to complete the download of a big file.
- For an even better handle on what is happening with a download, you can right-click on the link of the document you want, and from the resulting menu (shown at left),



select "Save Target As..." Then select the location where you want the file saved (e.g., Desktop or My Documents). You will then see a progress bar that shows how the download is progressing.

- There are other options for downloading documents from the Clinical Trials pages, especially if you need to download a number of documents. You can create a download list that contains all the files you need, then download them all as a single

ZIP file. This both reduces the downloading time slightly and saves you the time needed to repeatedly select and download individual files.

Online help at swog.org

For more information on downloading, check out these two sources on the [SWOG Web site](#):

- The Clinical Trials section Help page (<https://swog.org/Members/ClinicalTrials/howtouseclinicaltrials.asp>)

The FAQ (Frequently Asked Questions) item on downloading (<https://swog.org/Members/FAQ/index.asp>).

Use care when filling out SWOG-9346 QOL form

Many clinical research associates and nurses have been doing a great job submitting quality-of-life questionnaires for **SWOG-9346**, "Intermittent Androgen Deprivation in Patients with Stage D2 Prostate Cancer."

However, there is one recurring problem regarding registrations that could significantly impact the accuracy of assessment times in the database. We would appreciate your help in correcting this problem.

S9346 has two registrations. Registration 1 is for early or late induction therapy, while Registration 2 occurs at randomization to either the intermittent or continuous treatment arms. Only the prestudy form should be classified as Registration 1. All subsequent forms, including the randomization and three follow-up forms should be classified as Registration 2.

When filling out the form you may have checked the correct assessment time box, but if the registration number is incorrect it causes confusion in the database. Please pay careful attention to whether a form is associated with Registration 1 or 2 and whether the correct assessment time is checked prior to submitting forms to the Southwest Oncology Group Data Operations Office at Cancer Research and Biostatistics.

For more information, contact Carol M. Moinpour, Ph.D., cmoinpou@fhcrc.org or Donna L. Berry, Ph.D., R.N., donna1b@u.washington.edu.



Holiday schedules for 2005

Headquarters Office

Labor Day, September 5
Thanksgiving Day, November 24
Day after Thanksgiving, November 25
Christmas Holiday, December 26

Operations Office

Labor Day, September 5
Thanksgiving Day, November 24
Day after Thanksgiving, November 25
Christmas Holiday, December 26

Statistical Center Staff at Fred Hutchinson Cancer Research Center

Labor Day, September 5
Veterans Day, November 11
Thanksgiving Day, November 24
Day after Thanksgiving, November 25
Christmas Holiday, December 26

All CRAB Offices

Labor Day, September 5
Thanksgiving Day, November 24
Day after Thanksgiving, November 25
Winter Holiday, December 23
New Year's Eve, December 30

New NIH publications policy reinforces the importance of reporting SWOG trial results

The new National Institutes of Health (NIH) policy, designed to facilitate the dissemination of published research results to other researchers and the public, is just one more reason to inform others about the progress of your research.

The new policy became effective in May and encourages all NIH-funded investigators to make their peer-reviewed final manuscripts available to other researchers and the public at the NIH National Library of Medicine's PubMed Central Web site immediately after the final date of journal publication. This Web site is <http://pubmedcentral.nih.gov>.

This policy applies to all research grant and career development award mechanisms, cooperative agreements, contracts, institutional and individual Ruth L. Kirschstein National Research Service Awards, as well as NIH intramural research studies. It applies to peer-reviewed, original research publications that have been supported in whole or in part with direct costs from NIH, but does not apply to book chapters, editorials, reviews or conference proceedings.

NIH requests that authors submit publications resulting from currently funded NIH research projects or previously supported NIH research projects where manuscripts were accepted for publication on or after May 2, 2005. For more information, access <http://www.nih.gov/about/publicaccess>.

Proper credit for you and funding for the Group

The Southwest Oncology Group has always required investigators to keep the Group's publications specialist informed of the status of Group-related publications, whether they are abstracts or manuscripts.

All studies, whether the results were positive or negative, must be published to assure the Group continues to receive funding from the National Cancer Institute. All phases of the publication process with a journal or society meeting should be reported. This includes submissions, resubmissions, acceptances, acceptances pending revisions, as well as publications not accepted. This will ensure that complete and accurate information is reported regarding 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 a journal can be faxed to the Group publications specialist at 210-677-8808 or e-mailed to pubs@swog.org.





Abstracts Published

The abstracts listed below are those that have been received in published form by the Operations Office Publications Specialist from April 22 through June 24.

There are no manuscripts reported in this edition of the Group Newsletter.

***8507** Timing of recurrence and outcomes following induction BCG for high risk Ta, T1 Bladder Cancer. A Southwest Oncology Group trial. SP Lerner, C Tangen, H Sucharew, DP Wood, ED Crawford. *Journal of Urology* 171(Suppl 4):72(#273), 2004.

***8794** Adjuvant radiotherapy for pathologic T3 prostate cancer: results of a randomized, prospective clinical trial with metastasis-free survival endpoint. IM Thompson, C Tangen, G Miller, MS Lucia, D Troyer, J Paradelo, J Chin, E Messing, E Canby-Hagino, J Forman, ED Crawford. *Journal of Urology* 173(4):451 (#1665), 2005.

***8994** Short-and long-term genitourinary symptom status and global quality of life (QOL) from a Southwest Oncology Group (SWOG) trial. KA Hayden, CM Moinpour, J Faulkner, CM Tangen, ED Canby-Hagino, D Lemmon, S Breslin, IM Thompson, ED Crawford. Proc of the American Society of Clinical Oncology, *Journal of Clinical Oncology* 23(16S):391s (#4556), 2005.

***9217** Pathological assessment of high grade tumors in the Prostate Cancer Prevention Trial (PCPT). MS Lucia, A Darke, P Goodman, C Tangen, CA Coltman, IM Thompson. *Journal of Urology* 173(4):451 (#1664), 2005.

***9217** Prostate specific antigen (PSA) as a predictor of adverse pathological features at prostatectomy in the Prostate Cancer Prevention Trial (PCPT). MS Lucia, P Goodman, C Tangen, CA Coltman, IM Thompson. *Journal of Urology* 173(4):143(#525), 2005.

***9217** The performance characteristics of prostate-specific antigen IM Thompson Jr., DP Ankerst, C Chi, P Goodman, C Tangen, CA Coltman Jr. *Journal of Urology* 173(4):143(#526), 2005.

***9313** Prognostic value of cell cycle regulators p27 and cyclin E: tissue microarray analysis of 1753 women enrolled in SWOG breast cancer trial 9313. PL Porter, W Barlow, IT Yeh, MGLin, X Yuan, JN Ingle, CL Shapiro, GP Sledge, RB Livingston, DF Hayes. Proc of the American Society of Clinical Oncology, *Journal of Clinical Oncology* 23(16S):5s(#507), 2005.

***9504** Long term survival in stage IIIb non-small cell lung cancer (NSCLC) treated with consolidation docetaxel following concurrent chemoradiotherapy (SWOG S9504). DR Gandara, K Chansky, LE Gaspar, KS Albain, PN Lara, J Crowley. Proc of the American Society of Clinical Oncology, *Journal of Clinical Oncology* 23(16S):635s (#7059), 2005.

***S9701** Relationship between pretreatment CA-125 level and risk of relapse in advanced ovarian cancer (AOC) patients in a complete clinical response (CCR) who received "maintenance therapy." PY Liu, DS Alberts, BJ Monk, M Brady, M Markman. Proc of the American Society of Clinical Oncology, *Journal of Clinical Oncology* 23(16S):458s (#5013), 2005.

***S9900** S9900: A phase III trial of surgery alone or surgery plus preoperative paclitaxel/carboplatin (PC) chemotherapy in early stage non-small cell lung cancer (NSCLC): preliminary results. K

Pisters, E Vallieres, P Bunn, J Crowley, R Ginsberg, P Ellis, B Meyers, R Marks, J Treat, D Gandara. Proc of the American Society of Clinical Oncology, *Journal of Clinical Oncology* 23(16S):624s (#LBA7012), 2005.

***S0033** Clinical benefit of Imatinib in patients (pts) with metastatic gastrointestinal stromal tumors (GIST) negative for the expression of CD117 in the S0033 trial. ME Blackstein, C Rankin, C Fletcher, M Heinrich, R Benjamin, M von Mehren, C Blanke, JA Fletcher, E Borden, G Demetri. Proc of the American Society of Clinical Oncology, *Journal of Clinical Oncology* 23(16S):818s (#9010), 2005.

***S0033** Incidence and reasons for dose modification of standard-dose vs. high-dose imatinib mesylate (IM) in the phase III Intergroup study of S0033 of patients (pts) with unresectable or metastatic gastrointestinal stromal tumor (GIST). P Dileo, CJ Rankin, RS Benjamin, M von Mehren, C Blanke, V Bramwell, RMaki, C Fletcher, EC Borden, GD Demetri. Proc of the American Society of Clinical Oncology, *Journal of Clinical Oncology* 23(16S):824s (#9032), 2005.

***S0102** SWOG S0102: A phase II study of docetaxel (DOC) and Vinorelbine (VNR) + filgrastim for HER-2 negative, stage IV breast cancer. J Gralow, S Green, DLew, W Barlow, K Dammann, G Somlo, S Rivkin, S Taylor, L Wong, R Livingston. Proc of the American Society of Clinical Oncology, *Journal of Clinical Oncology* 23(16S):20s(#567), 2005.

***S0108** Phase II trial of single agent bevacizumab in patients with relapsed, aggressive non-Hodgkin's lymphoma (NHL): Southwest Oncology Group study S0108. AT Stopeck, W Bellamy, J Unger, L Rimsza, M Iannone, RI Fisher, TP Miller. Proc of the American Society of Clinical Oncology, *Journal of Clinical Oncology* 23(16S):583s(#6592), 2005.

***S0126** Increased EGFR gene copy number detected by FISH is associated with increased sensitivity to gefitinib in patients with bronchioloalveolar carcinoma (BAC) (S0226). FR Hirsch, DR Gandara, J McCoy, J Crowley, HJ West, PH Gumerlock, PA Bunn, WA Franklin, M Varella-Garcia. Proc of the American Society of Clinical Oncology, *Journal of Clinical Oncology* 23(16S):628s (#7030), 2005.

***S0327** The proteasome inhibitor PS-341 (bortezomib) in platinum (plat)-treated extensive-stage small cell lung cancer (E-SCLC): a SWOG (0327) phase II trial. J Johl, K Chansky, PN Lara, AM Davies, R Bold, DR Gandara. Proc of the American Society of Clinical Oncology, *Journal of Clinical Oncology* 23(16S):632s (#7047), 2005.

***Multiple Studies** The clinical spectrum of adult acute myeloid leukemia (AML) associated with core binding factor (CBF) translocations. FR Appelbaum, KJ Kopecky, ML Slovak, HM Gundacker, MTallman, H Kim, GW Dewald, E Estey, H Kantarjian, S Pierce. Proc of the American Society of Clinical Oncology, *Journal of Clinical Oncology* 23(16S):563s (#6513), 2005.

* Presented



Southwest Oncology Group Protocol Update from May 1 – July 1.

This PROTOCOL UPDATE serves as reference for protocol activity during the stated period. When noting Temporary Closures and Reactivated Protocols, bear in mind that temporarily closed studies are often reopened after observation of some degree of antitumor 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 reactivation, you may contact the study coordinator for more information.

ACTIVATIONS

BMT CTN Protocol #0102 “A Trial of Tandem Autologous Stem Cell Transplants ± Post Second Autologous Transplant Maintenance Therapy Versus Single Autologous Stem Cell Transplant Followed by Matched Sibling Non-Myeloablative Allogeneic Stem Cell Transplant for Patients with Multiple Myeloma.” Study coordinator: Dr. G. Somlo. **Activation 5/1/05.**

RTOG 0412/SWOG S0332 “A Phase III Randomized Trial of Preoperative Chemotherapy Versus Preoperative Concurrent Chemotherapy and Thoracic Radiotherapy Followed by Surgical Resection and Consolidation Chemotherapy in Favorable Prognosis Patients with Stage IIIA (N2) Non-Small Cell Lung Cancer.” Southwest Oncology Group study coordinators: Drs. H. West., D.R. Gandara, K.S. Albain, L.E. Gaspar, E. Vallieres, P.H. Gumerlock, W.A. Franklin, and Carol Moinpour, **Activation 5/1/05.**

S0414 “Cetuximab Plus Cisplatin, Irinotecan and Thoracic Radiotherapy (TRT) for Locally Advanced (Non-Metastatic), Clinically Unresectable Esophageal Cancer: A Phase II Trial with Molecular Correlates.” Study coordinator: Dr. Charles R. Thomas, Jr. **Activation 5/1/05.**

S0508 “A Phase II Trial of Combination Thalidomide plus Temozolomide in Patients with Metastatic Malignant Melanoma.” Study coordinators: Drs. J.I. Clark, L.F. Hutchins and J.A. Sosman. **Activation 6/1/05.**

S0515 “A Phase II Trial of Standard Dose Cyclophosphamide, Doxorubicin, Vincristine, Prednisone (CHOP) and Rituximab Plus Bevacizumab for Advanced Stage Diffuse Large B-Cell NHL.” Study coordinators: Drs. A. Stopeck, T. Miller, & L. Rimsza. **Activation 6/15/05.**

S0217 “Adjuvant Chemotherapy with Combination of Cisplatin (NSC-119875) and Docetaxel (NSC-628503) After Complete Resection of Locally Advanced (Stage III and IV) Squamous Cell Carcinoma of the Head and Neck (SCCHN).” Study coordinators: Drs. P.C. Neupane, H. Kim, S.K. Williamson and G.H. Yoo. **Activation 7/1/05.**

S0431 “A Phase II Study of Trastuzumab (NSC-688097) in Advanced High-Grade Salivary Gland Carcinoma.” Study coordinators: Drs. M. Kane, R.H. Wheeler, A.K. El-Naggar. **Activation 7/1/05.**

S0435 “A Phase II Trial of BAY 43-9006 (NSC-724772) in Patients with Platinum-Treated Extensive Stage Small Cell Lung Cancer.” Study coordinator: Drs. B.J. Gitlitz and B. Glisson. **Activation 7/1/05.**

S0501 “Nonmyeloablative Allogeneic Stem Cell Transplantation for Relapsed Hodgkin’s or Non-Hodgkin’s Lymphoma After Autologous Transplantation (ABMT Study).” Study coordinators: Drs. S.E. Smith and P.M. Stiff. **Activation 7/1/05.**

CLOSURES

CTSUN/NCIC BR.19 “A Phase III Prospective Randomized, Double-Blind, Placebo-Controlled Trial of the Epidermal Growth Factor Receptor Antagonist, ZD1839 (IRESSA) in Completely Resected Stage IB, II and IIIA Non-Small Cell Lung Cancer.” Southwest Oncology Group study coordinator: Peter F. Roberts. **Permanent Closure effective 4/22/05.**

S9811 “A Phase II Study of Hydroxyurea For Unresectable Meningioma.” Study coordinators: Drs. L. Swinnen and G. Barger. **Permanent Closure effective 6/1/05.**

S0032 “A Phase II Evaluation of Early Oral Estramustine, Oral Etoposide and Intravenous Paclitaxel in Combination With Hormone Therapy in Patients With High-Risk Metastatic Adenocarcinoma of the Prostate.” Study coordinators: Drs. D.C. Smith and M.H.A. Hussain. **Permanent closure effective 6/1/05.**

S0121 “A Phase II Evaluation of Carboplatin, Paclitaxel and Gemcitabine Followed by Concurrent Cisplatin and Radiation Therapy in Patients With Locally Advanced or Recurrent Urothelial Malignancy.” Study coordinators: Drs. U.N. Vaishampayan, M.H.A. Hussain, J.D. Forman and P.H. Gumerlock. **Permanent closure effective 6/1/05.**

S0125 “A Phase II Study of Chimerism-Mediated Immunotherapy (CMD) Using Nonmyeloablative Allogeneic Peripheral Blood Stem Cell Transplantation in Older Patients With Acute Myeloid Leukemia (AML) in First Complete Remission (A BMT Study).” Study Coordinators: Drs. P.A. McSweeney, T. Chauncey, S. Bearman, A. Mohamed and C. Willman. **Permanent closure effective 6/1/05.**

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).” Study coordinators: Drs. S. Martino, K.S. Albain, C. Gotay and D. Coleman, R.N. **Permanent closure effective 6/15/05.**

R9811, “A Phase III Randomized Study of 5-Fluorouracil,

(Continued page 19)



CTSU updates resources for healthcare professionals and public

The Cancer Trials Support Unit (CTSU) has recently updated online clinical trial resources for both healthcare professionals and the public.

By accessing these new pages – “On-line Training/Education for Healthcare Professionals,” and “On-line Training for the Public and Patients” – users can gain easy access to a number of resources developed by the National Cancer Institute. These include parts of the Clinical Trial Education Series, a guide to clinical trials developed by the Coalition of National Cancer Cooperative Groups, and the CTSU eCourse.

For example, research team members can learn how to incorporate clinical trials into their practice and can also fulfill their National Institutes for Health (NIH) human subjects training requirement by accessing and completing a free, Web-based tutorial. Patients and families can find step-by-step information on how to find an appropriate cancer treatment trial.

These new-and-improved educational listings can be found in the following locations:

- **Public Page** (<http://www.ctsu.org>):
Home page (left navigation bar, under “Guides/Training/Processes”)
Patients tab (left navigation bar)
Physicians tab (main section under “Researcher Resources”)
- **Members Page** (<http://members.ctsu.org>):
Education and Promotions tab

Researcher Resources

Patient Resources

Regardless of how much experience you may have in clinical trials, new and even seasoned users of the CTSU can benefit from a number of CTSU-specific resources that have been developed.

eCourse

Perhaps the best introduction to the CTSU and its procedures is the eCourse, an online educational program that introduces and explains the CTSU. It can be accessed from both the Public and Members Web sites by clicking on the eCourse tab along the top of either home page.

CTSU members can find content that is similar to the eCourse but in a different format (plain document with chapters) by reviewing the CTSU Operations Manual. This manual can be downloaded in its entirety or by chapter, and contains information on everything from joining the CTSU to enrolling patients to data submission and everything in between. If you decide to print all or part of the manual, please keep in mind that it is revised and updated every six months, with the new version posted every March and September. The CTSU Operations Manual is located on the Members Web site under the Education and Promotion tab in the section on CTSU Operations Information.

CTSU Process Checklist

For a very practical resource that you can easily post in your work space, we recommend the CTSU Process Checklist. This one-page document provides a step-by-step guide to the CTSU processes, including how to obtain a user name and password, how to select a protocol and get IRB approval, how to register your site to conduct a particular protocol and how to enroll patients. In some ways, it is the contents of the CTSU Operations Manual boiled down to one page of vital information.

The checklist can be found on the Public Web site on the left navigation bar under “Guides/Training/Processes,” and on the Members site under Education and Promotion and CTSU Operations Information.

Help Desk

If all else fails and the resources above, a close look at the protocol and further exploration of the CTSU Web site do not answer your questions, you can always contact the CTSU Help Desk. This resource is available Monday through Friday, 9 a.m. to 7 p.m. (ET), at 1-888-823-5923 or online at CTSUContact@westat.com.

CLOSURES

(Continued from page 18)

Mitomycin-C, and Radiotherapy Versus 5-Fluorouracil, Cisplatin and Radiotherapy in Carcinoma of the Anal Canal.” Southwest Oncology Group Study coordinators: Drs. C.R. Thomas, Jr., and K. Billingsley. **Permanent closure effective 6/27/05.**

S0117. “A Phase II Study of Gemtuzumab Ozogamicin (Mylotarg™) and Standard Dose Ara-C for Patients With Relapsed Acute Myeloid Leukemia (AML).” Study coordinators: Drs. J.E. Godwin, M.R. O’Donnell, D.R. Head, M.L. Slovak and C.L. Willman. **Temporary Closure effective 7/1/05.**

JPR3. “Intergroup (NCIC CTG, CUOG, ECOG, CALGB, SWOG) Phase III Randomized Trial Comparing Total Androgen Blockade Versus Total Androgen Blockade Plus Pelvic Irradiation in Clinical Stage T3 - 4, N0, M0 Adenocarcinoma of the Prostate.” Study coordinator: Dr. Gregory P. Swanson. **Permanent Closure effective 8/31/05.**



Clinical Trials Nurse Mentorship Program Application

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

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:

_____ Do not wish to give this information.
Name: _____
Address: _____
City: _____
State/Zip: _____
E-mail: _____
Best time to contact you: _____

Could your mentor/mentee visit you at your site of practice?
(Circle) Yes No
Could you visit your mentor/mentee at their site of practice?
(Circle) Yes No
Distance willing to travel: _____ miles

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: _____ years _____ months Time involved in clinical trials: _____ years _____ months

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

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

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@karmanos.org

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 have 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)

MAIL TAPES TO:

NAME: _____

ADDRESS: _____ DEPT: _____

CITY: _____ STATE: _____ ZIP CODE: _____

TELEPHONE: (____) _____ AFFILIATION/INSTITUTION: _____

E-Mail: _____ (Circle) Fed Ex or UPS Account # _____

_____ 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. There is a maximum loan period of one month.

SIGNATURE: _____

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

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