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Young Investigators, Class of Spring 2002



Joining Dr. Coltman for a "class photo" are, from left to right: Michele Basche, M.D., The University of Colorado Health Sciences Center; Ana Aparicio, M.D., USC/Norris Cancer Center; Tatjana Koleveska, M.D., Columbia University; and Purvi K. Shah, M.D., University of Rochester.

The Ortho Biotech and Hope Foundation Young Investigators Training Course was conceived in 1999; first class was held in Spring 2000. Since then, there have been five classes and 19 graduates of this innovative and productive program.

The graduates of the Fall 2001 and Spring 2002 classes are hard at work developing and fine-tuning their protocols, while the efforts of their predecessors are already bearing fruit. Drs. Sherry Morgan-Meadows, Jose Cruz, and Raja Mudad were graduates of the Spring 2000 class. Protocols developed by Drs. Morgan-Meadows and Mudad were activated in 2001 while Dr. Cruz's protocol has been tabled.

The four graduates in Fall 2000 were Drs. Ulka Vaishampayan, Syma Iqbal, Tarek Mekhail, and Andy

Jang. Dr. Iqbal's protocol has been approved by CTEP and **S0211**, developed by Dr. Jang, was activated in April 2002.

The Spring 2001 program graduated four more "Young Investigators," Drs. Prakash Neupane, Howard "Jack" West, Melanie Thomas, and Tomislav Dragovich. **S0120**, authored by Dr. West, was activated at the end of 2001 and he has another proposal under consideration. CTEP has approved Dr. Dragovich's protocol; however, they rejected a Letter of Intent submitted by Dr. Thomas.

With six of eleven proposals approved and four of the six activated, we are on the way of building a solid infrastructure of trained young investigators who are excited to play a role in cancer research and patient care. Our thanks are extended to Ortho Biotech for their continued generous support of this program.

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A Letter from the Cancer Control Research Committee

Dull Moments in Dallas? Never!

Gazing idly down from the restaurant atop the 50-story Reunion Tower next to the Hyatt Regency Hotel, you could see the Texas School Book Depository, the grassy knoll, and the curve in Elm Street where John F. Kennedy was shot. Permanently etched in violence by history and a jittery homemade film, the infamous scene was peaceful on this day 40 years later, and from such a height, like an architect's careful model. This was a haunting backdrop to the valuable work of the 2002 Spring Group Meeting that hummed inside the Hyatt in Dallas in April.

Cancer Control Research Committee (CCRC) members brought great enthusiasm to the meetings of the CCRC. Although Chair Dr. Patricia A. Ganz was delayed by interrupted travel, Drs. Carolyn C. Gotay and Carol Moinpour opened the Behavioral and Health Outcomes (BAHO) Subcommittee meeting on time on Thursday night, April 18, welcoming the 40 members and guests and presiding over productive detailed working discussions of 17 active, recently closed and proposed studies involving the Subcommittee. Dr. Ganz surmounted the barriers of air travel and arrived midway through the meeting. She introduced Laura A. Siminoff, PhD, of Case Western Reserve, who delivered an outstanding scientific slide presentation entitled "The Use of Decision Aids to Enhance Communications and Their Potential for Recruitment to Clinical Trials." Dr. Ganz closed the meeting with the sad news that she was retiring after seven years as BAHO Chair and the glad announcement that Dr. Gotay would succeed her as new BAHO Chair. Dr. Ganz expressed her utmost confidence in Dr. Gotay's abilities to lead the Subcommittee and said she looked forward to remaining an active member.

On Friday, April 19, Chair Dr. Regina M. Santella presided over the well-attended Molecular Epidemiology Subcommittee meeting. Dr. Santella led the over 25 members and guests through a productive agenda that included working discussions on the blood collection and a planned molecular epidemiologic program project grant based on the PCPT (**SWOG-9217**); new blood collection for identified cancer cases and priorities for use of the biospecimens, including postponing any access for a number of years, of SELECT (**S0000**); a proposal of Dr. Omer Kucuk to study oxidative stress in SELECT blood DNA; and recent proposals of Dr. Christine B. Ambrosone to study genetic predictors of toxicity and recurrence in breast cancer patients treated on **SWOG-8897** and a leukemia (AML) study funded with Group developmental funds.

Starting a little later on Friday, April 19, Co-Chair Dr. Powell H. Brown subbed for Dr. Gary E. Goodman in chairing the CCRC Chemoprevention Subcommittee meeting, attended by approximately 45 members and guests. Lively exchanges characterized the working discussions that included:

Active studies: **S9917** (selenium in high-grade prostate intraepithelial neoplasia patients), Dr. James R. Marshall, et al; **S9812** (selenium in pre-prostatectomy patients) Dr. Anita L. Sabichi, et al; and SELECT.

Closed studies: **SWOG-9041** (calcium prevention of recurrent colorectal adenomas and second primary carcinoma) Dr. David Z. J. Chu, et al.

Proposed studies: two celebrex proposals in the breast or cervix —**S0212**, and lycopene in pre-prostatectomy patients.

CCRC Chair Dr. Scott M. Lippman presided over the CCRC Open Meeting on Saturday, April 20. After welcoming the 135-145 assembled members and guests, Dr. Lippman made the Committee-wide announcement of Dr. Ganz' retirement as Chair of the BAHO Subcommittee. He expressed the CCRC's profound gratitude for Dr. Ganz' seven years of extraordinary service and warmly welcomed Dr. Gotay as Dr. Ganz' very capable successor.

The CCRC Open Meeting provides three hours of CME credit. Highlights of this informative meeting include:

- * An outstanding keynote address by Dr. David S. Alberts, University of Arizona, entitled "Establishing Networks of Gynecologists, Gastroenterologists, Urologists and Dermatologists for Cancer Chemoprevention Trials in the Southwest Oncology Group—What I Want to Do When I Grow Up."
 - * The Harry E. Hynes CCOP Symposium, Chaired and moderated by Dr. Philip J. Kuebler, featuring a presentation entitled "The CCOPs, NCI and SELECT," by Dr. Lori Minasian of the NCI.
 - * An interactive panel discussion on "Successful Accrual Methodologies for SELECT" by leaders of three CCOPs that are leading the accrual to SELECT. Included were Susan Tuttle, RN, and Dr. James E. Radford, Jr., of Southeast CCC CCOP; Peggy Verrill, RN, BSN, OCN, Vicki Hanneken, RN, and Dr. James L. Wade of Central Illinois CCOP; and Sid Pinkus and Bonnie Bensman, RN, of Dayton CCOP.
- The agenda finished with concise reviews of current business of the CCRC subcommittees.

You'd be crazy to miss tuning in to these pages next issue to see what's brewing for the San Antonio CCRC Open Meeting in October 2002.

Follow-up: **S9917**

In October 2001, the Group DSMC placed **S9917**, "L-Selenium-Based Chemoprevention of Prostate Cancer Among Men with High Grade PIN," on probation because of slow accrual. The peril to and benefits of this important protocol were featured in these pages and a companion article by Dr. Ian M. Thompson, Jr., in the December 2001 *Group Newsletter*. Primary Study Coordinator Dr. Marshall reported to the CCRC in Dallas that accrual was improving (145 registrations as of the meeting) and that re-review by the DSMC had resulted in allowing it to remain open. Dr. Marshall and the CCRC thank everyone who is contributing patients to **S9917** and urge your strong continued support to ensure the study's successful completion.

New Member Nomination Deadline

The next deadline for submitting membership nominations to the Operations Office is **September 27, 2002**. 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.

In order to process a new investigator nomination, all of the following must be received in the Operations Office **by the deadline**:

- Application for New Investigator Form
- Nomination letter from the Principal Investigator
- The nominee's most recent curriculum vitae, stating whether or not the nominee is board certified

- FDA Form 1572 for Group studies
- New investigator pharmacy information
- Affirmation of Integrity Statement
- Purchase Service Agreement (Affiliate investigators only)
- Certification of Education in the Protection of Human Subjects

Incomplete nominations will not be processed until a complete packet is received.

For a complete outline of the nomination process, please refer to Southwest Oncology Group Policy Memorandum No. 7 at the Group's web site (<http://swog.org>). For your convenience, the Application for New Investigator Form can be downloaded and printed.

In Support of Hope

Members of The Hope Foundation Platinum Campaign have provided over \$450,000 in support of Southwest Oncology Group research activities. Platinum members participate in a prize draw-

ing during each Group Meeting; a variety of prizes are featured each time. At each Fall Group Meeting a new Porsche Boxster is awarded to one lucky Platinum member.

The 2002 Spring Group Meeting prize drawing included a Gibson Les Paul guitar, a Nike golf club, and travel tickets and accommodations. To see who won, check out the photos below and on page 18.

For information about The Hope Foundation, go to:

<http://www.thehopefoundation.org>



ABOVE: Dr. William Cathcart-Rake was the winner of a Green Metallic Gibson Les Paul guitar. **RIGHT:** Dr. Marcel Conrad receives a pair of round-trip tickets on Southwest Airlines with Hyatt accommodations in New Orleans. Also victorious that evening was Dr. David Crawford (not pictured) who won a pair of round-trip tickets on Southwest Airlines with accommodations at the Hyatt in San Antonio.



— *In Memorium* —
Dr. Joel A. Childers

Dr. Joel A. Childers was tragically killed in a motorcycle accident earlier this year. Dr. Childers was credited with developing state-of-the-art treatments and surgical techniques that changed the way physicians manage gynecologic cancers today.

He was a Special Member of the Southwest Oncology Group from 1989 to 2000, and while at the University of Arizona, collaborated with Dr. David Alberts.

— **S0002 HAS OPENED** —

**Smoking Cessation Intervention
(Including Bupropion-Zyban® Versus Placebo)
for Completely Resected Stage I and II Non-Small Cell Lung
Cancer Survivors Who are Current Smokers**

The **S0002** protocol is available for review on line. Log on to the Southwest Oncology Group website at: <https://swog.org/members/ClinicalTrials/SearchProtocols.asp?Type=Open>. Note that there are **.7 cancer control credits** for this randomized trial.

If you have any questions regarding:

___ The Smoking Cessation Intervention

Please contact:

Amy B. Lazev, PhD: (713) 792-5781/ ablazev@mdanderson.org

___ Medical Issues

Please contact:

Kathy S. Albain, MD: (708) 327-3102/ kalbain@lumc.edu

___ Data Submission

Please contact:

Camille White: (206) 652-2267/ camillew@crab.org

Abstracts of the Scientific Presentations

at the

2001 Spring Group Meeting Plenary Session

Saturday, April 20, 2002 —Dallas, Texas

Excellent 2-year survival in women with optimally-debulked ovarian cancer treated with intraperitoneal and intravenous chemotherapy: A SWOG-ECOG-NCIC study (S9619)

Mace L Rothenberg, Vanderbilt-Ingram Cancer Center, Nashville, TN; PY Liu, Southwest Oncology Group Statistical Center, Seattle, WA; Sharon Wilczynski, City of Hope Medical Center, Duarte, CA; Patricia S Braly, LSU Medical Center, New Orleans, LA; Scott Wadler, Albert Einstein Medical Center, Bronx, NY; Gavin Stuart, Tom Baker Cancer Center, Calgary, Canada; Edward V Hannigan, U of Texas Medical Branch, Galveston, TX; Albert J Bonebrake, Ozark Regional CCOP, Atlanta, GA; David S Alberts, Arizona Cancer Center, Tucson, AZ; Maurie Markman, Cleveland Clinic Cancer Center; Cleveland, OH.

Women diagnosed with Stage III epithelial ovarian cancer (ov ca) who undergo optimal debulking surgery (≤ 1 cm residual) followed by intravenous (IV) chemotherapy survive a median of 41-52 months and have a 2-year survival probability of 65-70%. Recent studies that integrated intraperitoneal (IP) chemotherapy into front-line therapy reported promising results with median survivals of 49-63 months and 2-year survival rates of 70-80%. S9619 was designed to evaluate the 2-year survival rate and feasibility of a combined IV/IP approach using paclitaxel 135 mg/m² IV over 24 hours (D1-2), cisplatin 100 mg/m² IP (D2), and paclitaxel 60 mg/m² IP (D8) administered q 3 weeks x 6 cycles in women with optimally debulked Stage III ov ca. Sixty-five evaluable women were enrolled in this intergroup Phase II trial. Median age: 53.0 yrs, PS 0-1:97%, histologic grade 2-3: 95%. The 2-year survival rate was 92% (95% CI: 85-99%). Ninety-five per cent of all patients experienced at least one Grade 3-4 adverse event during therapy. The most common Grade 3-4 toxicities were neutropenia (80%), nausea (50%), vomiting (33%), and fatigue/malaise/lethargy (23%). Seventy-one per cent of patients completed all 6 cycles of IV/IP therapy as planned. The most common reason for discontinuation of treatment was toxicity. Those patients unable to complete all 6 cycles of IV/IP therapy due to problems with the IP catheter received the remaining cycles as standard IV cisplatin and paclitaxel. This regimen has gone on to a Phase III trial conducted by the Gynecologic Oncology Group (GOG172) that completed accrual in February, 2001. That trial will help to determine whether the excellent 2-year survival associated with IV/IP paclitaxel and IP cisplatin observed in S9619 translates into a survival advantage for women with optimally debulked Stage III ovarian cancer.

Impact of 12 monthly courses of single agent paclitaxel in patients with advanced ovarian cancer (OC) who attained a clinically-defined complete response to platinum/paclitaxel-based chemotherapy: A Southwest Oncology Group and Gynecologic Oncology Group phase 3 randomized trial

Maurie Markman, Cleveland Clinic Fndtn, Cleveland, OH, PY Liu, Southwest Oncology Group Statistical Center, Seattle, WA, Sharon P Wilczynski, City of Hope National Medical Center, Duarte, CA, Bradley J Monk, UC Irvine Medical Center, Orange, CA, Larry J Copeland, Ohio State University Health Center, Columbus, OH, David S Alberts, University of Arizona Cancer Center, Tucson, AZ

Purpose: We wished to determine if continuing the cycle-specific cytotoxic agent, paclitaxel (PAC), for an extended period of time in patients (pts) with advanced OC who had achieved a clinically-defined complete response (CR) to a platinum/Pac-based regimen could prolong the time of subsequent progression-free survival (PFS) and possibly impact ultimate survival. Method: Pts entered into this trial were randomized to either 3 or 12 cycles of single agent PAC (initially 175 mg/m² over 3 hours) given Q 28 days. Pts were then followed without further therapy and observed for PFS (primary study endpoint) and overall survival. Due to a higher rate of early withdrawal in the 12-cycle arm, due to peripheral neuropathy (PN), the dose of PAC in both arms was reduced to 135 mg/m². Results: As of 9/6/01, 277 pts (262 evaluable), well-balanced for prognostic factors, had entered the trial, with a total of 54 PFS events observed among 22 pts with follow-up data. With the exception of PN there were no major differences in toxicity between the arms. The median PFS was 21 and 28 months in the 3-cycle and 12-cycle PAC arms, respectively. One-sided p values from an unadjusted log rank test and an adjusted Cox model analysis (for stratification factors) were 0.0035 and 0.0023, respectively, both in favor of the 12-cycle arm. The Cox model adjusted 3-cycle vs. the 12-cycle PAC progression hazard ratio was estimated to be 2.31 (99% confidence interval of 1.08-4.94). With a protocol-specified early termination boundary of p=0.005, these findings led the SWOG Data and Safety Monitoring Committee to stop the trial. As of the date of study closure there was no difference in overall survival between the arms. Conclusion: 12 cycles of single agent PAC given to pts with advanced OC who attain a clinically-defined CR to initial platinum/PAC-based chemotherapy significantly prolongs the duration of PFS. Whether ultimate survival of this pt population is improved remains to be determined.

Continued...please turn to Page 6

HLA-A2 and/or HLA-C3 Expression Defines a Subset of T3N0 Melanoma Patients with Improved Overall Survival from Melacine Vaccine: Updated Analysis of SWOG 9035

Jeffrey A Sosman, Nashville, TN; Joseph M. Unger, PY Liu, Seattle, WA; Ray Kempf, Los Angeles, CA; Larry Flaherty, Detroit, MI; Vernon K Sondak, Ann Arbor, MI.

We have previously reported our findings of an association between HLA class I antigens and disease free survival (DFS) of melanoma patients entered on a randomized phase III adjuvant trial of Melacine vaccine versus observation (SWOG 9035). With 553 of 689 (80%) patients serotyped for HLA class I antigens, we found a striking benefit of vaccine in terms of DFS among those patients who expressed ≥ 2 of the 5 antigens HLA-A2, -A28, -B44, -B45 and -C3 (referred to as M5). This effect was based predominantly on HLA-A2 and -C3 expression. The HLA analyses were prospectively planned and were multivariate, adjusted for tumor thickness, site, ulceration, gender, and nodal staging method. We have updated the analysis with 15 months additional follow-up (median 5.6 years). In addition, we have analyzed overall survival (OS) which was not analyzed previously due to data immaturity. Overall, there was no significant effect of vaccine treatment on outcome for the patient population as a whole (eligible or all randomized). However, among patients with ≥ 2 of M5, vaccine patients had better DFS ($p=0.0005$) and better OS ($p=0.01$). Among patients expressing either HLA-A2 and/or C3, vaccine patients also had better DFS ($p=0.004$) and OS ($p=.003$). Outcome for patients on the observation arm was not affected by HLA expression. This updated analysis provides further support for an association of HLA class I alleles and benefit from Melacine. This merits confirmation in a prospective, randomized trial of Malacine in node-negative melanoma patients expressing the HLA-A2 and/or -C3 alleles.

Southwest Oncology Group Trial (SWOG) 9914: Phase II Trial of Paclitaxel, Carboplatin and Topotecan (PCT) in Untreated Patients (Pts) with Extensive Small Cell Lung Cancer (SCLC)

F. Dunphy, P. Hesketh, K. Chansky, D.R. Gandara; Southwest Oncology Group, San Antonio, TX.

To evaluate response (resp), toxicity (tox), and survival (sur) of Pts with extensive SCLC, 82 Pts were treated q 21 days with 6 cycles of paclitaxel 175 mg/m² iv 60 minutes (M) day (D) 4, carboplatin AUC 5 iv 60 M D 4, and topotecan 1.0 mg/m²/D iv 30 M D 1-4; with G-CSF 5 ug/kg/D beginning D 5 until absolute granulocyte count $> 10,000/\mu\text{l}$. Eligible Pts had measurable or evaluable disease, no prior systemic therapy, Performance Status 0-2, adequate organ function. As of November 14, 2001, 82 eligible Pts were entered; 79 evaluable for sur and 75 for tox. Pt characteristics: median age 61 (range, 43-79), men 58%, Caucasian 89%. Sur analysis: Median time to progression (MTTP) was 7 months (mo), median sur (MS) was 12 mo and a 50% 1-year sur was observed. Death from tox was observed in 5/75 (7%): 1 neutropenic infection, 1 dehydration, 2 respiratory infection, 1 not specified. Grade 3-4 tox included: neutropenia 36/75 (48%) but only 4 had febrile neutropenia; thrombocytopenia 33/75 (44%); anemia 11/75 (15%); sensory neuropathy 3/75 (4%); vomiting 9/75 (12%). Conclusion: Compared to SWOG historical trials, S9718 Gemcitabine/Cisplatin (GC) and S9705 Cisplatin/Etoposide/Taxol (PET), the PCT combination exhibited a favorable MS and MTTP without adding toxicity (Table). An impressive 50% 1-year survival was observed for extensive SCLC treated in a cooperative group setting.

	PCT	GC	PET
Number	80	88	88
Grade 4 tox (%)	33	27	39
Toxic Death (%)	7	6	8
MTTP mo	7	5	6
MS mo	12	9	11
1-year sur (%)	50	28	43

Continued...please turn to Page 7

Abstracts of the Scientific Presentations at the 2002 Spring Group Meeting Plenary Session (*Continued*)**SWOG 0004: Pilot Study of Tirapazamine (TPZ) plus Cisplatin/Etoposide (PE) and Concurrent Thoracic Radiotherapy (RT) in Limited Small Cell Lung Cancer (LSCLC)**

QT Le, K Chansky, S Williamson, M Edelman, J Ryu, LE Gaspar, K Chansky, J Crowley, DR Gandara, Southwest Oncology Group (SWOG), San Antonio, TX.

Objective: Tumor hypoxia reduces the efficacy of chemotherapy and RT and promotes malignant tumor progression. TPZ, a novel hypoxic cytotoxin, increases the effectiveness of chemotherapy and RT in both preclinical and clinical studies. PE/RT has been a standard for LSCLC for many years. In this pilot study, we evaluated the feasibility and toxicity of delivering TPZ concurrently with PE/RT in LSCLC, and compared results with the predecessor SWOG trial of similar PE/RT (S9713). Methods: The concurrent phase of therapy consisted of 2 cycles of P (50 mg/m², d1, 8, 29, 36) and E (50 mg/m² d1-5, 29-33) and once-daily thoracic RT (1.8-2 Gy/fx to 61 Gy). TPZ was given at 260 mg/m² 1 hour prior to each cisplatin dose with planned dose escalation in the absence of protocol-defined dose-limiting toxicity (DLT), $\geq 33\%$ esophagitis. Consolidation consisted of 2 cycles of TPZ (330 mg/m²), P (60 mg/m²) and E (120 mg/m², d1-3) on weeks 11 and 14. Patients with a complete response received prophylactic cranial irradiation. Results: 30 patients were enrolled at a TPZ dose of 260 mg/m². Median age: 62. PS (0/1): 16/14. DLT was grade 3-4 esophagitis in 10 of 26 assessable patients (34%). Febrile neutropenia occurred in 14%. There were 2 treatment-related deaths, 1 from neutropenic fever during the concurrent phase and 1 from respiratory infection during consolidation. Preliminary overall response rate from concurrent phase alone was 71%. Major toxicities from the concurrent phase of S0004 and S9713 are compared below. **Conclusions:** 1. DLT was observed at a TPZ dose of 260 mg/m², consisting of esophagitis; 2. TPZ may have increased vomiting and febrile neutropenia; 3. Further study of this TPZ regimen is warranted.

Grade 3-4 toxicities (concurrent phase only)	S0004 (TPZ/PE/RT)	S9713 (PE/RT)
Patients	26	86
Neutropenia	56%	62%
Febrile Neutropenia	14%	7%
Nausea/Vomiting	34%	22%
Esophagitis	31%	23%
Pneumonitis	0%	1%

Adjuvant Chemohormonal Therapy for Primary Breast Cancer Should be Sequential Instead of Concurrent: Initial Results from Intergroup Trial 0100 (SWOG-8814)

Kathy S. Albain, Stephanie J. Green, Peter M. Ravdin, Charles D. Cobau, Ellis G. Levine, James N. Ingle, Kathleen I. Pritchard, Daniel J. Schneider, Martin D. Abeloff, Larry Norton, I. Craig Henderson, Danika Lew, Robert B. Livingston, Silvana Martino, and C. Kent Osborne for SWOG, ECOG, CALGB, NCCTG, NCIC-CTG, Loyola University Medical Center, Maywood, IL.

PURPOSE: Both adjuvant chemotherapy and tamoxifen (T) are of proven value for hormone receptor-positive (R+) breast cancer. But, there are no data regarding the proper timing of these two systemic modalities. Laboratory evidence suggests that T antagonizes the cytotoxicity of certain chemotherapy drugs. Thus, we conducted a phase III trial to determine 1) if CAF+T (oral cyclophosphamide, Adriamycin, 5FU X6; T, 5 years) is superior to T alone in postmenopausal women with node(+), R(+) disease, the results of which were previously reported showing a strong survival benefit for CAF+T; and 2) if CAF followed by T (CAF-T) is superior to concurrent therapy followed by T (CAFT-T), reported herein. METHODS: After stratification by nodes, PgR and interval from surgery, patients were randomized to T, CAF-T, or CAFT-T in a 2:3:3 ratio. One-sided testing at p=.04 was planned for the hypothesis that CAF-T superior to CAFT-T. RESULTS: Of 1477 eligible patients, 361 received T, 566 CAFT-T and 550 CAF-T. Toxicities were similar between CAF-T and CAFT-T. Median follow-up is 8.5 years. At 6 years DFS curves began to diverge. Eight-year DFS estimates are 67% for CAF-T and 62% for CAFT-T, with a one sided p=.045 after adjustment or stratification factors. Both CAF arms are superior to T alone (8-year DFS = 55%). Multivariate analysis showed that 4(+) nodes, PgR(-), T3 tumors and African American race were predictors of adverse DFS. The CAFT-T/CAF-T hazard ratio was 1.18 (.98-1.43) after adjustment for these factors. The survival comparison is currently not significant, but the curves began to separate after 8 years with more late events on CAFT-T than CAF-T. Additional follow-up for survival is required, since due to the strong CAF benefit over T alone, there are fewer events than projected the CAF arms. CONCLUSION: Delaying T until after CAF resulted in an estimated DFS advantage of 18% when compared to the concurrent use of these agents. These data are consistent with the hypothesis that T may antagonize drugs used in this or similar regimens and support a practice standard of starting adjuvant T when chemotherapy is completed.

Continued...please turn to Page 8

Abstracts of the Scientific Presentations at the 2002 Spring Group Meeting Plenary Session (Continued)

Phase III Comparison of Adjuvant Chemotherapy with High-Dose Doxorubicin plus Cyclophosphamide (AC) Versus Sequential Doxorubicin Followed by Cyclophosphamide (A→C) in Breast Cancer Patients with 0-3 Positive Nodes (Intergroup 0137).

Charles M. Haskell, Stephanie J. Green, George W. Sledge, Jr., Charles L. Shapiro, James N. Ingle, Danika Lew, Silvana Martino, Robert Livingston, and C. Kent Osborne for SWOG, ECOG, CALGB and the NCCTG.

BACKGROUND: Chemotherapy efficacy is considered a function of dose intensity (DI). Theoretically, DI is greater with sequential than with concurrent combination chemotherapy. **PURPOSE:** Compare disease-free survival (DFS), overall survival (OS), and toxicity of breast cancer patients with 0-3 positive axillary lymph nodes treated with the same total dose of chemotherapy over 18 weeks using an AC schedule versus an A→C schedule. **METHODS:** Between 4/18/94 and 5/1/97, 3,176 patients were randomized to receive AC or A→C. Both groups were to receive 324 mg/m² of A and 7,200 mg/m² of C iv over 18 weeks with concurrent filgrastim. The D (mg/m²/wk) of AC was 18 of A and 400 of C over 18 weeks. The DI of A→C was 27 of A over 12 weeks and 1200 of C over 6 weeks. **RESULTS:** The groups are well balanced for all prognostic factors; 78 patients are ineligible; median follow-up is 5.2 years. Estimated 5 year DFS is 80% for AC and 81% for A→C (one-sided p=0.15; 627 events). Hazard ratio estimate (HR) for DFS for AC/A→C is 1.09, with 95% confidence interval (CI) (.93, 1.27). The HR for OS (381 events) is 1.07, 95%CI (.88, 1.31). Acute toxicity of A→C was greater than AC, with 88% of AC and 83% of A→C patients completing treatment as planned. Grade 4 hematologic toxicity was more common (p<.00001) with A→C (56%) than with AC (48%), as was Grade 4 emesis (p=0.03). One toxic death occurred (on A→C). **CONCLUSIONS:** These results rule out the 30% improvement in DFS with sequential therapy that the study was designed to detect. A→C caused more acute toxicity than AC, but without greater efficacy at 5 years. We will continue follow-up, but at 5 years AC has a better therapeutic index than A→C.

Induction Chemotherapy Followed by Chemoradiation for Organ Preservation in Patients (Pts) with Advanced Resectable Cancer of the Base of Tongue (BOT) and Hypopharynx (HP).

S. Urba, J Moon, M LeBlanc, J Forman, D Adelstein, P Giri, E Hanna, J Ensley, D Schuller.

The Southwest Oncology Group conducted an organ preservation protocol for pts with Stage III or IV resectable squamous cell carcinoma of the BOT or HP. Pts achieving histologic complete response (HCR) of the primary site were interpreted as having achieved organ preservation. Pts were first treated with 2 cycles of cisplatin 100 mg/m² and 5-fluorouracil 1000 mg/m²/day x 5. Those who achieved a 50% reduction of the primary tumor were treated with concurrent chemoradiation – 180 cGy qd to a total dose of 72 Gy and cisplatin 100 mg/m² q 21 days x 3. Patients with a lesser response underwent surgery. After chemoradiation was completed, those who achieved histologic complete response were observed; those with residual disease were scheduled for surgery. Fifty-nine eligible pts were enrolled: BOT – 38, HP – 21. Across both strata, 59% of evaluable pts were N2-N3, and 68% were T3. Forty-three pts went on to receive concurrent chemoradiation: BOT – 30, HP – 13. There was one Grade 5 toxicity (infection/renal failure) during induction chemotherapy. Grade 4 toxicities (mostly hematologic) occurred in 29% of pts during induction chemotherapy and in 19% of pts during concurrent chemoradiation. After all treatment, 24/38 (63%) of BOT pts, and 9/21 (45%) of HP pts achieved HCR. Estimated 2-year progression-free survival was 66% for BOT pts and 69% for HP pts. Estimated 2-year progression-free survival with organ preservation was 50% for BOT pts and 29% for HP pts. Estimated overall 2-year survival was 76% for BOT pts and 74% for HP pts. This treatment schedule proved feasible within a cooperative group and resulted in a good likelihood of non-laryngeal organ preservation, with excellent progression-free and overall survival.

HAPPY FOURTH OF JULY

Intergroup Trials and the CTSU: New Approaches

Now that the Cancer Trials Support Unit (CTSU) is fully operational, several new approaches are possible for Intergroup trials. In the past, most Intergroup trials were developed jointly by the collaborating Cooperative Groups from the outset. While this approach is still feasible, Cooperative Groups can now elect to “endorse” any trial on the CTSU menu of trials, even if they did not participate in the initial concept development. It is hoped that this option will provide stimulus to increased Intergroup collaboration.

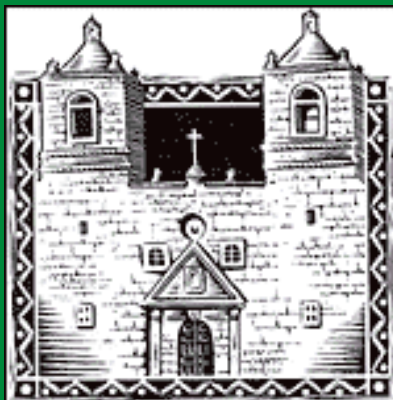
When a Group endorses a trial, a new Co-Chair from that Group is added to the existing protocol team. As agreed upon by the Cooperative Group Chairs, this new Co-Chair will have the same responsibilities and privileges as any Intergroup study co-chair, including participation in the analysis of the study and eventual authorship. Intergroup guidelines will apply regarding authorship. The Co-Chair will be responsible for reporting on the study at Group Meetings and promoting it actively within the Group. Through this Intergroup mechanism the Southwest Oncology Group has added Co-Chairs to **CALGB 40101** (concept), **NSABP B-30**, and **RTOG-98-04**. Also, CALGB added a Co-Chair to **S0003** and ECOG added a Co-Chair to **S9921**.

The availability of the endorsement option will offer Groups greater flexibility to rapidly move their members from one trial to another so downtime between protocols in the Group’s menu is minimized. In addition, the availability of the CTSU will provide a mechanism for Groups to participate in trials in which they have not traditionally performed research. It is hoped that this endorse-

ment option will boost accrual to trials and facilitate the speed with which important research questions can be answered. When Group members participate in these endorsed trials, their Group can still receive credit for the accrual in that disease site, a fact which will prove helpful at the time of NCI grant review. Members also receive credit towards their Group’s membership requirement when they participate in these endorsed protocols.

The other change in Intergroup trials that has recently taken effect relates to procedural mechanisms on new Intergroup trials. While members of the Lead Group for an Intergroup trial will continue to enroll via their Groups, all participating Groups will use the CTSU to complete enrollment procedures and data collection. Although this change will require some modifications for sites, the transition process will, hopefully, be a smooth one. (To avoid confusion, this change will not be retrospective and Intergroup trials currently being conducted using the traditional Group mechanism will not be affected.)

The CTSU offers easy access to protocols, protocol-related forms, and patient educational materials. CTSU-registered members also receive e-mail announcements communicating timely updates regarding protocol activation, closure, and amendments for clinical trials available on the CTSU menu. Use of the CTSU is free of charge to all Cooperative Group members and their research staff. All you need to do is activate your membership by registering at www.ctsu.org or calling 888-823-5923. The CTSU can also be contacted by e-mail at CTSUContact@westat.com.



2002 Fall Group Meeting
Thursday, October 24 – Monday, October 28
Hyatt Regency San Antonio on the Riverwalk
San Antonio, Texas



SOUTHWEST ONCOLOGY GROUP PROTOCOL UPDATE

— from the February 15 through June 1 Mailings —

ACTIVATIONS (Note: No Activations 02/15/02 and 03/15/02 mailings.)

S0120, A Prospective Observational Biologic Study of Asymptomatic Patients With Monoclonal Gammopathy and Plasma Proliferative Disorders. Study Coordinators: Drs. M. V. Dhodapkar, S.R. Wolman, B. Barlogie and J.D. Shaughnessy, Jr. **Activation, 06/01/02.**

S0127, A Phase II Study of OSI-774 (NSC 718781) in Unresectable or Metastatic Adenocarcinoma of the Stomach and Gastroesophageal Junction. Study Coordinator: Dr. T. Dragovich. **Activation, 06/01/02.**

S0207, Phase II Study of Arsenic Trioxide in Patients with Refractory Germ Cell Malignancies. Study Coordinators: Drs. T.M. Beer and C.R. Nichols. **Activation, 04/01/02.**

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

Cancer and Primary Peritoneal Cancer. Study Coordinators: Drs. D.S. Alberts, A. Jang and S. Wilczynski. **Activation, 04/15/02.**

S0218, A Phase II Study of Oral EGFR Tyrosine Kinase Inhibitor OSI-774 (NSC-718781) in Patients with Malignant Pleural Mesothelioma. Study Coordinators: Drs. L.L. Garland and M. Lobell. **Activation, 05/01/02.**

E4697, A Randomized, Placebo-Controlled Phase III Trial of Yeast Derived GM-CSF Versus Peptide Vaccination Versus GM-CSF Plus Peptide Vaccination Versus Placebo in Patients with 'No Evidence of Disease' after Complete Surgical Resection of 'Locally Advanced' and/or Stage IV Melanoma. Southwest Oncology Group Study Coordinator: Dr. K.A. Margolin. **Activation, 03/01/02.**

PERMANENT CLOSURES (Note: No CLOSURES 03/01/02 and 04/01/02 mailings.)

SWOG-9218, Measurement of Biologic and Molecular Tumor Markers In Patients With High Grade Primary Brain Tumors Treated on **SWOG-8737**, Ancillary Study. Study Coordinators: Drs. J. Townsend, J. Holden and K. Jaeckle. **Permanent Closure (effective 04/01/02).**

SWOG-9402 (INT-0149, RTOG 94-02), Phase III Intergroup Randomized Comparison of Radiation Alone Vs. Pre-Radiation Chemotherapy for Pure and Mixed Anaplastic Oligodendrogliomas. Southwest Oncology Group Study Coordinators: Drs. K.L. Fink and H. Sandler. **Permanent Closure (effective 03/29/02).**

SWOG-9450 (T94-0131, PIVOT: CSP #407, VAMC-407), Prostate Cancer Intervention Versus Observation Trial. Southwest Oncology Group Study Coordinator: Dr. D.J. Culkin. **Permanent Closure (effective 11/30/01).**

S0004, A Phase I Study of Tirapazamine/Cisplatin/Etoposide and Concurrent Thoracic Radiotherapy for Limited Stage Small Cell Lung Cancer. Study Coordinators: Drs. Q. Le and S.K. Williamson. **Permanent Closure (effective 04/01/02).**

C9581, Phase III Randomized Study of Adjuvant Immunotherapy with Monoclonal Antibody 17-1A vs. No Adjuvant Therapy Following Resection for Stage II (Modified Astler - Coller B2) Adenocarcinoma of the Colon. Southwest Oncology Group Study Coordinator: Dr. R.L. Martino. **Permanent Closure (effective 5/31/02).**

E2697, Correlation of DNA Damage Index and Clinical Response in the Context of ECOG Trial **E3695**: A Randomized Phase III Trial of Concurrent Biochemotherapy with Cisplatin, Vinblastine, Dacarbazine, IL-2 and Interferon Alfa-2b Versus Cisplatin, Vinblastine, Dacarbazine Alone in Patients with Metastatic Malignant Melanoma. Southwest Oncology Group Study Coordinator: Dr. J.A. Sosman. **Permanent Closure (effective 04/18/02).**

E3695, A Randomized Phase III Trial of concurrent Biochemotherapy with Cisplatin, Vinblastine, Dacarbazine, IL-2 and Interferon a-2b versus Cisplatin, Vinblastine, Dacarbazine Alone in Patients with Metastatic Malignant Melanoma. Southwest Oncology Group Study Coordinator: Dr. L. Flaherty. **Permanent Closure (effective 4/17/02).**

TEMPORARY AND PARTIAL CLOSURES

S0101, Gemcitabine Plus Irinotecan in Patients With Esophageal Cancer, Phase II. Study Coordinator: Dr. S.K. Williamson. **Temporary Closure (effective 1/30/02).**

S0107, A Phase II Trial of Etoposide B Analogue BMS-247550 (NSC #710428) Every 21 Days in Patients with Advanced Pancreas Cancer. Study Coordinator: Dr. R.P. Whitehead. **Temporary Closure (effective 4/15/02).**

N9741, A Randomized Phase III Trial of Combinations of Oxaliplatin (OXAL), 5-Fluorouracil (5-FU) and Irinotecan (CPT-11) as Initial Treatment of Patients with Advanced Adenocarcinoma of the Colon and Rectum. Southwest Oncology Group Study Coordinator: Dr. S.K. Williamson. **Partial Closure (Arm G) (effective 03/15/02).**

N9741, A Randomized Phase III Trial of Combinations of Oxaliplatin (OXAL), 5-Fluorouracil (5-FU) and Irinotecan (CPT-11) as Initial Treatment of Patients with Advanced Adenocarcinoma of the Colon and Rectum. Southwest Oncology Group Study Coordinator: Dr. S.K. Williamson. **Partial Closure (Arm A) and Amendment (effective 4/23/02).**

N9831, Phase III Trial of Doxorubicin and Cyclophosphamide (AC) Followed by Weekly Paclitaxel With or Without Trastuzumab as Adjuvant Treatment for Women With HER-2 Overexpressing Node Positive Breast Cancer. Southwest Oncology Group Study Coordinator: Dr. S. Martino. **Partial Closure – Arm C (effective 1/28/02).**

Manuscripts and Abstracts Published

January 28 — May 30, 2002

The publications listed below are those that have been received in published form by the Operations Office Publication Specialist.

MANUSCRIPTS PUBLISHED SINCE LAST NEWSLETTER (February 2002)

- 8819** Expression of vascular endothelial growth factor and its receptors in hematopoietic malignancies. WT Bellamy, L Richter, Y Frutiger, TM Grogan. Cancer Research 59(3):728-733, 1999.
- 8829** Phase II trial of amonafide in central nervous system tumors: a Southwest Oncology Group study. SA Taylor, C Rankin, JJ Townsend, JB Craig, RB Vance, DL Solank, TD Brown, K Jaeckle. Investigational New Drugs 20:113-115, 2002.
- 9035** Adjuvant immunotherapy of resected, intermediate-thickness, node-negative melanoma with an allogeneic tumor vaccine: Impact of HLA class I antigen expression on outcome. JA Sosman, JM Unger, PY Liu, LE Flaherty, MS Park, RA Kempf, JA Thompson, PI Terasaki, VK Sondak. Journal of Clinical Oncology 20(8):2067-2075, 2002.
- 9111** Implications of microscopic satellites of the primary and extracapsular lymph node spread in patients with high-risk melanoma: pathologic corollary of Eastern Cooperative Oncology Group trial E1690. UNM Rao, J Ibrahim, LE Flaherty, J Richards, JM Kirkwood. Journal of Clinical Oncology 20(8):2053-2057, 2002.
- 9210** Maintenance therapy with alternate-day prednisone improves survival in multiple myeloma patients. JR Berenson, JJ Crowley, TM Grogan, J Zangmeister, AD Briggs, GM Mills, B Barlogie, SE Salmon. Blood 99(9):3163-3168, 2002.
- 9217** Dietary supplement use in the prostate cancer prevention trial: implications for prevention trials. ML Neuhouser, AR Kristal, RE Patterson, PJ Goodman, IM Thompson. Nutrition and Cancer 39(1):12-18, 2001.
- 9331** Prediction of node-negative breast cancer outcome by histologic grading and S-phase analysis by flow cytometry: An Eastern Cooperative Oncology Group study (2192). DL Page, R Gray, DC Allred, LG Dressler, AK Hatfield, S Martino, NJ Robert, WC Wood. American Journal of Clinical Oncology 24(1):10-18, 2001.
- 9505** A phase II trial of pyrazine diazohydroxide in patients with disseminated malignant melanoma and no prior chemotherapy - a Southwest Oncology Group study. RP Whitehead, JM Unger, LE Flaherty, EH Kraut, GM Mills, CE Klein, RA Chapman, GC Doolittle, N Hammond, VK Sondak. Investigational New Drugs 20:105-111, 2002.
- 9509** Quality of life in advanced non-small cell lung cancer: results of a Southwest Oncology Group randomized trial. CM Moinpour, B Lyons, PK Grevstad, LC Lovato, J Crowley, K Czaplicki, ZM Buckner, PA Ganz, K Kelly, DR Gandara. Quality of Life Research 11:115-126, 2002.
- 9518** Phase II trial of topotecan by continuous infusion in patients with advanced soft tissue sarcomas, a SWOG study. GT Budd, C Rankin, LF Hutchins, L Wong, PJ Petruska, K Antman. Investigational New Drugs 20:129-132, 2002.
- S9803** The evaluation of gemcitabine in resistant or relapsing multiple myeloma, phase II: a Southwest Oncology Group study. JK Weick, JJ Crowley, MA Hussein, DF Moore, B Barlogie. Investigational New Drugs 20:117-121, 2002.
- Multiple Studies** Cross-tool communication: from protocol authoring to eligibility determination. JH Gennari, D Sklar, J Silva. Journal of the American Medical Informatics Association Symposium Suppl:199-203, 2001.
- Multiple Studies** PK11195, a peripheral benzodiazepine receptor ligand, chemosensitizes acute myeloid leukemia cells to relevant therapeutic agents by more than one mechanism. DE Banker, JJ Cooper, DA Fennell, CL Willman, FR Appelbaum, FE Cotter. Leukemia Research 26:91-106, 2002.
- Multiple Studies** Vascular endothelial cell growth factor is an autocrine promoter of abnormal localized immature myeloid precursors and leukemia progenitor formation in myelodysplastic syndromes. WT Bellamy, L Richter, D Sirjani, C Roxas, B Glinsmann-Gibson, Y Frutiger, TM Grogan, AF List. Blood 97(5):1427-1434, 2001.

ABSTRACTS PUBLISHED SINCE LAST NEWSLETTER (February 2002)

- 7827** Adjuvant chemo and endocrine therapy for node positive breast cancer. 15 year results of Southwest Oncology Group (SWOG) study 7827. SE Rivkin, S Green, SJ Altman, JJ Costanzi, AB Cruz, C Giarritta, WR Jewell, RM O'Bryan, CK Osborne. Breast Cancer Research and Treatment 69(3):249, (#252), 2001.
- 8819** Biological response to thalidomide in remitting patients with myelodysplastic syndrome (MDS): evidence for induction of neoplastic vascular endothelial growth factor (VEGF) resistance. AF Baker, WT Bellamy, BJ Glinsmann-Gibson, R Heaton, A Buresh, TM Grogan, AF List. Blood 98(11):353a, (#1490), 2001.
- 8819** Failure of beta-globin gene detection does not predict non-amplification of DNA in JH/Bcl-2 PCR analysis: insights from a national follicular lymphoma clinical trial. G Fan, RM Braziel, T Grogan. Modern Pathology 15(1):240a (#1002), 2002.

Continued...please turn to Page 12

Manuscripts and Abstracts Published (continued)

- 8819** Gene expression profiling in laser microdissected normal follicular mantles, mantle cell lymphoma (MCL), and blastoid variant of mantle cell lymphoma. S de Vos, U Krug, WK Hofman, GS Pinkus, SH Swerdlow, W Wachsman, T Grogan, C Yue, HP Koeffler, JW Said. Modern Pathology 15(1):237a (#991), 2002.
- 9041** Adenoma recurrences after resection of colorectal carcinoma (CRC). Results from the SWOG 9041 calcium chemoprevention pilot study. D Chu, K Chansky, C Fonoglio-Preiser, D Alberts, R Meyskens, G Goodman, S Lippman. Annals of Surgical Oncology 9(1) Suppl:S24 (#52), 2002.
- 9133** A phase III randomized intergroup trial of subtotal lymphoid irradiation versus doxorubicin, vinblastine, and subtotal lymphoid irradiation for stage IA-IIA Hodgkin's disease (SWOG 9133, CALGB 9391). OW Press, M LeBlanc, A Lichter, TH Wasserman, J Unger, T Miller, RI Fisher. Leukemia & Lymphoma 42 (Suppl 2):52 (#P-089), 2001.
- S9626** Double blind phase III trial of placebo (P) vs. megestrol acetate (MA) 20 mg vs. MA 40 mg as treatment for symptoms of ovarian failure in breast cancer survivors: Initial results of Southwest Oncology Group S9626. JW Goodwin, SJ Green, S Giarritta, JK Giguere, K Hoelzer, J Bearden, RB Livingston, J Gralow, PA Ganz, S Martino, KS Albain. Breast Cancer Research and Treatment 69(3):292, (#462), 2001.
- S9701** Phase 3 randomized trial of 12 versus 3 months of single-agent paclitaxel in patients with advanced ovarian cancer who attained a clinically-defined complete response to platinum/paclitaxel-based chemotherapy, a Southwest Oncology Group and Gynecologic Oncology Group trial. M Markman, PY Liu, S Wilczynski, BJ Monk, L Copeland, D Alberts. Gynecologic Oncology 84:479 (#1), 2002.
- S9812** Selenium accumulates in prostate tissue of prostate cancer patients after short-term administration of I -selenomethionine. AL Sabichi, JJ lee, RJ Taylor, IM Thompson Jr, BJ Miles, JW Basler, LL Platera, M Wargo, D Menter, CM Tangen, ED Crawford, SM Lippman. Proc of the American Association for Cancer Research 43:1007 (#4993), 2002.

CRA OPEN FORUM UPDATE

Amalia Rincon, CTR, CCRP, and Linda Balla, CTR, CCRP, would like to thank all those who attended the CRA Open Forum during the 2002 Spring Group Meeting in Dallas. Overall, attendance at the Open Forum was down at this meeting with only 153 contacts. For those of you who could not make it, topics presented included "Time Management Tools," with a total of 17 people in attendance; "Basic Pathology" and how to read pathology reports, with 15 people in attendance; "Surviving the IRB Process," also with 15 people in attendance; and a table on TNM staging of breast cancer. Other topics included a table dealing with how to complete Southwest Oncology Group forms, how to prepare for an Audit, and when and how to report SAE's.

As a result of the upcoming Southwest Oncology Group grant renewal, the CRA Committee is working on a way to show some type of verification that the services we provide through the different CRA subcommittees are serving the needs of the Group. One way of doing this is through the use of evaluation forms. However, since only 2 people filled out the evaluation form, this committee will be randomly sending special evaluation forms to those who attended the CRA Open Forum. We ask your cooperation in completing these forms and returning them as soon as possible. We hope to use the results to provide documentation that

the roundtables are a valid means of communication. We will also use this information in an attempt to obtain SoCRA and Nursing credits for attending the roundtables.

New topics we are working on for the October meeting include a roundtable dealing with tumor markers, a table on how to evaluate Lymphoma response, a table on Statistical Center issues, a table on Data Coordinator issues, and a table on how to make a poster. If you would like to volunteer as a facilitator or have a suggestion for a topic, please don't hesitate to contact us by e-mail. **I can be reached at arincon@mednet.ucla.edu. Linda can be reached at linda.balla@ucdmc.ucdavis.edu.**

In conclusion, we would like to give special thanks to the American Cancer Society for their continued participation at the Open Forum. A big thank you is also extended to all the facilitators who donated their time and expertise so others can benefit. A final thank you is extended to Dennis Dominguez of Pharmacia Oncology for providing us with refreshments.

Remember that this is your committee, it is through your participation and involvement that we will continue to flourish as professionals. Thank you and see you at the 2002 Fall Group Meeting in San Antonio. Remember to look in your registration packet for a full Agenda of what we have in store for you!



Pharmacy Committee Notes

Membership Application Information

You are invited to join us! All applications for membership in the Pharmacy Committee should be addressed to Group Chair Dr. Charles A. Coltman, Jr., at the Southwest Oncology Group Operations Office. The application must include a letter of recommendation from the Principal Investigator of the institution **and** the curriculum vitae of the applicant. For pharmacists who are already Group members, a letter of interest in joining the Pharmacy Committee may be sent directly to Dr. Siu-Fun Wong or to Dr. Coltman.

Welcome To Our New NCI Pharmacist Liaison

The Pharmacy Committee wishes to welcome our new National Cancer Institute pharmacist liaison, Mr. Matthew Boron. We also wish to send Dr. Aiman Shalabi our best wishes and sincere appreciation for his support and contribution to the Pharmacy Committee.

Disease Committee Pharmacist Liaisons

Pharmacist liaisons have been attending various disease committees at the Southwest Oncology Group Meetings. We are looking for more pharmacist liaisons. If you attend the Group Meetings on a regular basis and are interested in being a pharmacist liaison, please contact Dr. Siu-Fun Wong.

Investigational Drug Handling Workshop

The workshop will continue to be offered at future group meetings. A new schedule is being considered at this time. Please look for an announcement before the next Group Meeting and mark your calendar.

What's Happening?

In addition to participation in various education programs, disease committees, and protocol drug information, we are working on obtaining Continuing Education accreditation for pharmacists, patient education monographs, investigational agents extravasation policy and procedures, and a Pharmacy Committee Reference Manual. Got any good ideas? Call us.

Working Group Roster:

Siu-Fun Wong, PharmD – Chair of Pharmacy Committee (909)469-5591

Keith Wagner, RPh – Chair of Drug Information Subcommittee (808)833-0808

Matthew Boron, RPh – NCI Pharmacist Liaison (301)496-5725

Suzie Rosendahl, RPh – Investigational Drug Handling Workshop (814)838-9000

Gerry Migaki, RPh (503)216-7913

Larry VanHole, RPh (970)244-1910



ON-LINE Pre-Registration for Group Meetings
The ONLY Way To Go! No Other Options Available

The final count is in! Attendance at the 2002 Spring Group Meeting in Dallas, Texas was **1,171**. The popularity and ease of registration was clearly demonstrated by the approximately 1,000 Group Members who registered on-line through the Group web page. Most people registered during the day while at work, but others took advantage of the 24/7 availability and registered at night and on weekends.

Conversion to on-line registration began with the Spring 2000 Group Meeting. For two years the web site and the on-line registration process were fine tuned; on-line registration is not limited to just the Group Meeting, but now includes the many individual workshops and events within the Meeting.

The conversion is now complete! During the conversion period, we accepted registrations by fax or mail. **As of the 2002 Fall Group Meeting, pre-registration to the Group Meeting and all meetings and workshops within the Group Meeting, is to be accomplished through the Southwest Oncology Group web site; no fax or mailed registrations will be accepted.** The

Group Meeting Web Registration will be activated on August 20 and close at noon on October 18. Also on August 20, the tentative Group Meeting Schedule will be posted along with The Group Newsletter. On-site registration to the **Group Meeting** will be available at the Group Meeting Registration and Information Desk, beginning October 24.

For your convenience, here are a few tips that will help facilitate your successful registration:

1. Always click on "Submit your registration" to complete the process. When that step is missed, your registration is not recorded.
2. Print your confirmation page and keep a copy for future reference.
3. On some computers, the "continue" button is below the screen; be sure to scroll down to the bottom of the page in order to be certain you have provided all necessary information.
4. Do not register using another person's Roster ID#. The system will not accept any changes you enter. Follow the on-screen steps to obtain a Roster ID# if you do not have one.



Operations Office Staff News

This April, **William Coker** was promoted from Quality Assurance/SAE Assistant/Auditor to Quality Assurance Auditor. William joined the Operations Office in July 2001.

Loretta (Lorey) Shrader has joined the Operations Office staff as Meetings Planner. Lorey is a transplant to San Antonio from Washington, DC, where she planned meetings and provided research support for a healthcare consulting agency.

Prior to joining the Operations Office staff this past April as Protocol Coordinator, **Gretchen Jackson** worked as a research associate at the UT Health Science Center and at Brown University. Her Committee responsibilities include the GI and GYN committees; additionally, she is the Surgery Designate.

Statistical Center Staff News

Two new employees joined the Data Operations Center this past March. We welcome **Kelly Balch** and **Christine McLeod**. Kelly joins us as a Data Processing Specialist and Christine as a Data Control Technician.

Two of our statisticians, **Sheryl (formerly Giarritta)** and **Jason McCoy**, were married in February. Please join us in congratulating them.

Larry Kaye, one of our Data Control Technicians, has been promoted to Data Coordinator. Larry will be a definite asset to the Head and Neck and the Melanoma committees.

Mark Blitzer has joined the Administration Team as Administrative Coordinator replacing long time staff member Anita Pang. Mark comes to us from the Fred Hutchinson Center Finance Department.

Beth Callentine joined the PCPT Statistical Center staff in January as a Data Control Technician. She is a recent graduate of Seattle Pacific University where she received a Bachelor of Arts degree in Music.

- In Memorium -

It is with not only great sadness and reflection, but also celebration of life that the Statistical Center announces the passing of staff member **Linda Marie Joos**. Linda, a data entry technician since 1997, passed away peacefully on Saturday, April 27, from islet cell pancreatic cancer. Linda will be missed for many reasons, including her charm, grace, wit, and unrelenting commitment to her work.

A Linda Haiku

*A faithful colleague
With subtle wit and smile
Surely, to be missed*

*Larry Kaye,
SWOG Data Coordinator*

— IMPORTANT SOUTHWEST ONCOLOGY GROUP ADDRESSES —

— Operations Office —

Southwest Oncology Group Operations Office

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

— Statistical Center —

Southwest Oncology Group STATISTICAL CENTER

Fred Hutchinson Cancer Research Center • 1100 Fairview Avenue North, MP-557 • P. O. Box 19024 • Seattle, WA 98109-1024

Phone: 206-667-4623 • FAX: 206-667-4408

For Quick Delivery, send Express letter/packages to:

Southwest Oncology Group Statistical Center • 1730 Minor Avenue, 2nd Floor • Seattle, WA 98101

CANCER RESEARCH & BIOSTATISTICS (CRAB)

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

PROSTATE CANCER PREVENTION TRIAL (PCPT)

Southwest Oncology Group Statistical Center

Fred Hutchinson Cancer Research Center

1100 Fairview Avenue North, MP-651

P. O. Box 19024

Seattle, WA 98109-1024

Phone: 206-667-6868 FAX: 206-667-6869

SELENIUM and VITAMIN E

CANCER PREVENTION TRIAL (SELECT)

1100 Olive Way, Suite 1150, Seattle, WA 98101-1892

Deliveries: 1100 Olive Way, Suite 1470, Seattle, WA 98101-1892

Phone: 206-652-1338 Correspondence Fax: 206-652-1339

Fax Data Submission: 888-652-2940 or 206-829-1726

DATA OPERATIONS CENTER at CRAB:

Data Operations Center c/o Cancer Research and Biostatistics • 1100 Olive Way, Suite 1150 • Seattle, WA 98101

PHONE: 206-652-2267 **FAX:** 206 839-1760 or 206-652-4612

Delivery (FedEX, UPS, etc.):

SWOG Data Operations Center • c/o Cancer Research & Biostatistics • 1100 Olive Way, Suite 1470 Seattle, WA 98101

Put These GROUP MEETING Dates On Your Calendar!

2002

— October 2002 —
Thursday, October 24
through
Monday, October 28
Hyatt Regency San Antonio
on the Riverwalk
San Antonio, Texas

2003

— April 9-13, 2003 —
Hyatt Regency San Diego
San Diego, California

— October 1-5, 2003 —
Sheraton Seattle Hotel & Towers
Seattle, Washington

Special Thanks
for Educational Grants in support of the
Spring 2002 Group Meeting
in Dallas, Texas

PATRON Aventis Oncology GlaxoSmithKline **Centurion**

Genentech, Inc.
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Schering Oncology/Biotech
Super Gen

Supporter

AstraZeneca
Chiron Therapeutics
EMD Pharmaceuticals
IDEC Pharmaceuticals
Maxim Pharmaceuticals, Inc.
MedImmune Oncology, Inc.
MGI Pharma
Oncotech
Titan Pharmaceuticals
Wyeth Pharmaceuticals

Southwest Oncology Group Audits & Consent Documents

Southwest Oncology Group Quality Assurance Coordinator Elaine Armstrong reported at the Head CRA meeting that there have been recent changes in the audit system. A new mandate from the NCI requires that unannounced cases will now be reinstated at site visits. This will involve a limited review of eligibility and consent. The requirement will be for member and CCOP institutions as well as affiliates.

The NCI is also requesting an on-site review of pharmacies for all institutions. This will occur at least once every other site visit. The Southwest Oncology Group requires that IRB review include follow-up protocols as well as open and active studies. All consent forms (including older studies that are still open) must comply with current regulatory elements. The FDA mandates that version dates, or another method of identifying the most current version, must be added to the informed consent.

All protocol modifications that require full board review will now have a reason checked on the amendment cover sheet. The reasons for full board review include: increased risk to patient, complete study redesign, addition of tissue banking requirements, and study closure not built into study design. In addition, protocol modifications requiring full board review must go through the IRB within 90 days.



Holiday Schedule for Operations Office Statistical Center & all CRAB offices

INDEPENDENCE DAY

Thursday, July 4, 2002

LABOR DAY

Monday, September 2, 2002

All CRAB offices
Day After INDEPENDENCE DAY
Friday, July 5, 2002

IMPORTANT NOTICE from the SARCOMA COMMITTEE regarding S0033 OUTSTANDING DATA

From: SWOG Sarcoma Committee
Regarding: S0033

**S0033 - "Phase III Randomized, Inter-
group Trial Assessing the Clinical Ac-
tivity of STI-571 at Two Dose Levels in
Patients with Unresectable or Metastatic
Gastrointestinal Stromal Tumors (GIST)
Expressing the KIT Receptor Tyrosine
Kinase (CD117)"** is undergoing prepara-
tions for the final analysis.

This is by far the biggest trial for GIST and it is extremely important that all outstanding data, queries and overdue follow-up be submitted to the Southwest Oncology Group Data Operations Center by July 31, 2002.

We are accepting data faxed to:
206-652-4612

and addressed to **Stephanie Edwards** using the **CRAB fax cover sheet** (downloaded at www.crab.org).

We greatly appreciate your cooperation.

*Southwest Oncology Group
Sarcoma Committee*



Southwest Oncology Group Nurse Oncologist Committee

The Chair's NOTES

The Nurse Oncologist Committee (NOC) has had a busy six months during which new programs have been in development. The *Quality of Life* liaison program is from the Research subcommittee and a *Mentorship* program for new RNs is a collaborative effort between the Disease/Discipline subcommittee and the ONS Clinical Trials SIG.

At the 2002 Spring Group Meeting in Dallas, a new NOC presentation was "**Research 101.**" This presentation by Maggie Ramsey, co-chair of the Research subcommittee, was such a success that it will be a regular presentation. This summer the NOC is participating in a "Nursing Research in the Cooperative Groups" summit sponsored by CALGB.

After reading about the multiple ongoing projects, CONTACT one of us and become an active member of our team:

Marcia Grove-Conrad, Chair & CWSP liaison	251-435-3941
Lisa Hansen, Vice-chair & Cancer Control liaison	503-413-6285
Linda Davis, Sec. & Lay Advocates liaison	313-745-2188
Dorothy Coleman, Co-chair Education subcommittee	808-586-2979
Rose Ermete, Co-chair Program subcommittee	313-593-8090
Marge Good, CCOP liaison & RAC chair	316-268-5784
Patra Grevstad, Chair Membership subcommittee	206-386-2442
Karen Mack, Co-chair Program subcommittee	501-296-1502
Maggie Ramsey, Co-chair Research subcommittee	504-585-6062
Carolyn Schmidt, Co-chair Disease/Discipline subcmte ..	313-916-7277
Anna Schwartz, Co-chair Research subcommittee	503-494-8167
Deb Ward, Co-chair Disease/Discipline subcmte	313-993-0965
Pam Williams, Co-chair Education subcommittee	864-560-6812

Membership Report

The Nurse Oncologist Committee would like to welcome the following new members: Janet Bloch, RN, MS, ANP, OCN, Charleston, South Carolina; Cynthia Molnar, RN, MSN, Louisiana State University; Shirley Raltz, RN, MSN, Swedish Cancer Institute; and Teresa Taton, RN, OCN, Patricia Bluml, RN, ARNP, Elsie Dalziel, RN, OCN, Marta Guerrero, RN, Cheri Hartman, RN, BSN, Lisa Schmidt, RN, BSN, Patricia Stone, RN, OCN, and Kimberly Keller, RN, BSN, all from Wichita CCOP. The Nurse Oncologist Committee now has 119 members.

Committee on Women and Special Populations Liaison Report

A report on "Survivorship Statistical Data" was shared with the committee. This data will appear in two or more future publications. Nursing researchers and co-chairs of the NOC Research subcommittee are *investigators* on two separate studies from this committee. Anna Schwartz, PhD, has an ancillary study to Lung **S0023** dealing with an "exercise intervention" during the maintenance therapy phase. Maggie Ramsey, MSN, AOCN, is an investigator on the "Barriers to Participation" study that is a survey pilot study in five institutions. Dr. Schwartz will be the featured speaker at the *Scientific* session for this committee at the 2002 Fall Group Meeting. The CWSP has new projects in development that address different women's issues of toxicity and/or side effects of treatment as well as the study related to GYN **SWOG-8501** participants.

Cancer Control Nurse Liaison Report

The Cancer Control Research Committee meeting included a presentation from long-time Southwest Oncology Group cancer prevention scientist, David S. Alberts, MD. Dr. Alberts summarized cancer prevention trials and the networks established by The University of Arizona Cancer Center with area subspecialists and primary care physicians. Successful strategies for partnering with gynecologists, gastroenterologists, and internists were shared by several CCOP members as well. Minimizing extra workload for busy PCP practices and having mobile research nurse units were consistently recognized as valuable to cancer control accrual. The Harry E. Hynes Memorial CCOP Symposium provided useful information to CCOPs via Dr. Lori Minaian's discussion of NCI priorities under the new NCI Director, Dr. Andrew von Eschenbach. A panel of highly successful CCOPs shared their secrets for high accrual on the SELECT trial.

The Chemoprevention Subcommittee has several new studies in development that include COX-2 inhibitors. News from the Molecular Epidemiology Subcommittee focused on molecular studies on specimens from PCPT and SELECT. Institutions were strongly encouraged to submit the WBC samples from PCPT participants as the scientific value of the biologic companion trials to PCPT are of extreme importance for future research in prostate cancer prevention.

The Behavioral & Health Outcomes Subcommittee expressed heartfelt appreciation for the extensive contribution of outgoing Chair, Patricia Ganz, MD. Carolyn Gotay, PhD, has accepted the chairmanship. Several Quality of Life trials are closed and data is being analyzed. Dr. Ganz encouraged institutions with long-term patients on the early stage Hodgkin's Disease trial, **SWOG-9133**, to continue working to contact patients for the quality of life assessments. Training sessions were offered at the Group Meeting for **S9908** (Glutamine vs. Placebo for Radiation-Induced Mucositis in Head & Neck Cancer Patients) and **S0002** (Smoking Cessation in Non-Small Cell Lung Cancer). The "Nicalert" strips designed to detect salivary cotinine levels are now available to send to institutions.

Disease and Discipline Committee

A decision was made that liaisons would serve as quality of life coordinator for studies being conducted within their disease/discipline. Rose Ermete will continue development of a Mentorship program. A Brain Committee liaison position remains available.

Education Subcommittee

Seven nurses attended the Nurse Oncologist Education Subcommittee. New nurses were urged to submit membership applications to the Nurse Oncologist Committee. Three posters were submitted by nurses for the Group Meeting. Posters and newsletter were discussed by Marge Good, CCOP Subcommittee Chair.

Pam Williams, Co-Chair of the Pharmacy/Nursing Subcommittee, announced that three new drug monographs were approved at the meeting and seven monographs are pending. All drug monographs will be reviewed every two years. All updates will be posted on the web. An ongoing collaboration between the Clinical

Continued...please turn to Page 18

Southwest Oncology Group Nurse Oncologist Committee *(Continued from page 17)*

Research Associates (CRA) Committee and the Nurse Oncologist Committee called Partnership for Life continues. A subcommittee made up of CRAs, nurses plus a Pharmacia representative have met and edited the Partnership for Life brochure. Once finalized, it will be submitted to the Operations Office for review.

Dorothy Coleman, Co-Chair of the Nurse Oncologist Education subcommittee announced that the nursing manual will be updated in October on an annual basis. Updates will be placed on the web. Other projects, i.e., auditing, tools, were discussed.

Research Committee

There was a good attendance and reception to RESEARCH 101. The program will be continued at the next meeting. The program will also be put on a disc so others can teach the course. There are plans to make it a regular feature, just like the BSE program. The regular research subcommittee meeting may become a Quality of Life liaison meeting. There will be more discussion in the Fall concerning this.

Program Committee

The Nurse Oncologist Workshop "Conducting QOL Studies in the Cooperative Group Setting" was attended by 105 nurses and CRAs. Presentations covered a variety of topics related to quality of life studies as well as a drug update. Many positive comments were received for Carolyn Gotay's keynote address. The Oncology Nursing Society and the Society of Clinical Research Associates awarded continuing education credits for the program.

CCOP Nurse Subcommittee

The meeting was focused on the presentation of information received as a result of the CCOP Nurse/CRA survey. Please see related article in this newsletter.

After the survey results were reported discussion was focused on areas of the survey to focus attention. Many present were interested in a patient satisfaction tool. Areas to focus the tool on should include if the education received was understandable, was the treatment started in a timely manner, did they feel they had consistent availability of research staff, did they feel it was a benefit for them to participate in a clinical trial, what were some advantages/disadvantages, and with whom did you feel you had the most contact. Other areas to focus included sharing the research base forms information with the appropriate research bases. Vicki Green did report that the Group is doing away with flow sheet reporting which will simplify reporting as new trials are activated. Discussion was also held regarding the need for standardization of forms across bases. This will be a continued discussion at future meetings.

Members present will evaluate patient satisfaction tools and report to Marge Good who will present them at the Fall Group Meeting. Steps will then be taken to evaluate the possibility of conducting CCOP wide patient satisfaction assessments. If anyone has a currently available patient satisfaction tool or knows of a tool please contact Marge Good at (316)268-5696 or by e-mail at marge_good@via-christi.org.

More Hope Foundation Prize Winners!



From the Top:

Platinum Prize winner Nickey McCasland, RN, MHA, couldn't believe his good fortune! He was the winner of the new Nike Tour Driver, the same club purported to be used by a guy with the improbable name of Tiger.

Susan Schulman, CCRA, won a pair of round-trip tickets on Southwest Airlines as part of the Hope Foundation CRA/Nurse/Ops/Stat Center Campaign. Additional winners in this drawing were Debbie Hensley, RN, and Nannette Thomas, RN.

CCOP Nurse/CRA Survey Results Are In!!

A recent survey of CCOP nurses and CRAs was conducted as a means of assessing various aspects of clinical trial job roles being conducted within the CCOP system, as well as to evaluate satisfaction variables related to various research base generated data forms. The survey was a 37-item questionnaire that was distributed via the CCOP Administrators List Serve in March 2002. Administrators dispersed the survey to their nurses and CRAs that were "out in the field" conducting daily clinical trial activities. The survey had 4 items related to demographic information, 9 CCOP specific questions, 5 consent related questions, 2 clinical trial approval related questions, 2 job training related questions, 8 research base related questions and 3 reimbursement issue questions. Eighty (80) surveys were returned and tabulated.

Over half of those reporting indicated they were nurses (69%); 35% were OCN/AOCN, 34% were BSN, 23% were CRA, 20% were CCRA, and 5% were MSN. A majority verify patient eligibility as a portion of their job (99%), 94% register patients to trials, 91% complete data forms, 86% participate in the informed consent process, 76% recruit patients to cancer control trials and 73% recruit patients to treatment trials. Sixty-seven (67%) reported writing chemotherapy and protocol treatment orders, 56% maintain drug accountability, 49% order study drug supplies, 39% assist in getting reimbursement/free drug for patients going on clinical trials, 24% verify insurance coverage, 18% do administrative work (grant writing, budget, etc) and IRB preparation/regulatory oversight. Only 10% actually administer chemotherapy.

Most of those reporting have been in their current position for 2-5 years (49%), 21% had been in their current position for < 1 year as well as 21% reported being in their position for > 10 years, and 9% reported being in their current position for 6-10 years. Forty-four percent (44%) reported annual salaries of \$41,000 - \$50,000, 26% reported salaries of \$31,000 - \$40,000, 16% reported salaries of < \$30,000, 11% reported salaries of \$51,000 - \$60,000 and 3% reported salaries of > \$60,000.

The average number of patients reported as being followed by a nurse/CRA on active treatment were 30 and 98 patients per nurse/CRA on off treatment follow-up. Nurses/CRAs reported an average of 26 active cancer control patients each. Responders reported they feel the average number of active treatment patients per nurse/CRA should be 24 and that there should be an average of 73 patients on long term follow-up per nurse/CRA.

The average number of physician members per CCOP were 54, with an average of 6 hospitals and 3 satellites per CCOP. The average number of nurses per CCOP were reported to be 12 with an average of 5 non-nurse CRAs per CCOP. The average number of open treatment trials per CCOP was 100 with an average of 11 open cancer control trials. Of an average of 13 medical oncologists, 9 were felt to be active accruals to clinical trials, whereas out of 4 radiation therapists, 2 were active. Out of an average of 5 surgeons only 1 was an active accrual. Most reporting CCOPs stated they had a local review process to determine which trials to participate in

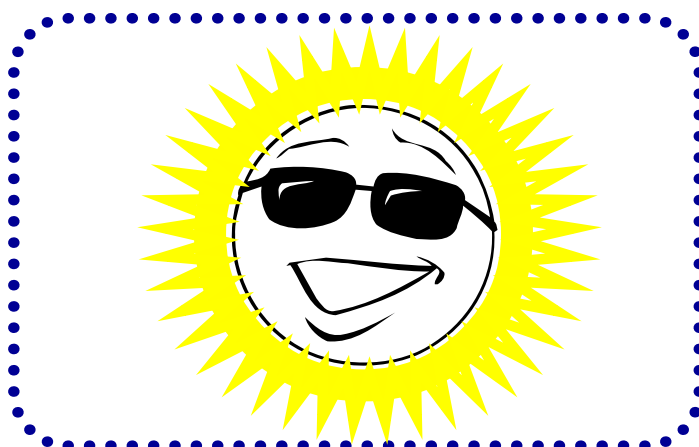
before opening the trials (79%) while 14% reported not having this review process.

Fifty-four percent (54%) reported the average length of time for local IRB approval to be 1-2 months, 20% reported 2-4 months and 1% > 6 months. Seventy percent (70%) reported not currently assessing patient satisfaction with the clinical trial process, whereas 25% reported assessing satisfaction by asking the patient or having them complete a survey.

The majority of those responding (95%) felt standardization of data forms would be beneficial to them in their daily clinical trial work activities. When asked which research base form sets were *easiest/least* confusing to use they reported NSABP at 55%, SWOG at 14%, NCCTG at 9%, ECOG at 4%, RTOG at 3%, POG/CCG at 2%. When asked which research base form sets were *least time consuming* to use they reported again NSABP 57%, SWOG 13%, NCCTG 8%, ECOG 6%, RTOG 3%, POG 2%. Similarly, when asked which research base did they receive the *least queries* responders reported NSABP 46%, SWOG 10%, NCCTG 6%, COG, 2%, MDACC 2%, CALGB 1%, ECOG 1%, GOG 1%, RTOG 1%, and URCC 1%.

Inversely when asked which research base they felt the form sets were the *most confusing* to use responders reported RTOG 36%, SWOG 11%, ECOG 10%, GOG 9%, NCCTG 7%, CALGB 4%, MDACC 4%, NCIC 3%, NSABP 2%, CCG 1% and URCC 1%. When asked which research base form sets were the *most time consuming* responders reported RTOG 35%, SWOG 16%, ECOG 10%, GOG 9%, NCCTG 6%, MDACC 4%, CALGB 2%, NCIC 2%, NSABP 2%, and CCG 1%. Accordingly, the research bases that send the most queries were thought to be RTOG 22%, SWOG 16%, NCCTG 12%, ECOG 10%, CALGB 4%, NSABP 3%, and MDACC 1%.

Sixty-nine percent (69%) of the nurse/CRA responders reported experiencing reimbursement issues for patients on clinical trials or considering clinical trial participation. Fifty-nine percent (59%) reported considering reimbursement issues before opening a trial to accrual. Fifty percent (50%) reported research staff to be responsible for validating availability of reimbursement for drugs/ tests in a protocol whereas 39% reported non-research staff were responsible.



One of the Best “Crush the Crab” 5Ks, Ever!

That was what we heard from the early-morning athletes who ran and/or walked as the sun came up over Bachman Lake in Dallas on Saturday, April 20. The popular Group Meeting event drew 33 runners and 18 walkers.

Those who “crushed the crabs” were: Elaine Armstrong, MS, Southwest Oncology Group Operations Office (**1st Place, Women 40-49**); Helen K. Chew, MD, University of California, Davis (**2nd Place, Women 39 & Under**); David Z. J. Chu, MD, City of Hope National Medical Center; Lewis Clayman, MD, University of Detroit Mercy (**3rd Place, Men 50 & Over**); William Coker, Southwest Oncology Group Operations Office (**1st Place, Men 39 & Under**); Traci Cordonnier, RN, Dayton CCOP; E. David Crawford, MD (**2nd Place, Men 50 & Over**); Diann Fischesser, RN, MSN, University of Cincinnati (**1st Place, Women 39 & Under**); Glen L. French, Detroit, Michigan; Margaret French, RN, BSN, Karmanos Cancer Center (**3rd Place, Women 40-49**); Nora K. Galvin, RN, CTR, Grand Rapids CCOP (**1st Place, Women 50 & Over**); Melanie Crystal, BSA, University of Arizona; Lisa M. Deabel, Cardinal Bernardin Cancer Center; Johanna Hardin, PhD, Southwest Oncology Group Statistical Center, (**3rd Place, Women 39 & Under**); Daniel F. Hayes, MD, University of Michigan (**1st**

Place, men 50 & Over); Brian F. Issell, MD, University of Hawaii Cancer Research Center; Glyndon J. Kennerly, RPH, Schering-Plough Corp; Cathy T. Leggette, RN, MSN, Schering-Plough Corp; Sheryl McCoy, Southwest Oncology Group Statistical Center; Alan M. Miller, PhD, MD, Tulane University School of Medicine; Maggie Ramsey, RN, MSN, Tulane University School of Medicine, (**2nd Place, Women 40-49**); F. Gary Renshaw, DO, Eli Lilly & Company (**3rd Place, Men 40-49**); Peter F. Roberts, MD, UC Davis Medical Center (**3rd Place, Men 39 & Under**); Elliot K. Reno, IDEC Pharmaceuticals (**1st Place, Men 40-49**); Susan Riley, Genentech BioOncology (**3rd Place, Women 50 & Over**); Susan B. Schulman, CCRA, University of Utah, (**2nd Place, Women 50 & Over**); Alice P. Senko, RN, MSN, Schering-Plough Corp; Marcia Thompson, RN, Springfield, Missouri; Marilyn J. Turner, MT, Feist-Weiller Cancer Center; Cecilia J. Wagoner, RN, BSN, Ozarks Regional CCOP; Keith A. Wagner, RPH, Tripler Army Medical Center (**2nd Place, Men 39 & Under**); Michael G. Wortman, RN, Mission St. Hoseph’s Hospital; and, Bennett W. Yu, MD, Wayne State University (**2nd Place, Men 40-49**).

We look forward to another great run and walk in San Antonio on Sunday, October 27!



FIRST PLACE Winners (from left to right): William Coker, Elaine Armstrong, Dan Hayes, Elliot Reno, Nora Galvin, and Diann Fischesser.

SECOND PLACE Winners (from left to right): Bennett Yu, E. David Crawford, Keith Wagner, Maggie Ramsey, Helen Chew, and Susan Schulman.



THIRD PLACE Winners (from left to right): Lewis Clayman, Margaret French, Peter Roberts, F. Gary Renshaw, Sue Riley, and Johanna Hardin.



VIDEOTAPE ORDER FORM

CLINICAL RESEARCH ASSOCIATES COMMITTEE

- ☐ GU Diseases: Renal Cancer Overview (4/98)
- ☐ GU Diseases: Locally Advanced Bladder Cancer Overview (4/98)
- ☐ GU Diseases: Advanced Bladder Cancer Overview (4/98)
- ☐ Everything You Need to Know About Radiotherapy...But, Were Afraid to Ask (4/98)
- ☐ Side Effects and Toxicities of Radiation Therapy (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: Quality Improvement - Achieving Compliance; Hot Spots & Various Sundries (4/01)
- ☐ Federal Guidelines Governing Research and IRBs: Common SWOG Audit Deficiencies; The IRB Decision Process (4/01)
- ☐ Federal Guidelines Governing Research and IRBs: Misconduct in Clinical Research (4/01)
- ☐ Multiple Myeloma: Myeloma Therapy, Past, Present, and Future; Overview of Myeloma (10/01)
- ☐ Multiple Myeloma: Gene Expression Profiling; New and Improved Response Coding on SWOG Protocols (10/01)
- ☐ Breast Carcinoma: Surgical Intervention & New Techniques, Role of Immunohistochemistry in Cancer Diagnosis, Biomarker Studies, What's New in Adjuvant Therapy for Breast Cancer (4/02)
- ☐ Surviving Cancer: Surviving Breast Cancer, Dealing With a Diagnosis of Breast Cancer, Surviving Prostate Cancer, Reconstructive Surgery After a Mastectomy (4/02)

MAIL TAPES TO:

NAME: _____

ADDRESS: _____ DEPT: _____

CITY: _____ STATE: _____ ZIP CODE: _____

TELEPHONE: (____) _____ AFFILIATION/INSTITUTION: _____

_____ **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 three (3) week loan period.**

SIGNATURE: _____

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

MAIL ORDER FORM TO: Angela Allred, CCRA; Arkansas Cancer Research Center; 4301 West Markham, Slot 724, Little Rock, AR 72205.

We'll see you in San Antonio!

**– October 24–28, 2002 –
Hyatt Regency San Antonio
on the Riverwalk!**



Make it a habit to check the Group web site at <http://swog.org> on a regular basis.