THE CAL·GAB

SPRING 2008

QUARTERLY NEWSLETTER OF THE CANCER AND LEUKEMIA GROUP B

CALGB

Tomorrow's Cancer Treatments Today

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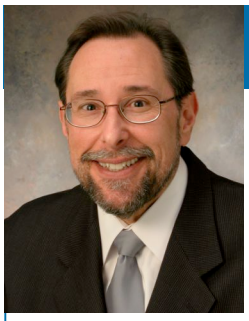
Leader in Research and Cancer: Role of a Clinical Trial Cooperative Group Chair

Just like captains of industry, Group Chairs leverage their vision, knowledge, experience, ingenuity and compassion to effectively lead clinical trial cooperative groups – dedicated collectives of scientific minds – to the next level of discovery in cancer research. And this role is not taken lightly. Cooperative groups account for about 85 percent of patient enrollment into cancer clinical trials sponsored by the National Cancer Institute (NCI), and place more than 25,000 new patients into trials each year. Since the inception of the cooperative groups more than 50 years ago, Group Chairs have provided direction to thousands of cancer clinical trials, resulting in unprecedented advances from the development of new cancer therapies used to treat cancer that have helped to save or extend the lives of millions of people in the United States and around the world. Group Chairs have not only shepherded promising new treatment opportunities, but they have encouraged the investigation of new methods of cancer prevention and early detection, along with the study of quality of life issues, molecular predictors of treatment response, and rehabilitation during and after treatment. These milestones provide the foundation of the clinical trial enterprise.

The role of the clinical trial cooperative Group Chair is paramount to advancing cancer research. It is the catalyst to creating an environment where innovative ideas, unique findings and novel approaches can be shared, fostered, developed and executed. Group Chairs work in tandem with other NCI-sponsored programs and other partners, including the pharmaceutical industry, to ensure this happens.

Overall, under the guidance of their Group Chairs, cooperative groups have led and continue to lead the way to ushering in some of the most promising avenues of research. To get more insight into the role of a Group Chair, turn the page and read the column from Richard L. Schilsky, M.D., Chair of the Cancer and Leukemia Group B.



Richard L. Schilsky, M.D.

MESSAGE FROM THE GROUP CHAIR

CALGB Tenure: "Most Challenging, Stimulating and Rewarding Aspect of My Career Thus Far"

By now many of you have seen the "Call for Nominations" for the position of CALGB Group Chair that has been broadcast to the membership. I will complete my third term as CALGB Group Chair in the spring of 2010 and, on my recommendation, the Board of Directors decided to accelerate the election schedule in order to ensure a smooth transition in leadership.

As required by the CALGB Constitution, the Executive Committee has appointed a three-person nominating committee chaired by Hy Muss, M.D. The nominating committee has the responsibility to consider all applicants and nominees for the position as well as to solicit the interest of well-qualified individuals who have not been nominated by others.

In June, they will present a slate of recommended candidates to the Board of Directors for approval. The Board may also nominate individuals by following a process that is described in the CALGB Constitution. In November, the institutional representatives on the Board of Directors will elect the next Group Chair, who will take office in April 2010.

Until then, I am fully committed to leading CALGB and will work closely with the Group Chair-elect to plan our future and assure stability in Group operations during the transition period.

Some prospective candidates for Group Chair have asked me if being a cooperative group chair is a "good job," something to which they should devote the next 10-15 years of their career. Before I answer the question, let me briefly delineate the responsibilities of the position.

The Group Chair serves as the Chairman and Chief Executive Officer of CALGB, leading the Board of Directors in developing CALGB policies and implementing CALGB programs through oversight and management of the Central Office and, in partnership with the Group Statistician, the Statistical Center.

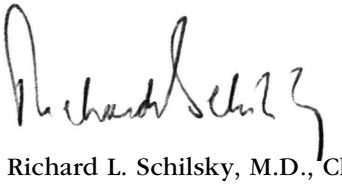
The Group Chair is also the principal investigator for the NCI cooperative agreements and other grants that support the work of CALGB and must assure that CALGB procedures conform to the NCI cooperative group guidelines. The Group Chair appoints all CALGB committee chairs and has overall responsibility to conduct an innovative and productive scientific program while also wisely shepherding Group resources.

In collaboration with the institutional principal investigators, the Group Chair manages the CALGB network, monitors study accrual and ensures data quality. The Group Chair also works closely with NCI leadership, FDA officials and the chairs of the other cooperative groups to sustain a vibrant, publicly funded, national clinical trials program. To be sure, it is an awesome responsibility and an extraordinary opportunity.

Over the course of my career, I have had the opportunity to run a phase I clinical trials program, an RO1-funded lab, and an NCI-designated cancer center, as well as the CALGB.

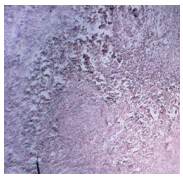
Without question, my work in CALGB has been the most challenging, stimulating and rewarding aspect of my career thus far. Fundamentally, leading CALGB is about working with wonderful, smart, dedicated people. The thousands of physicians, scientists, nurses, CRAs, pharmacists, patient advocates and others working at hundreds of CALGB institutions sustain and nurture the Group and will provide for its future.

It is up to the Group Chair to harness the energy, creativity and drive of CALGB members to design and conduct studies that improve outcomes for our patients. I don't think there can be a better job and I am confident that the nominating committee will have outstanding candidates to present to the Board in June.



Richard L. Schilsky, M.D., Chair

CALGB Study to Determine Benefit of Combined Therapy on Poor-Risk Lung Cancer Patients



30605 A phase II study of induction chemotherapy followed by thoracic radiotherapy and erlotinib in poor-risk stage III non-small cell lung cancer

Combined modality therapy (CMT) is the standard treatment for patients with unresectable stage III non-small cell lung cancer (NSCLC). Patients are typically treated with concurrent chemotherapy (CT) and thoracic radiotherapy (TRT), respectively preceded or followed by induction or consolidation chemotherapy.

Poor-risk patients comprise a substantial percentage of stage III patients in clinical practice. Yet, little data are available with respect to the optimal management of this group of patients. The majority of clinical trials in stage III NSCLC have excluded patients with poor performance status (2 or higher) and/or significant weight loss (greater than 10 percent). A multivariate analysis by the Radiation Therapy Oncology Group (RTOG) demonstrated that patients with PS > 2, ≥ 5 percent weight loss, and advanced age do not seem to benefit from standard combined modality therapy.[1]

A previous RTOG trial (9701) attempted to randomize poor-risk patients to CMT or to TRT alone, but accrued only 19 patients and the results have never been reported. A more recent RTOG trial (0213) tested the addition of celecoxib to TRT in a similar patient population but also failed to reach the target accrual. Southwest Oncology Group (SWOG) investigators have tested carboplatin-etoposide and TRT, with (trial 9712) and without (trial 9429) consolidation with paclitaxel in poor-risk patients, defined by PS of 2, greater than 10% weight loss, and various co-morbidities.[2,3] Two-year survival rates of 27 percent and 21 percent, respectively, were reported, which are substantially inferior to the results obtained in better prognosis patients.

In a multivariate analysis of CALGB 39801, which tested concurrent CT/TRT with or without induction chemo-therapy, older age, PS 2, and weight loss were significant predictors of poor outcome.

Although the overall results showed no advantage for the induction arm, this strategy seemed, in retrospect, to have had a favorable impact on poor-prognosis patients. A more recent stratified phase II trial (CALGB 30106), tested weekly chemotherapy with gefitinib and TRT in patients with PS 0-1 and < 5 percent weight loss, and gefitinib alone with TRT in the poor-risk stratum. Both groups received two cycles of induction chemotherapy with carboplatin and paclitaxel. Preliminary results indicate a failure-free survival of 11 months and median overall survival of 19 months in the poor-risk cohort, which compare favorably with past experiences.[4]

The encouraging results of CALGB 30106, along with those of a pivotal randomized trial in head and neck carcinoma,[5] provide the impetus for testing the epidermal growth factor receptor (EGFR) blockade in combination with radiotherapy in other aerodigestive malignancies. While there are ongoing trials with cetuximab and TRT in stage III NSCLC, there are limited safety and efficacy data for the combination of oral tyrosine kinase inhibitors (TKI) and TRT in this setting.

Induction chemotherapy in CALGB trials has traditionally been based on the combination of carboplatin and paclitaxel. More recently, albumin-bound paclitaxel, a solvent-free, nano-particle taxane with a favorable toxicity profile and ease of administration, has shown superiority over single-agent paclitaxel in patients with advanced breast cancer.[6] Preliminary studies of albumin-bound paclitaxel in combination with carboplatin in advanced NSCLC have demonstrated good tolerability and an activity level within the expected range for a platinum-based doublet.[7] Although different schedules have been tested, carboplatin on day 1, with albumin-bound paclitaxel on days 1 and 8 every 21 days, or days 1, 8, and 15, every 28 days, appear the most promising. In poor-risk patients, who tend to tolerate chemotherapy less well, carboplatin and albumin-bound paclitaxel seems to be a particularly attractive combination.

Stage III poor-risk patients are quite prevalent in clinical practice. Clinical trial data in this patient subset are lacking, and dedicated studies are warranted. Induction chemotherapy appears to play a role in the treatment of these patients, and the investigation of newer regimens is an important goal. Further exploration of the inter-action between a TKI and TRT in stage III disease,

— see **SPOTLIGHT ON CALGB TRIALS**, next page

The ***CAL•GAB*** is published by the Cancer and Leukemia Group B quarterly and distributed to CALGB active membership through the CALGB Web site (www.calgb.org). Suggestions for articles are encouraged. Contributions for the Summer 2008 issue are due April 21, 2008. Forward articles, suggestions and other correspondence to jowens@uchicago.edu.

The ***CAL•GAB*** reserves the right to make corrections, changes and deletions in submitted copy in conformity with the newsletter's editorial policies.

SPOTLIGHT ON CALGB TRIALS / 30605 and 30610

continued from page 3

along with a careful analysis of molecular correlates, provides the rationale for this study.

This trial, CALGB 30605—A phase II study of induction chemotherapy followed by thoracic radiotherapy and erlotinib in poor-risk stage III non-small cell lung cancer, will study the role of erlotinib in 76 stage III unresectable patients with a performance status of 2 and/or patients with equal or greater than 10 percent weight loss, which historically constitutes a poor-prognosis category, and one that has been excluded from prior trials.

The combination of carboplatin and albumin-bound paclitaxel, which will be used as induction, has been shown to be well tolerated and applies in particular to the study population, which is prone to greater risks related to systemic hemotherapy. After two cycles of induction chemotherapy, patients will be treated with thoracic radiotherapy concomitant with erlotinib. There are clear guidelines for dose adjustment of erlotinib concurrent with radiation, should toxicity issues become a concern. Because the main goal of the combined modality phase of the study is to assess the potential radiosensitizing properties of erlotinib, rather than its possible role in controlling systemic disease, this agent will not be continued after the radiotherapy is completed.

Refer to the study protocol (CALGB 30605), which can be found on the CALGB Member Web site (www.calgb.org), for complete information on the trial design, patient eligibility and the treatment plan.

The Study Chair is Rogerio Lilenbaum, M.D., Mount Sinai Medical Center, e-mail: rlilenbaum@aptium oncology.com.

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3 Lau DH, Crowley JJ, Gandara DR, et al. Southwest Oncology Group phase II trial of concurrent carboplatin, etoposide and radiation for poor-risk stage III non-small cell lung cancer. *J Clin Oncol* 1998;16:3078-3081
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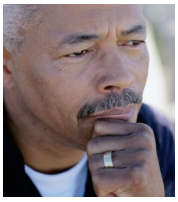
Newly-opened CALGB Trial Looks for Optimal RT Regimen in Limited-Small Cell Lung Cancer



30610 Phase III comparison of thoracic radiotherapy regimens in patients with limited small cell lung cancer also receiving cisplatin and etoposide

Defining an optimal thoracic radiotherapy (TRT) regimen in limited-stage small cell lung cancer (LSCLC) remains critical and will have a major impact on clinical practice, according to CALGB Study Chair Jeffrey Bogart, M.D., of State University of New York Upstate Medical University, and CALGB Study Co-Chair Gregory Masters, M.D., of the Helen Graham Cancer Center. Intergroup study 0096 – a well-conducted phase III trial – clearly established that improving the efficacy of TRT can significantly impact survival in patients with LSCLC. Given the reluctance for practitioners to adopt 45 GY BID TRT, the validity of this regimen needs to be assessed in the context of TRT regimens that have higher predicted biologic efficacy and may have improved tolerability and acceptance, the chairs contend.

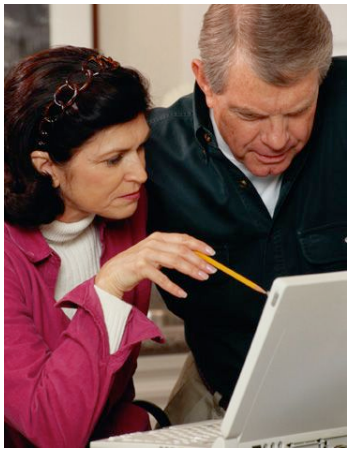
Superior outcomes on an experimental arm would lead to establishing a change in the standard of care for patients with LSCLC. Conversely, if the best outcomes were observed with accelerated 45 Gy BID TRT, then the results of this study, CALGB 30610—Phase III comparison of thoracic radiotherapy regimens in patients with limited small cell lung cancer also receiving cisplatin and etoposide, would provide convincing and definitive evidence for practitioners to adopt this regimen.

CALGB 30610 will determine whether administering high dose thoracic radiotherapy, 70 Gy (2 Gy once-daily over 7 weeks) or 61.2 Gy (1.8 Gy once-daily for 16 days followed by 1.8 Gy twice-daily for 9 days), will improve median and two-year survival compared with 45 Gy (1.5 Gy twice-daily over 3 weeks) in patients with limited-stage small cell lung cancer.

Refer to the study protocol (CALGB 30610), which can be found on the CALGB Member Web site (www.calgb.org), for complete information on the trial design, patient eligibility and the treatment plan.

Dr. Bogart can be reached at bogartj@upstate.edu and Dr. Masters at gmasters@cbg.org.

Role of Clinical Research Associate Liaisons in CALGB



The Clinical Research Associates (CRA) Committee provides liaisons to each Cancer and Leukemia B (CALGB) disease and/or modality committee. CRA Liaisons are available to provide analysis of draft protocols from a CRA's perspective, particularly the schema, eligibility criteria, treatment plan, required data and forms, and model consent form sections. Comments are sent to the respective Study Chair and Protocol Coordinator. CRA Liaisons also attend disease/modality committee meetings and can assist with protocol development and implementation.

Additional Support

In addition to reviewing draft protocols, CRA Liaisons evaluate new and revised data collection forms and instructions. Field tests are warranted if the form is new, has been extensively revised or has caused some coding problems in the past and has, therefore, been revised. When field testing a form, the CRA abstracts actual data from several patient charts and enters them onto the draft form in order to identify potential problems. Forms and instructions are reviewed for content, format, ease of understanding, feasibility and usability.

Here is a list of CRA Liaisons, their area of responsibility and e-mail addresses.

Role	Participant	Liaison	Contact Info
Chair	Kandie Price, M.S., R.N., O.C.N. C.C.R.P.		kprice@christianacare.org
Vice-Chair	Barbara Barrett, M.S., C.C.R.P.		barrettba@health.missouri
Cadre Member	Rebecca Laughlin, C.C.R.P.	Quality of Life Cancer in the Elderly	rebecca.laughlin@uvm.edu
Cadre Member	Angela Dodley, L.P.N.	Breast	anjied@aol.com
Cadre Member	Anne M. Burgess, B.S.N., R.N., C.C.R.C.	Surgery	aburgess1@partners.org
Cadre Member	Debra Herzan, R.N., B.S.N., O.C.N.	Respiratory	herza001@umn.edu
Cadre Member	Mary Dierker	Lymphoma	mcd2785@bjc.org
Cadre Member	Carolyn Mobley, C.C.R.P.	Leukemia	cmobley@wfubmc.edu
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Cadre Member	Linda Spillett, C.C.R.P.	Imaging	spilletl@upstate.edu
Cadre Member	Howard Weiner, C.C.R.P.	Genitourinary	hweiner@medicine.bsd.uchicago.edu
Cadre Member	Susan Tuttle, R.N., C.C.R.P.	Prevention Symptom Control	stuttle@wfubmc.edu
Cadre Member	Linda Veit, B.S.	Surgery	veitl@upstate.edu
Cadre Member	Margaret White, R.N., O.C.N., C.C.R.P.	CARE	m.white@nhoh.com

CRA Liaisons are ready and available to assist disease and modality committees.

ONCOLOGY NURSING PERSPECTIVE

Gene Profile of Breast Cancer and What It Tells Us

By Gail McCue Donnery, M.S.N., N.P., State University of New York Upstate Medical University

Are women with a Stage I breast cancer who are at low risk of recurrence being exposed to unnecessary toxicities and medical expenses? Many practitioners are asking the question: "Do all women with node negative, ER+ breast cancer benefit from chemotherapy and hormonal therapy? Or is hormonal therapy alone sufficient?"

The current practice guidelines recommend chemotherapy for women whose tumors are >1cm or <1cm with unfavorable features. The American Cancer Society reported that 180,000 women were diagnosed with breast cancer in 2007. Of these women approximately 137,000 were diagnosed with node negative, estrogen and/or progesterone positive disease. Surveillance Epidemiology and End Results (SEER) data presented in the 2006 *Journal of Clinical Oncology* reported community-based use of chemotherapy and hormonal therapy for early stage breast cancer (ER+, > 1 cm, node negative) according to age as:

Age	Chemotherapy Used
All ages	25%
< 50	50%
50-69	75%
70 +	5%

Did all these women need chemotherapy and the toxicity associated with it? Genetic testing is now being utilized to help answer these questions. One such test that has been developed and is commercially available to predict distant recurrence in women with node negative ER and/or PR+ breast cancer is the Onco*type* DX®.

Using formalin-fixed paraffin embedded tumor tissue the Onco*type* DX uses a 21-gene assay to look at the "fingerprint "of a breast cancer (*see Figure 1, page 7*). The gene panel uses 16 cancer-related genes and five control genes. The results are reported as the recurrence score (RS).

Genes are grouped on the basis of function, correlated expression or both. A positive sign indicates that that increased expression is associated with an increased risk of recurrence and a minus sign is associated with a decreased risk of recurrence.

RS Equals

+ 0.47 x HER2 Group Score
- 0.34 x ER Group Score
+ 1.04 x Proliferation Group Score
+ 0.10 x Invasion Group Score
+ 0.50 x CD 68
- 0.08 x GSTM1
- 0.07 x BAG 1

Risk of Distance Recurrence

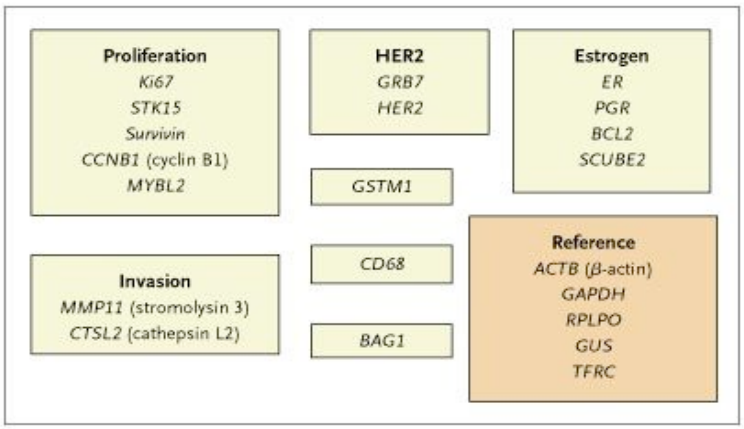
6.8% Low-Risk Group
14.3% Intermediate-Risk Group
30.5% High-Risk Group

Category	RS (0 – 100)
Low Risk	RS < 18
Intermediate Risk	RS > 18 and < 31
High Risk	RS > 31

Overexpression of HER 2/neu oncoprotein has been associated with an aggressive tumor and predicts breast cancer patients at risk for metastatic disease, whereas the expression of estrogen (ER) and the BCL2 protein have been associated with favorable outcomes in early stage breast cancer.

The BAG-1 protein expressed in breast cancer tumors was

— see **ONCOLOGY NURSING**, next page



Oncotype DX Assay Panel (Figure 1). *Source: Paik S, Shak S, Tang G, et al. A multigene assay to predict recurrence of tamoxifen-treated, node-negative breast cancer. New England Journal of Medicine 351(27):2817-2826, 2004.*

continued from page 6

analyzed in breast tumors of early stage breast cancer patients. Results showed that over expression of BAG-1 was significantly associated with a longer disease-free survival rate.

GSTM1 and GSTT1 are involved in the metabolism and detoxification of many potential carcinogens. They also contribute to tumor cell survival by detoxification of numerous products induced by cancer therapy. The gene deletion of GSTs may predict the early onset of breast cancer as well as the clinical response to chemotherapy and the recurrence-free survival of patients with lymph node-negative breast cancer.

When looked at in ductal carcinoma in situ (DCIS), CD68 correlates with markers known to be associated with higher recurrence of DCIS.

So what does the Onco*type* DX tell us? Tumors with a low RS may not respond well to chemotherapy, but may respond to hormones alone and the chance of a distant metastasis is very low. Tumors with a high RS are aggressive and respond better to chemotherapy and hormonal therapy. There are ongoing studies to determine what to offer women whose RS falls into the intermediate range, including the Eastern Cooperative Group (ECOG) PAACT-1 trial.

The Onco*type* DX is only one of the tests now in use looking at the genetic makeup of a breast cancer tumor. The MammaPrint® has been approved by the Federal Drug Administration (FDA) to classify women as being at a high risk or low risk for recurrence of their breast cancer. These tests now offer women more options and enhance their ability to make an informed decision in the treatment of their breast cancer.

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IS CORNER

CALGB Member IDs, Passwords and Rules for HIPAA Compliance

The Privacy and Security Rules of the Health Insurance Portability and Accountability Act (HIPAA) specify protection standards for the use, disclosure, security and communication of Protected Health Information (PHI). PHI is defined as confidential, personal, identifiable health information about an individual – that is created, transmitted, received or maintained by any health care plan, provider or clearinghouse.

CALGB Information Systems (IS) has designed Web-based applications (Patient PreRegistration, Patient Registration, LabTrak and the Reporting System) to protect PHI by requiring secure logins, limiting access by role and implementing a timeout feature that shuts down the application if no activity occurs within 15 minutes. In addition, the Secure Mail system protects PHI by requiring participants to log in before accessing e-mail messages that may contain protected patient information.

Every CALGB participant who will access PHI is limited to viewing patient information specific to his or her assigned role and assigned studies and patients. To access the CALGB Member Web site, CALGB requires that each participant use his or her unique Member ID and password. To access Web applications, many of which display PHI, CALGB requires that each CALGB participant use the Member ID and a separate Web application password.

Obtaining a CALGB Member ID and Passwords

When a participant registers at CALGB, an account is set up, and the participant receives a welcome e-mail message showing the Member ID for the account and instructions for setting up the password needed for CALGB Member Web site access. To activate access to CALGB Information Systems applications, CALGB participants must contact the CALGB Help Desk (877-442-2542) to set up an IS Web application password.

To satisfy HIPAA-mandated patient information protection, all CALGB participants, including those at affiliate institutions, need to have unique CALGB Member IDs and passwords to access the CALGB Member Web site and CALGB applications.

HIPAA Violations

The following practices violate HIPAA mandates:

- Borrowing or sharing another participant's Member ID and passwords
- Using one participant's Member ID and passwords for multiple participants (i.e., using a participant's Member ID and passwords for a group or department)

These are violations because the individual who "owns" the shared Member ID and passwords has permission to access and perform only his or her authorized tasks with specific records. Another individual using those identifiers may not have permission to access and work with those records.

The CALGB has an obligation to ensure that PHI is protected and must report violations to the offending institution's security officers.

Please be sure that you are using your own Member ID and passwords. If you do not have, or do not know your Member ID and passwords (both for accessing the CALGB Member Web site and CALGB IS applications), contact the CALGB Help Desk at 877-442-2542 to receive the information and assistance you need to access these resources under your own account.

TRAINING UPDATE

More CALGB Training Courses Come Online

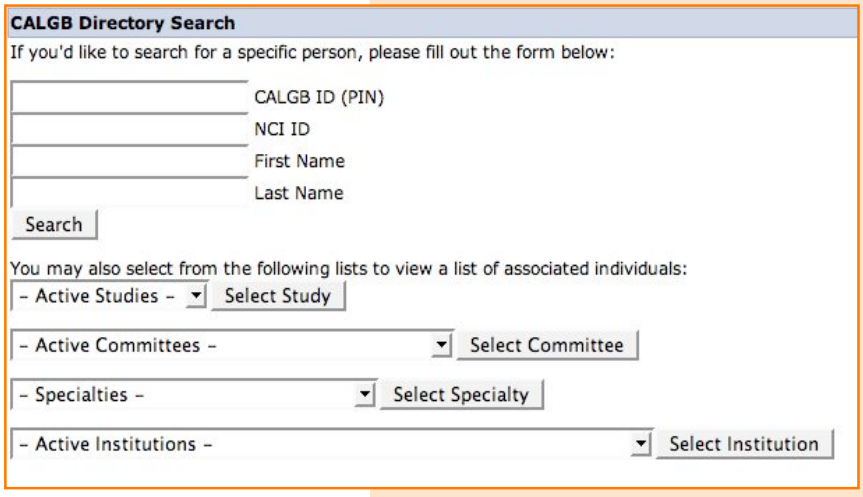
CALGB is working hard to create and launch new training courses to ensure that you, CALGB participants, have the most current information and tools you need. If you have not visited the Training Section of the CALGB Member Web site lately, you should check it out today.

The Statistical Center Institutional Performance Evaluation Tools Training Course is now available online for CALGB members to take any time. The course, which previously was presented live at CRA Orientation, provides an overview of tools used by the Institutional Performance Evaluation Committee (IPEC) to evaluate institutional performance. Log in to the CALGB Member Web site, select the Training tab and then click the course title under Online Training to access this course. For those with limited computer access, a print version is also available. If you choose to review the printed version, you can return to the online module to complete the assessment at the end of the module to receive credit for completing the training.

Future online courses include videotaped sessions of Disease Overview presentations presented by Michael Perry, M.D., University of Missouri/Ellis Fischel Cancer Center and Stephen Grubbs, M.D., Christiana Care Health Services, Inc. at the upcoming 2008 CRA Orientation. These courses include overviews of the following disease sites: lung, GU, GI and leukemia/lymphoma.

Watch this column for updates on these and other new modules!

Keeping the CALGB Directory Current



CALGB needs your help to keep the CALGB Directory current.

If you're a Principal Investigator (PI) or Lead Clinical Research Associate (CRA), make sure to inform the Central Office of CALGB participant changes that occur at your institutions.

Send a Roster Update Request Form (found on the CALGB Member Web site under Directory, then Quick Links on left) with new or amended information to Rena Williams (rwilliams@uchicago.edu) in the Central Office as soon as possible after a change occurs.

2008 CALGB SUMMER GROUP MEETING

SNEAK PREVIEW

Survivorship: Living With, Through and Beyond Cancer

2008 CALGB Plenary Panelists. *From far left: Caroline Bridges; Patricia Ganz, M.D.; Carol Estwing Ferrans, Ph.D., R.N., F.A.A.N.; Electra Paskett, Ph.D., M.P.H. and Charles Shapiro, M.D.*

Plenary Session
Saturday, June 28 / 1:30 p.m. to 4 p.m.*

Today, more people are surviving cancer. According to the Centers for Disease Control and Prevention (CDC) and the National Cancer Institute (NCI), more than 11 million people in the United States can say that they are cancer survivors. And that number continues to grow each year thanks to improved strategies to detect and fight cancer through better treatments and better prevention of cancer recurrences and secondary cancers, and lower death rates from other causes, says the American Cancer Society.

- **Caroline Bridges,** a 21-year-old cancer survivor and college student at Boston University, can attest to such strides being made in cancer research, and will share her story at this year's session. In 2006, the photography major was diagnosed with acute lymphocytic leukemia and returned to Chicago where she was treated at the University of Chicago Medical Center on CALGB 10102—A phase I/II dose escalation study of subcutaneous CAMPATH-1H (NSC# 715969, IND# 10864 during intensification therapy in adults with untreated acute lymphoblastic leukemia (ALL). Last fall, she was referred to the Dana Farber Cancer Institute in Boston to continue therapy and returned to school to continue her studies.

- **Patricia (Patti) Ganz, M.D.**, Director of the Division of Cancer Prevention & Control Center Research, Jonsson Comprehensive Cancer Center, will discuss her work with survivorship. As a medical oncologist, Dr. Ganz has spent the past 20 years conducting systematic research on the health-related quality of life impact of cancer and its treatment. Her research has contributed to our understanding of how women adjust to the diagnosis of breast cancer, including its effects on their physical, emotional, social and sexual well-being. Dr. Ganz is a founding member of the National Coalition for Cancer Survivorship (NCCS), and was previously awarded the Susan G. Komen Professor of Survivorship.

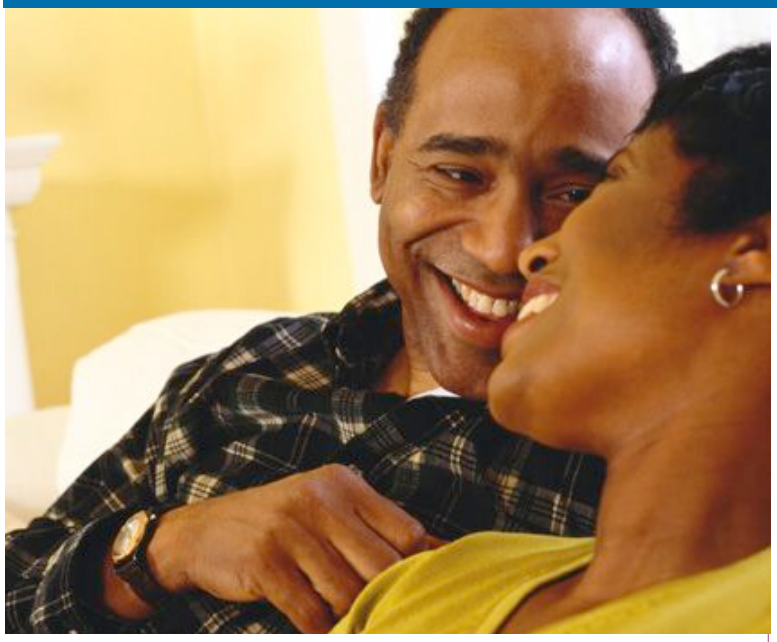
- **Carol Estwing Ferrans, Ph.D., R.N., F.A.A.N.**, Professor and Associate Dean for Research in the University of Illinois College of Nursing and Deputy Director for the Center for Population Health and Health Disparities at UIC, will speak about her work with African-American cancer survivorship, including CALGB 119901—Quality of life of African-American cancer survivors. She has been conducting studies focusing on quality of life and minority issues in health care over the past 20 years, funded by the NCI and the National Institute for Nursing Research. Dr. Ferrans' research has focused on cross-cultural issues, including approaches to increase validity of data and participation in research for minority populations in the U.S., including the development of culturally specific measures for African-Americans and Hispanic Americans.

- **Electra Paskett, Ph.D., M.P.H.,** Marion N. Rowley Professor of Cancer Research, Division of Epidemiology at The Ohio State University College of Public Health and Associate Director for Population Sciences and Co-Program Leader of the Cancer Control Program in the OSU Comprehensive Cancer Center, will discuss her work in intervention research around cancer prevention, early detection and survivorship issues among underserved populations. Dr. Paskett successfully competed for an NCI-funded P50 (Center for Population Health and Health Disparities) and has received funding from the Breast Cancer Research Foundation for the OSU Evelyn Lauder Breast Cancer Prevention through Nutrition Program. She is Chair of the CALGB Cancer Control and Health Outcomes Committee, and is currently working on CALGB 70305—A randomized study to prevent lymphedema in women treated for breast cancer.

- **Charles Shapiro, M.D.**, Associate Professor, James Cancer Hospital and Solove Research Institute, Hematology and Oncology at The Ohio State University College of Medicine, will discuss breast cancer survivor-ship. His research interests focus on developing novel therapies for the treatment of breast cancer. Dr. Shapiro has recently authored "Surviving recurrence: Psychological and quality-of-life recovery," which can be found in *Cancer* 112(5): 1178-1187, 2008 (Yang HC, Thornton LM, Shapiro CL, Andersen BL). He has served as chair and co-chair on a number of CALGB protocols to advance the treatment of breast cancer.

— see **SUMMER GROUP MEETING**, next page

2008 CALGB SUMMER GROUP MEETING



continued from page 10

CRA Continuing Education Workshop
Friday, June 27 / 8 a.m. to 12 p.m.*

- In a session designed especially for Clinical Research Associates, discussion will also focus on survivorship. **Laura Neal, M.S.W., M.P.H., L.C.S.W.**, Coordinator, Quality of Life Services, Oncology Clinical Social Worker at Ellis Fischel Cancer Center and Practicum Instructor at the MU School of Social Work in Columbia, MO, will present "Lost in Transition: From Cancer Patient to Cancer Survivor." Her talk will help define the concept of survivorship and explain the transition from cancer patient to cancer survivor. Other speakers are being confirmed. Refer to the CALGB Web site (www.calgb.org) for updates.

Making Clinical Trials Count for Everyone: Strategies to Improve Compliance for Research Participants
Friday, June 27 / 10 a.m. to 2 p.m.*

- Sponsored by the CALGB CARE (Committee on Advocacy, Research Communication and Ethics) and Oncology Nursing committees, this open forum will address the issue of research participant adherence to medical regimens, which is widely studied. **Mary Managan**, of GlaxoSmithKline, will facilitate discussion on this topic. **Ann Partridge, M.D., M.P.H.**, a medical oncologist at Dana-Farber Cancer Institute, and an Assistant Professor at Harvard Medical School, will discuss patient adherence to oral medication in CALGB 49907 (A randomized trial of adjuvant chemotherapy with standard regimens, cyclophosphamide, methotrexate and fluorouracil – (CMF) or doxorubicin and cyclophosphamide – (AC), versus capecitabine in women 65 years and older with node positive or node-negative breast cancer).

CRA Workshop for Surgical Protocols
Friday, June 27 / 1 p.m. to 3 p.m.*

- **Anne Burgess**, **R.N.,** of Brigham and Women's Hospital, and **Linda Veit**, of State University of New York Upstate Medical University at Syracuse, as members of the CALGB CRA Committee, in conjunction with the CALGB Surgery Committee, will coordinate a session to help educate Clinical Research Associates (involved or interested in surgical protocols) on active and pending surgically intrinsic protocols (SIP) and specific surgical data management issues. This workshop will be presented by principal investigators, and will include a protocol overview followed by forms review.

CRA Kiosks
Saturday, June 28 / 11:30 a.m. to 1:30 p.m.*
(two concurrent sessions)

- These small sessions will give Clinical Research Associates an opportunity to ask questions in a one-on-one setting. This year's topics include: **RECIST** (Response Evaluation Criteria In Solid Tumors); **Information Systems** (Secure Mail and IS applications such as specimen tracking, Patient Registration, CALGB Reporting System, and the CALGB Web site); **PMB** (Pharmaceutical Management Branch) and **IRB** (Institutional Review Board). If you have questions that may require research, send them in advance to CALGBTraining@mc.duke.edu.

CRA Committee Meeting
Thursday, June 26 / 1 p.m. to 5 p.m.*

- This year's Clinical Research Associates Committee Meeting focus will be three-fold, focusing on audits, patient registration and correlative science. **Susan Tuttle, R.N**, of the Southeast Cancer Control Consortium, Inc. and Vice Chair of the CALGB Audit Committee, will present "Twenty Ways to Improve IRB Audits" to help Clinical Research Associates become more proficient with the auditing process. Staff from the Cancer Trials Support Unit (CTSU) will discuss the Oncology Patient Enrollment Network (OPEN), a new Web-based patient registration system to help streamline the clinical trial enrollment process. **Paula Friedman, Ph.D.**, CALGB Director of Biospecimen and Correlative Science Operations, will talk about pathology and the new CALGB Specimen Tracking System.

* Dates and times subject to change. Consult final schedule at June meeting.

CALGB
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Register Early!
Cancer and Leukemia Group B
2008 Summer Group Meeting
June 26-29
The Fairmont Chicago
Chicago, Illinois

CALGB Statistical Center Undergoes Reorganization

The Cancer and Leukemia Group B Statistical Center, located at Duke University, has recently undergone a reorganization effort that will help improve the overall efficiency and effectiveness of the center directed by **Stephen George, Ph.D.**, CALGB Group Statistician and Chief of the Division of Biostatistics in the Department of Biostatistics and Bioinformatics at the Duke Comprehensive Cancer Center. In the restructuring, two new positions have been created: Senior Director and Director of Biostatistics.

Donna Niedzwiecki, Ph.D., Assistant Professor in the Department of Biostatistics Bioinformatics at Duke University, is the new Senior Director of the CALGB Statistical Center. She has worked for the center for 11 years and has served as Faculty Statistician on the GI, Lymphoma and Surgery committees. In her new capacity, Dr. Niedzwiecki is responsible for the supervision and oversight of the Biostatistics, Data Operations and Information Systems units of the Statistical Center. She is also responsible for ensuring that the activities of each unit are well integrated and consistent with the goals of the Statistical Center. The Senior Director reports to the Group Statistician.

Sin-Ho Jung, Ph.D., Professor in the Department of Biostatistics and Bioinformatics at Duke University, is the new Director of Biostatistics of the CALGB Statistical Center. He has worked for the center for four years and serves as Faculty Statistician on the Lymphoma and Imaging committees, and the Prevention Subcommittee of the Cancer Control and Health Outcomes Committee. In his new capacity, Dr. Jung is responsible for supervision and management of the CALGB Faculty and Staff Statisticians and for establishing and maintaining appropriate standards of quality for statistical design and analysis of CALGB studies. The Biostatistics Director reports to the Senior Director.

CALGB Executive Officer Steps Down

Ann Mauer, M.D., former Associate Professor of Medicine at the University of Chicago, recently stepped down as a CALGB Executive Officer to become Medical Director and Creticos Cancer Care Chief, Medical Oncology at Advocate Illinois Masonic Medical Center. At CALGB, Dr. Mauer was responsible for the oversight, development and conduct of the Group's phase I, II and III cancer trials. She was largely involved with the Breast, Respiratory, and Pharmacology and Experimental Therapeutics committees. Part of her research focused on a project funded by NCI and the National Institute of Aging to study breast cancer in the elderly – CALGB 49907 (A phase III trial comparing standard chemo-therapy versus a novel chemotherapy, capecitabine, as adjuvant therapy for older women with high risk, early breast cancer).

Olwen Hahn, M.D., an Assistant Instructor in the Section of Hematology/Oncology of Medicine at the University of Chicago, will replace Dr. Mauer as a CALGB Executive Officer. She has assumed responsibilities for the Breast, GU, Respiratory, and Pharmacology and Experimental Therapeutics committees. Dr. Hahn has recently co-authored an article on the role of non-receptor tyrosine kinases in lung cancer and the development of agents that target the proteins – Hahn O and Salgia R, Non-Receptor Tyrosine Kinase Inhibitors in Lung Cancer, *Anti-Cancer Agents in Medicinal Chemistry* 7(6):633-42, 2007.

STAFF UPDATES

@ The Central Office

Kelly Colclasure brings her research experience from the University of Chicago and the University of Illinois at Chicago to CALGB as a new Protocol Coordinator. She will work with Study and Committee Chairs to manage the protocol development process.

— see **CALGB GROUP NEWS**, next page

PROTOCOL NEWS

BREAST COMMITTEE

OPENED

CTSU—CTSU N063D: ALTTO: adj lapat, trastuz HER2/ErbB2 + br ca
Study Chair: L. Harris

GI COMMITTEE

OPENED

80502—Ir+AZD2171 in colrec ca aftr prog on ffox+cetx or ffox+bev cetx
Study Chair: B. O'Neil

CLOSED

CTSU—E2204: Bev/cetux + (Cape + rad) in pts w/comp resctd panc ca
Study Chair: W. Blackstock

GU COMMITTEE

CLOSED

90401—Docetaxel and predn w/ and w/out bevacizumab for HRPC
Study Chair: K. Kelly

LEUKEMIA COMMITTEE

OPENED

10404—CLL: Phase II study of three flu/antibody comb in prev untrtd CLL
Study Chair: J. Byrd

10501—CLL: a rand study of early interv in CLL pts w/ hi risk genetic
Study Chair: J. Byrd

CTSU—E1A06: MM: Ph III trial comp mel, pred, thal vs mel, pred, rev
Study Chair: A. Chanan-Khan

10603—AML: Ind + intensification chemo fol by PKC412 vs Placebo
Study Chair: R. Stone

LYMPHOMA COMMITTEE

OPENED

50701—Ph II trial of epratuzumab + rituxan in prev untd follicular NHL
Study Chair: B. Grant

RESPIRATORY COMMITTEE

OPENED

30605—Chemo followed by XRT & erlotinib for stg 3 NSCLC
Study Chair: R. Lilenbaum

30609—CTSU/R0617: Standard XRT vs high-dose confrml XRT w/ chemo
Study Chair: J. Bogart

30610—Comparison of XRT regimens in LSCLC
Study Chair: J. Bogart

CLOSED

30305—2 schedules/doses using PCI in LSCLC (RTOG 0212)
Study Chair: J. Bogart

30407—XRT, pemetrexed & carbo w/ or w/out cetuximab in stg 3 NSCLC
Study Chair: R. Govindan

TRANSPLANT COMMITTEE

CLOSED

100001—Auto -> mini-allo transplant for multiple myeloma
Study Chair: K. Anderson

100101—Ph II trial of pentostatin for refractory chronic GVHD
Study Chair: S. Farag

STAFF UPDATES

continued from page 12

@ The Statistical Center

Mitchener L. Beasley, M.M., joins CALGB as a Data Technician. He will provide back-up for the registrar and assist Data Coordinators with master updating clinical and survival status, querying missing data and filing.

Allison Booth, M.S., brings experience from Rho, Inc. to her new position at CALGB as a Data Coordinator III. She will develop Data Operations components of protocols and will work on leukemia trials.

Rachel Hardy, M.A., joins CALGB as a Data Technician with experience as Clinical Trials Research Associate. She will provide back-up support for the registrar and assist Data Coordinators with master updating clinical and survival status, querying missing data and filing.

As a CALGB Data Technician, **Phillip Jeffries** will assist Data Coordinators with master updating clinical and survival status, querying missing data, and filing specified studies.

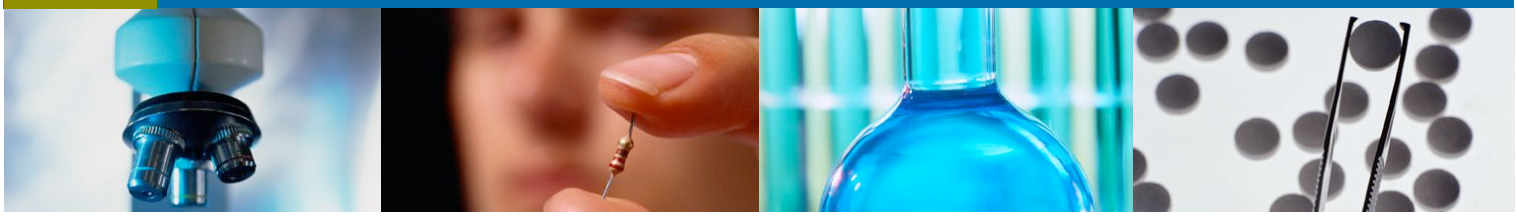
Catherine Maher joins CALGB as a Data Technician. She will work with Data Coordinators to update clinical and survival status, query missing data, and file specified studies.

As a CALGB Data Technician, **David Puffer** will assist Data Coordinators with master updating clinical and survival status, querying missing data, and filing specified studies.

Insuk Sohn, Ph.D., joins CALGB as a Faculty Statistician, conducting methodological research on gene microarray data analysis and study design. As a new Post Doctoral Associate in the Department of Biostatistics and Bioinformatics at Duke University, he brings to the position experience in bioinformatics, data mining, machine learning, microarray data analysis, promoter analysis and system biology.

Shawn Trutna joins CALGB as a Registrar/Clinical Trials Assistant II. He will provide support for the automated registration system and complete registration and randomization processes for Intergroup studies and studies not available for direct registration.

SUPPORT



The following have provided support to Cancer and Leukemia Group B research and educational programs in 2008. Thank you for your support.

Abbott Laboratories
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Bristol-Myers Squibb Oncology
Genentech BioOncology
Millennium Pharmaceuticals
Novartis Oncology
OSI Pharmaceuticals
Pfizer, Inc.
Roche Pharmaceuticals
Sanofi-Aventis
Schering Plough

Thank you to individuals who donated in 2007 to provide support to Cancer and Leukemia Group B research and educational programs.

Elizabeth Ackelson
Nancy Bartlett
Cecil Blaschke
Louise Brady
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Qiana Christian
Laura Cleveland
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Marc Ernstoff
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Marcio Fagundes
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The Cancer and Leukemia Group B Foundation is a nonprofit, tax-exempt foundation dedicated to assisting the Cancer and Leukemia Group B – a cooperative group of 29 of the nation's most prestigious medical centers and more than 250 affiliated institutions working together on large-scale clinical trials.

The CALGB Foundation supports the clinical trials and laboratory research of the CALGB and efforts to educate the medical community on methods of cancer diagnosis, treatment and prevention.

Recent initiatives supported by the CALGB Foundation include:

- New chemotherapy treatments for breast, prostate, lung and colorectal cancer.
- New surgical techniques for breast and colon cancer.
- Genetic studies of breast cancer risk.
- Molecular determinants of response to therapy for breast, colorectal and lung cancers, and leukemia.
- Research that improves the quality of life for cancer patients and their caregivers.

Your contribution will support our efforts to find ways to prevent and cure many types of cancer, including leukemia and lymphoma, and cancers of the breast, prostate, lung and GI tract.

Gifts to the Foundation may be designated according to your wishes, and are tax-deductible to the extent permitted by law.

Please make checks payable to:
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Thank you for your support.

Enclosed is my/our contribution of $ _____ to support the research of the Cancer and Leukemia Group B.

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Please mail donations to the address below. Also, for information about major gift opportunities and assistance with gifts of securities, gifts of appreciated property or gifts in-kind, please contact:

Mary A. Sherrell, M.A.
Treasurer, CALGB Foundation
230 W. Monroe Street, Suite 2050, Chicago IL 60606
(773) 702-9856 phone / (312) 345-0117 fax
e-mail: msherrel@uchicago.edu

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