

## CALGB

*Tomorrow's Cancer Treatments Today*

QUARTERLY NEWSLETTER OF THE CANCER AND LEUKEMIA GROUP B

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## Cancer Care in the Community: 20+ Years and Counting

According to the American Cancer Society, more than 1.4 million new cancer cases will be diagnosed this year and more than a half million people are expected to die from the disease. Last year brought news that overall cancer death rates have been declining in the United States since 1991. Nonetheless, cancer still remains a major health concern among many Americans and one of the most feared diseases. The good news is that about 10.5 million people are alive today with a history of cancer – thanks in part to clinical cancer research. For nearly 25 years now, the National Cancer Institute’s Division of Cancer Prevention (NCI-DCP) has managed a cancer control effort that combines the expertise of community health care professionals

(including cancer specialists, primary care physicians and others) with NCI-supported clinical research programs through cooperative groups and cancer centers. Today, the Community Clinical Oncology Program (CCOP), which ensures that cancer patients have access to quality medical care in their own communities, has a large network with more than 400 community hospitals in 36 states, including the District of Columbia and Puerto Rico. Currently, there are about 70 active cancer prevention and control trials and some 300 active cancer treatment trials in the CCOP network.

### Making a Difference

Within 10 years of its inception, the CCOP network made a significant contribution in breast cancer research, studying the first cancer prevention drug, tamoxifen. The National Surgical Adjuvant Breast and Bowel Project (NSABP) conducted the Breast Cancer Prevention Trial (NSABP-P-1),

which evaluated the efficacy of tamoxifen in preventing breast cancer in women at high risk for the disease. It has been said that such an intervention might not have reached patients without a CCOP network. Tamoxifen was later approved by the Food and Drug Administration (FDA) for reducing the risk of breast cancer in high-risk women. In another trial, the CCOP network spearheaded the evaluation of finasteride as a prostate cancer prevention drug in the Southwest Oncology Group (SWOG) Prostate Cancer Prevention Trial (SWOG-9271) in 1993.

### Celebrating 20 Years

This year, three CCOPs affiliated with the Cancer and Leukemia Group B will celebrate 20-year anniversaries. They include Christiana Care Health Services, Inc., Southeast Cancer Control Consortium, Inc., and Mount Sinai Medical Center.

— see **CANCER CARE**, page 12

## MESSAGE FROM THE GROUP CHAIR

# Cooperative Groups, Industry and Clinical Trials



Richard L. Schilsky, M.D.

In a recent issue of *Nature* magazine, Martine Piccart, current President of the European Organization for Research and Treatment of Cancer (EORTC), and her colleagues published their views of the proper relationship between academic investigators and the pharmaceutical industry in conducting large, multi-center, prospective, randomized clinical trials.<sup>1</sup>

They raise concerns about the alignment of goals between academic investigators and industry in the design, conduct and reporting of such trials and about whether important features of clinical trials such as trial design, duration of patient follow-up, subset analysis, adverse event reporting and transparency in data analysis and reporting may be excessively influenced or controlled by an industry sponsor.

They propose a model for collaboration between academic investigators and industry wherein the clinical trial database is maintained by the academic investigators until the trial endpoints are met and not disclosed to the industry sponsor without the approval of an independent data monitoring committee. Once the primary endpoints of the trial are met, the database can be provided to the industry sponsor for preparation of an application for marketing approval for the new drug or new indication.

Dr. Piccart and colleagues suggest that such a model for collaboration is a "...win-win situation resulting in commercial registration of products, academic publications, and last but not least, hopefully better outcomes for patient treatments."

In reading Dr. Piccart's commentary, it struck me that the model she proposes has been the foundation of the CALGB collaboration with the pharmaceutical industry for many years now. When I became the Group Chairman in 1995 it was distinctly uncommon for CALGB, or any cooperative group, to work closely with industry in a clinical trial.

Few companies were interested in oncology products at that time and most of the new anti-cancer drugs in development were available to the cooperative groups only through the National Cancer Institute (NCI). In 1995, CALGB had only eight agreements with an industry partner to support CALGB studies. Much has changed in the past 12 years.

Dozens of pharmaceutical and biotechnology companies now have cancer drugs in development and hundreds of novel agents are flooding industry pipelines. While NCI continues to maintain a portfolio of new drugs that are available to academic investigators, most new agents, sometimes the most interesting ones, are available only from the drug sponsor.

Thus, cooperative group investigators have increasingly found it necessary to work directly with industry partners if they wish to obtain novel compounds for clinical trials. Access to new agents coupled with chronic under-funding of the cooperative groups by NCI has led to the development of much closer relationships between the cooperative groups and the pharmaceutical industry than at any time in the past.

During the past decade, CALGB studies have led to Food and Drug Administration (FDA) approved indications for paclitaxel as adjuvant therapy for node positive breast cancer, 5-azacytidine as treatment for myelodysplastic syndrome and nelarabine as therapy for refractory T cell leukemia and lymphoma. In each of these examples, CALGB was solely responsible for the design, conduct and analysis of the clinical trial and the clinical trial database was provided to the drug sponsor only after the trial was completed and the results were known.

More recently, however, CALGB has begun to work prospectively with many companies in the design and execution of our clinical trials. At the present time, the Group holds INDs for 19 compounds that are being studied in 27 protocols in diseases as diverse as acute myeloid leukemia, colorectal cancer and mesothelioma. We now have in place 37 agreements with industry partners to support CALGB studies.

In many cases these protocols are designed to support regulatory approval of a new agent for a new marketing indication and, as such, are designed collaboratively with the drug sponsor and with the input and approval of NCI and the FDA. In every case, however, the trials are conceived by CALGB investigators, the database is maintained exclusively by CALGB and no primary outcome data are provided to the drug sponsor without the approval of the CALGB Data and Safety Monitoring Board. CALGB always retains the right to publish the study results regardless of the study outcomes.

As Dr. Piccart points out, such relationships are a "win-

— see **GROUP CHAIR**, page 5

# SPOTLIGHT ON CALGB TRIALS / 170601 / 140503

## First CALGB Nurse-led Drug Intervention Trial Slated to Activate in late 2007



**170601 A phase III double blind trial of oral duloxetine for treatment of pain associated with chemotherapy-induced peripheral neuropathy (CIPN)**

The Cancer and Leukemia Group B will lead the way among national adult cancer cooperative groups by opening its first nurse-led drug intervention clinical trial later this year. Chaired by Ellen Lavoie Smith, Ph.D. (c), M.S., A.P.R.N.-B.C., A.O.C.N., of Dartmouth-Hitchcock Medical Center, CALGB 170601—A phase III double blind trial of oral duloxetine for treatment of pain associated with chemotherapy-induced peripheral neuropathy (CIPN)—will determine what effects duloxetine has on 206 patients with painful sensory CIPN caused by prior treatment with paclitaxel or oxaliplatin and whether duloxetine will help reduce the amount of pain caused by peripheral neuropathy. CIPN, which describes a painful numbness and tingling in the hands and feet in cancer patients caused by some chemotherapy agents, may lead to difficulty with walking, sleeping, holding objects, typing, placing instruments and performing craft work. Duloxetine has been approved recently for use in treating painful neuropathy associated with diabetes, but has not been fully studied in treating neuropathy due to chemotherapy.

CALGB 170601 follows on the heels of CALGB 9371, a trial chaired by Consuelo Skosey, R.N., of the University of Chicago, as a pioneering CALGB nurse-led study. In 1993, CALGB activated CALGB 9371—A weight loss program of women with breast cancer: A pilot feasibility study—and sought to determine if 150 overweight women with breast cancer placed on a weight reduction program would lose weight and ultimately, reduce their risk of the recurrence of breast cancer.

Traditionally, Smith said that “most nursing research has been conducted at single institutions, utilizing small and minimally diverse patient populations,” leaving large multi-center nursing research a rare occurrence.

That has begun to change, as these CALGB trials (and those of other groups) represent a step forward for cooperative group cancer nursing research and will result in “paramount advances in nursing science and resultant improvements in patient care,” according to Smith.

## Newly-opened Trial Employs Innovative Approach for CALGB to Randomizing Participants



**140503 A phase III randomized trial of lobectomy versus sublobar resection for small ( $\leq 2$  cm) peripheral non-small cell lung cancer**

CALGB 140503—A phase III randomized trial of lobectomy versus sublobar resection for small ( $\leq 2$  cm) peripheral non-small cell lung cancer—will compare two ways of conducting surgery for lung cancer in patients who have small tumors with no evidence of spread. Recent studies have questioned whether removing a larger portion of the lung containing the tumor offers better control of the cancer than removing a smaller portion of the lung. This study will determine whether sublobar resection is equal to a lobectomy, while studying the overall effects of both procedures. An interesting component of this study includes the randomization of eligible patients during surgery.

During surgery, a surgeon will examine the tumor and determine if it is small and that the cancer has not spread. Upon confirmation and while the patient is still under anesthesia in the operating room, the patient will be randomized to either arm (Arm A for the standard operation for lung cancer, a lobectomy, or Arm B where a smaller portion of the lung will be removed by sublobar resection). Regardless of the type of surgery done, the entire tumor will be removed. The difference is the amount of surrounding normal lung tissue that is removed with the tumor.

The study also includes an imaging sub-study (CALGB 580602), which will review CT and PET scans.

— 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](http://www.calgb.org)). Suggestions for articles are encouraged. Contributions for the Winter 2007 issue are due October 22, 2007. Forward articles, suggestions and other correspondence to Jamilah Owens at [jowens@uchicago.edu](mailto: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 / 140503

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Here are additional aspects of CALGB 140503:

## Rationale

The surgical standard of care for early stage non-small cell lung cancer (NSCLC) is an anatomic lobectomy with mediastinal nodal staging. This is the result of a randomized trial conducted by the Lung Cancer Study Group (LCSG) in which 267 patients with peripheral T<sub>1</sub>N<sub>0</sub> tumors were randomly assigned to lobectomy or limited resection (segmentectomy or wedge).<sup>1</sup> Despite several criticisms and concerns leveled at this study (including the relatively small sample size, the inclusion of patients with tumors up to 3 cm in size, and possibly a sub-optimal statistical design), the LCSG study stands alone as the only randomized trial comparing lobectomy to sublobar resection.

Recent evidence appears to question the relevance of the results of the LCSG study.<sup>2-7</sup> Specifically, several studies have suggested that survival is significantly better in patients whose tumors are 2.0 cm or less in size.<sup>8,9</sup>

In CALGB 140503, patients with small peripheral ( $\leq 2$  cm) NSCLC will be randomized to lobectomy or a sublobar resection. If limited resection is proven to be equivalent to lobectomy, it will offer several advantages including:

- Preservation of pulmonary function.
- Wider applicability of minimal invasive surgical techniques with attendant reduced hospitalization and enhanced QOL.
- Increased likelihood of the possibility of a curative surgical intervention in the event of a secondary primary lung cancer.

## Trial Design

This randomized trial will determine whether disease-free survival (DFS) after sublobar resection (segmentectomy or wedge) is non-inferior to that after lobectomy in patients with small peripheral ( $\leq 2$  cm) NSCLC. It will determine whether overall survival (OS) (after sublobar resection) is non-inferior to that after lobectomy. The study will also determine the rates of loco-regional and systemic recurrence (exclusive of second primaries) after lobar and sublobar resection, and determine the difference between the study arms in pulmonary function as determined by expiratory flow rates measured at six months postoperatively.

The imaging sub-study (CALGB 580602) will explore the relationship between characteristics of the primary lung cancer, as revealed by pre-operative CT and PET

imaging, and outcomes; determine the false-negative rate of the pre-operative PET scan for identification of involved hilar and mediastinal lymph nodes; and assess the utility of annual follow-up CT imaging after surgical resection of small stage IA NSCLC.

## Eligibility

There are pre-operative eligibility criteria and intra-operative eligibility criteria. Only patients meeting both the pre-operative and intra-operative criteria will be registered and will follow the protocol requirements. Pre-registration eligibility includes patients who have a peripheral lung nodule  $\leq 2$  cm on preoperative CT scan that is presumed to be lung cancer. The tumor location must be suitable for either lobar or sublobar resection (wedge or segment). The patient must have an ECOG performance status of 0-2, and no prior malignancy within five years other than non-melanoma skin cancer, superficial bladder cancer, or CIS of the cervix. For intra-operative eligibility, patients must have a histologic confirmation of NSCLC (if not already obtained), and confirmation of N<sub>0</sub> status by frozen section examination of nodal levels 4, 7, and 10 on the right side and 5, 6, 7 and 10 on the left side. *Refer to the protocol for a complete list of eligibility requirements.*

## Treatment Plan

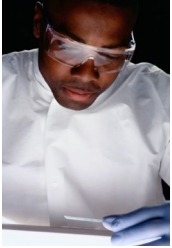
About 908 eligible patients will be randomized on one of two arms – Arm A being lobectomy and Arm B being sublobar (or limited) resection (segmentectomy or wedge resection).

The Study Chair is Nasser Altorki, M.D., Weill Medical College of Cornell University, e-mail: [nkaltork@med.cornell.edu](mailto:nkaltork@med.cornell.edu). The Imaging Co-chair is Ernest Scalzetti, M.D., State University of New York Upstate Medical University, e-mail: [scalzete@upstate.edu](mailto:scalzete@upstate.edu).

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## Soon-to-open Trial Explores How Early Intervention May Delay Time to Second Treatment



**10501/CTSU C10501 A phase III intergroup CLL study of asymptomatic patients with untreated chronic lymphocytic leukemia randomized to early intervention versus observation with later treatment in the high risk genetic subset with IgV<sub>H</sub> unmutated disease**

CALGB 10501/CTSU C10501, chaired by John Byrd, M.D., of The Ohio State University Medical Center, will determine whether early treatment of high risk chronic lymphocytic leukemia (CLL) that has not yet developed common secondary chromosomal aberrations with a highly effective chemoimmunotherapy regimen will prolong the time to requiring second treatment and ultimately overall survival. In essence, the study will determine the best time to begin treatment for patients with CLL that has certain high-risk features, and will determine whether patients with these high-risk features will live longer if treatment is given earlier.

In the 1980s, researchers studied whether the drug chlorambucil (a standard CLL treatment), when given to CLL patients who had no health problems due to CLL, would help them live longer. The studies showed that early treatment with chlorambucil before CLL patients develop disease-related symptoms did not help CLL patients live longer than those whose treatment with chlorambucil started later after disease-related symptoms had appeared. In addition, early treatment meant early exposure to various side effects from the treatment itself. As a result, treatment for CLL is usually not recommended until the disease worsens. Current treatments for CLL, however, have proven to be more effective than those used in the 1980s, such as chlorambucil. Additionally, new blood tests may predict more accurately if the disease is either likely to worsen quickly (high-risk CLL) or is likely to remain stable or progress slowly (low-risk CLL).

The treatments used in this study include the drugs fludarabine and rituximab, which were first studied in CALGB 9712. Fludarabine has been approved by the Food and Drug Administration (FDA) for the treatment of CLL and related diseases. Although not approved by the FDA for the treatment of CLL, rituximab has been approved for the treatment of patients diagnosed with non-Hodgkin lymphoma whose disease has recurred despite previous treatment or resisted previous

### GROUP CHAIR

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-win" for all parties involved in the collaboration. For CALGB, the support of a pharmaceutical company partner provides access to interesting new drugs, financial support to conduct the trial and, often, resources to conduct important correlative science or quality of life studies that are not funded by CALGB grants.

For the drug sponsor, CALGB provides access to an established network of high quality clinical trial sites, expertise in clinical trial design, input from key opinion leaders and an ability to leverage public funding to extend the scope of the company's clinical development program. Perhaps most importantly, our patients benefit from broader testing of new agents in more diverse patient populations, greater access to promising new agents and confidence that CALGB trials are independently designed and monitored and that the trial results will be completely and accurately reported to the medical community in a timely fashion.

Developing these collaborations is not always easy. The negotiations required to achieve the objectives of the investigators and the sponsors, as well as the approval of the regulatory authorities, are often complex and protracted involving not only clinical investigators and statisticians but regulatory managers, lawyers and financial officers.

Nevertheless, by adhering to the principles set forth by Dr. Piccart and colleagues, CALGB has developed an array of successful partnerships with industry that will help us achieve our primary objective of improving the survival and quality of life of cancer patients by developing "Tomorrow's Cancer Treatments Today."

Richard L. Schilsky, M.D., Chairman

Source

I. Piccart, M., Goldhirsch, A., Wood, W., et. al. Keeping faith with trial volunteers, *Nature*, 446:137, 2007.

treatment. Its use in this study is considered experimental. This research is being done because there is no proven cure for CLL. The most beneficial time to begin treatment for patients with high risk CLL is uncertain. For patients with advanced disease or disease-related symptoms at diagnosis a separate study, CALGB 10404, is under development.

## CRA PERSPECTIVE

# What Correlative Science Protocols Mean for CRAs

By Anne Burgess, B.S.N., R.N., C.C.R.C., Brigham and Women's Hospital, Boston, MA and Linda Veit, B.S., C.C.R.P., SUNY Upstate Medical University Hospital, Syracuse, NY



Over the past several years, there has been a significant increase in the number of correlative science studies performed within the Cancer and Leukemia Group B (CALGB). Therefore, it is now even more important for Clinical Research Associates (CRAs) to understand what correlative science studies are, what they encompass and how to implement any additional requirements needed into the research infrastructure.

### Understanding Correlative Science Protocols

Correlative science protocols involve the collection of biospecimens, which facilitate scientific study in predicting, diagnosing, staging and treating illness. Biospecimen collection also allows for research on innovative therapies, including targeted therapies, to treat disease. These biospecimens include, but are not limited to, blood, urine, bone marrow, lymph nodes and tissue obtained at the time of surgery. The timely and accurate collection of these biospecimens as outlined in each protocol is key to the success of answering the scientific inquiries.

Correlative science research can be embedded within a protocol or be a separate companion protocol. Participation in these protocols can be optional or requisite, require Institutional Review Board (IRB) approval, and all subjects must be fully informed and consented. There may be separate consent questions related to the collection of biospecimens included within the main protocol consent. It is imperative to follow the CALGB model consents when initiating protocols.

### Making Connections Early

Before or while submitting protocols to your IRB, it is timely to initiate a conversation with those who are considered key personnel in collecting specimens. For example, a correlative science protocol, which is embedded in a treatment protocol may require tissue obtained at the time of surgery. In this case, the IRB application should include surgeons as a member of the research team. In particular, the pathologists who will allocate tissue for those protocols that require submission of fresh tissue are critical to the CRAs' ability to fulfill the protocol requirements.

It is helpful when the engagement of the local team is a joint effort by the site principal investigator and the responsible CRAs. Open and effective communication between all disciplines including medical oncologists, surgical oncologist, pathologist and CRAs is vital to the success of correlative science research.

### Staying Ahead of the Process

Once a protocol that includes a correlative science

component or a correlative science companion protocol has received IRB approval, any supplies needed to collect biospecimens should be ordered and obtained at this time. Prior to the first subject, it may be helpful to perform a "test run" to determine and observe the various locations where biospecimens are obtained, establish logistics for obtaining biospecimens and identify potential obstacles. This is also an opportunity for CRAs to introduce themselves to phlebotomists, pathologists, and others who may be valuable in assisting with biospecimen collection. As soon as a subject is screened, eligible and consented to a protocol, the collection of biospecimens will begin.

### Consider these helpful tips:

- Inform those involved in the tissue procurement process of the subject's willingness to participate and provide a copy of the signed consent as per institutional guidelines.
- Send a schedule to those involved which includes biospecimens required and dates and times of collection.
- Provide a copy of the procurement specification guidelines included in the protocol in advance of the first subject for reference.
- Provide supplies needed (dry ice, aliquots, medium, labels [subject and shipping], shipping boxes, and any other protocol specific supplies required to securely and safely procure and send biospecimens).
- Be available on the day of tissue collection, particularly if procurement is required from a subject undergoing surgery. Participating in a "test run" may give you an estimate of the time needed to collect, process and ship or store (per protocol guidelines) biospecimens.
- Utilize LabTrak for biospecimen collection tracking (per protocol).
- Ensure that those involved in collecting and shipping biospecimens have current biohazard shipping education and training.

### Need More Information

Resources are available for CRAs and subjects who participate in correlative science protocols on the CALGB Web site ([www.calgb.org](http://www.calgb.org)). Of particular note, a recent *CAL-GAB* (Spring 2007) issue featured the Group's selection by the National Cancer Institute to engage in the Cancer Genome Atlas Pilot Project and Oncology Biomarker Qualification Initiative ([www.cancer.gov](http://www.cancer.gov)). This illustrates the high-quality research and commitment to correlative science of CALGB. Correlative science research is of vital importance to the mission of CALGB and its charge to spearhead "Tomorrow's Cancer Treatments Today."



## Colorectal Cancer The Facts about Prevention and Screening

*By Sherri G. Homan, R.N., Ph.D., Missouri Department of Health and Senior Services*

Approximately 60 percent of invasive colorectal cancer occurs in individuals of average risk.<sup>1</sup> Much can be done to prevent its occurrence through preventive action and screening.<sup>1-6</sup> Yet, many individuals remain unaware of risk factors and do not engage in preventive measures. Many individuals who could benefit greatly are not getting screened.<sup>7-9</sup> According to the 2005 Behavioral Risk Factor Surveillance System (BRFSS), fewer than a quarter of adults (23.2 percent) eat the recommended five servings of fruits and vegetables daily; and in 2006, only a little more than one-half (57.1 percent) of persons aged 50 and older reported ever having had a lower endoscopy (i.e., sigmoidoscopy or colonoscopy), and fewer than one-fourth (24.2 percent) reported having had a blood stool test in the preceding two years.<sup>10</sup>

About 80 percent of colorectal cancers arise from adenomatous polyps.<sup>1</sup> Many of the remaining cases occur in individuals with a family history of colorectal cancer in a first-degree relative, particularly if it occurred before age 60, and in those with genetic syndromes. Fewer than 1 percent of adenomatous polyps less than 1 cm will develop into cancer. However, about 10 percent of the polyps greater than or equal to 1 cm become malignant within 10 years and about 25 percent become malignant after 20 years.<sup>11</sup>

Screening measures decrease the morbidity and mortality from colorectal cancer by detecting the disease early and removing precancerous lesions (i.e., adenomatous polyps). However, as a result of the under-use of prevention and screening, colorectal cancer remains the second leading cause of cancer-related death and third most common cancer in the United States.<sup>12</sup> In 2007, an estimated 153,760 new cases and 52,180 deaths of colorectal cancer will occur in the U.S.<sup>13</sup>

In 2003, the U.S. colorectal cancer incidence rate was significantly higher among men (60.4 per 100,000) than among women (44.2 per 100,000), with the mortality rate having similar gender disparity (23.0 for men and 16.1 for women per 100,000).<sup>14</sup> Moreover, U.S. African-Americans (26.4 per 100,000) died at a significantly higher rate from the disease than Whites (18.5 per 100,000).<sup>14</sup> This racial disparity is likely due to socioeconomic status (i.e., poverty and deprivation) rather than race per se.<sup>15</sup>

The average person dying of colorectal cancer now loses approximately 14 years of life.<sup>11</sup> With current treatment, the incidence and mortality of colorectal cancer could be reduced by 50 percent to 60 percent if all individuals aged 50 and older actively engaged in recommended colorectal cancer preventive and screening practices.<sup>1, 16</sup>

Assessing risks and family and personal history is an essential component of cancer primary and secondary prevention. For primary prevention, risk and history assessment not only documents exposure to risk factors but measures the impact of these factors, and provides the opportunity to intervene by tailoring the colorectal screening schedule based on the medical and family history.

The U.S. Preventive Services Task Force (USPSTF), American Cancer Society, and other science-based organizations strongly recommend colorectal screening for those 50 years of age and older at average risk.<sup>1, 13</sup> Recommended screening tests (alone or in combination) and intervals include: fecal occult blood test (FOBT) every year; flexible sigmoidoscopy (FSIG) every 5 years; double-contrast barium enema every 5 years; and/or colonoscopy every 10 years. In addition, USPSTF recommends increasing screening in people with no usual source of health care, no health insurance, and recent U.S. immigrants (i.e., within the previous 10 years).<sup>2</sup>

— see **ONCOLOGY NURSING**, next page

# ONCOLOGY NURSING PERSPECTIVE



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Three sample guaiac-based FOBT testing has been shown effective in reducing colorectal cancer incidence and mortality.<sup>11, 17</sup> Although FOBT alone has shown effectiveness, combining FOBT with flexible sigmoidoscopy substantially improves overall detection of significant polyps (greater than 1 cm) or cancer. Flexible sigmoidoscopy is a safe and effective screening test that visualizes the lower half of the colon, and is estimated to identify 80 percent of patients with significant findings in the colon detecting approximately seven cancers and 60 large (high risk) polyps per 1,000 examinations.<sup>11</sup> Double contrast barium enema (DCBE) has the benefit of visualizing the entire colon, but detects only 48 percent of polyps greater than 1 cm. Colonoscopy, which is the gold standard for comparison, has an estimated first-exam sensitivity of 90 percent for large polyps and 75 percent for small polyps (less than 1 cm).<sup>1</sup> The use of colonoscopy has been associated with a lower incidence rate of colon cancer (odds ratio [OR] 0.47; 95 percent CI 0.37 to 0.58), as well as a lower mortality rate (OR 0.43; 95 percent CI 0.30 to 0.63).

While FOBT is highly acceptable to participants, it can lead to more invasive procedures. However, sigmoidoscopy can lead to bowel perforation (1 to 2 per 10,000 examinations), and complications may arise in approximately one in every 10,000 barium enema examinations. Although colonoscopy is highly effective,

the rate of perforation and major bleeding is about one per 1,000 procedures. Nevertheless, lower endoscopy with FSIG or even more preferably, colonoscopy, offer direct visualization of the colon and the highest protection against colorectal cancer. Digital rectal exam (DRE) and office FOBT are not adequate colorectal screening methods. Other methods, such as virtual colonoscopy, show promise but there is insufficient evidence currently to promote these methods for average risk mass screening.

The Healthy People 2010 midcourse objectives for colorectal cancer are to increase the use of FOBT and sigmoidoscopy and to reduce the U.S. death rate to 13.7 deaths per 100,000 population.<sup>18</sup> The U.S. rate in 2003, for both sexes and all races combined, was 19.0 per 100,000 population requiring an almost 28 percent reduction to reach the mortality objective.<sup>14</sup>

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## CALGB ONCOLOGY NURSES

The Oncology Nursing Committee (ONC) is currently seeking to recruit nurse liaisons to become ONC cadre members. We are specifically seeking nurse liaisons for the following disease/modality committees:

- Lymphoma
- Committee on Advocacy, Research, Communication and Ethics (CARE)
- Cancer in the Elderly

Responsibilities of Nurse Liaisons are as follows:

1. Mandatory attendance at all core and main meetings. (3-4 meetings/year)
2. Review of research studies emerging from the assigned disease/modality committee.
3. Review of all new data-collection forms relevant to studies from the assigned committee.
4. Periodic submission of a brief, nursing-focused article to the CAL-GAB newsletter.
5. Participation in the planning and execution of educational endeavors which enhance the knowledge of nurses, patients, and other health-care professionals regarding issues relevant to CALGB trials.
6. Participation in the development of nurse-generated CALGB studies.

Optimal candidates for nurse liaison positions are individuals with a strong clinical and/or research focus in areas of lymphoma, CARE or Cancer in the Elderly. A Master's Degree is preferred.

**Interested candidates should send a cover letter and CV to:**

**Ellen M. Lavoie Smith, Ph.D.(c), M.S., A.P.R.N.-B.C., A.O.C.N.**

**Chair, CALGB Oncology Nursing Committee**

**Ellen.L.Smith@Hitchcock.org**



## NURSE RESEARCHERS

The Oncology Nursing Committee (ONC) is currently seeking to recruit a nurse researcher whose program of research is focused in symptom management or cancer survivorship.

Responsibilities of an ONC Nurse Researcher are as follows:

1. Mandatory attendance at all core and main meetings. (3-4 meetings/year).
2. Cross-Committee Collaboration in Disease/Modality Committees  
Nurse researchers are expected to:
  - Inform respective disease committees of ONC activities/initiatives;
  - Offer nursing perspective and expertise during study design discussions and through formal protocol and new data collection form review; and
  - Participate in cross-committee educational endeavors such as educational sessions or material development targeting CALGB professionals and patients.
3. Serve as a Principal and/or Co-investigator on CALGB trials
4. Mentor CALGB advanced practice nurses interested in becoming CALGB investigators.
5. Periodic submission of a brief, nursing-focused article to the CAL-GAB newsletter.
6. Publication/Dissemination of CALGB-related research findings.

Optimal candidates for this nurse researcher position are individuals with a strong drive to conduct cooperative group research, and willingness to mentor others.

**Interested candidates should send a cover letter and CV to:**

**Ellen M. Lavoie Smith, Ph.D.(c), M.S., A.P.R.N.-B.C., A.O.C.N.**

**Chair, CALGB Oncology Nursing Committee**

**Ellen.L.Smith@Hitchcock.org**

# TRAINING UPDATE

## CRA Kiosks Debut at Summer Group Meeting

*CRA Kiosks made their debut at the 2007 CALGB Summer Group Meeting. The CALGB Training Steering Committee and Clinical Research Associates Committee worked together to develop a new format to address questions from CRAs at Group meetings.*

Based on previous surveys from CRAs, three topics were determined to be of the greatest interest – audit preparation, case report forms and long-term follow-up, and Information Systems. These topics provided the basis for three so-named kiosks. (The Information Systems kiosk covered Secure Mail and IS applications such as LabTrak, Patient Registration and the Reporting System.) At the kiosks, a CRA selected from the CRA Committee and a Data Coordinator from the CALGB Statistical Center and other CALGB staff answered questions on these topics.

### Feedback from CRAs

CRAs visiting each kiosk provided positive feedback and appreciated the opportunity to ask institution- or case-specific questions. CRAs also expressed that the one-on-one format was more conducive to getting the information they needed than more formal group sessions. Kiosk staff happily answered a variety of questions. Here is a sampling of general questions that were brought to the kiosks, along with resources that are available to CALGB members at [www.calgb.org](http://www.calgb.org).

### Audit Kiosk

Most questions asked at the audit kiosk were specific to an institution. Those interested in general audit information should attend the Audit Preparation Workshop offered annually at the Group meeting. Pre-registration is required. All Lead CRAs receive information about the workshop prior to Group meetings and should forward it to all other eligible CRAs within their network.

**Download** the 2007 Audit Preparation Workshop presentation from the CALGB Web site at [http://www.calgb.org/Public/meetings/presentations/2007/audit\\_062007.php](http://www.calgb.org/Public/meetings/presentations/2007/audit_062007.php)

**Check out** other CALGB audit resources online at [http://www.calgb.org/Private/COOP\\_Groups/CALGB/resources/audit/audit\\_resources.php](http://www.calgb.org/Private/COOP_Groups/CALGB/resources/audit/audit_resources.php)

### Case Report Forms and Long-term Follow-up Kiosk

Online data form submission garnered many questions at this kiosk. For more information on online data form submission, check out the CALGB Protocol posting on August 15, 2007. Additional information is available online under the CALGB Training tab at [www.calgb.org](http://www.calgb.org).

Other commonly asked general questions:

**Q:** How do you know which companions are optional?

**A:** Most companions must be offered by the institution to the patient. In some instances, the patient must participate in the companion in order to participate in the treatment study. Other companions are optional for the patient. You can consult the registration/randomization section of the protocol, posted under the Studies tab at [www.calgb.org](http://www.calgb.org) or contact the Data Coordinator or Protocol Coordinator for further protocol-specific information.

**Q:** Is it okay to mark outside the boxes on a TeleForm data form?

**A:** Ideally, now that you can complete and submit a form online, this should not be an issue. However, if you must complete a form by hand, confine responses to the box or the area specified for that response on the form so the TeleForm scanner can recognize your selection. Please refer to the TeleForm instructions for correct examples: [http://www.calgb.org/Private/COOP\\_Groups/CALGB/studies/forms/TELEform\\_Instructions.pdf](http://www.calgb.org/Private/COOP_Groups/CALGB/studies/forms/TELEform_Instructions.pdf)

In addition, if your responses exceed the length of a field on a form, use the C-260 Remarks Addenda form to submit additional information.

### Information Systems Kiosk

Questions at this kiosk centered on Web applications such as LabTrak, Patient Registration and Web Reports. There were also questions about specimen submission.

To find resources on IS applications, visit the Training tab online at [www.calgb.org](http://www.calgb.org). Many questions can be answered by referring to this material or by contacting the Help Desk at 1-877-442-2542. Also, refer to the IS Corner column found in quarterly CAL-GAB newsletters (see page 11 in this issue).

For information on the future of specimen submission, refer to the recent CRA Committee presentation delivered by Paula Friedman, Ph.D., Director of CALGB Biospecimen and Correlative Science Operations, at [http://www.calgb.org/Public/meetings/presentations/2007/cra\\_committee/09-Pathology-Friedman062007.pdf](http://www.calgb.org/Public/meetings/presentations/2007/cra_committee/09-Pathology-Friedman062007.pdf). Also, she can be contacted in the CALGB Central Office at [pfriedman@uchicago.edu](mailto:pfriedman@uchicago.edu) for additional information on the new system.

## New Applications Enhance Systemwide Usability

*CALGB Information Systems (IS) has recently developed three new applications to better serve CALGB members. The CALGB Reporting System will help improve access to CALGB reports while the Pre-Registration feature introduces a new step in the patient registration process for some protocols. And TeleForm® Web Submit will allow for the electronic submission of specific data forms, expediting data entry.*

### CALGB Reporting System

In June, IS released the CALGB Reporting System to replace the CALGB Web Reports System. This new application supports all reports contained in the previous system. It also supports the current Health Insurance Portability and Accountability Act (HIPAA) requirements by requiring a secure login, which automatically logs off if there is no activity and limits access by role to reports and information.

The CALGB Reporting System is easy to use and available on the CALGB Web site to CALGB members under the IS Applications tab. It allows CRAs and CALGB members and staff to run and schedule reports relevant to individual jobs (roles), view descriptions of available reports, and access previously run reports. Scheduled reports can be set to run one time or multiple times at various intervals, including daily, weekly and monthly. Reports can include information on study accruals, patient registrations, sample summaries and institution Institutional Review Board (IRB) status.

### Pre-Registration Feature

Patient Pre-Registration, also released in June, is a new feature found in the Patient Registration Application. Patient Pre-Registration associates (but does not register) a patient to a study and assigns a Patient ID after the required data is entered.

Patient Pre-Registration must be used when the protocol (for example, CALGB 10001) specifies a pre-registration step. Typically, pre-registration information is used by other applications or processes that determine a patient's eligibility for the specified study.

### TeleForm® Web Submit

The new TeleForm Web Submit – a forms format that allows CRAs to submit certain study data forms electronically – launched in August. It enables data to be entered into the database more quickly, which will reduce the need to fax or mail forms, reduce the chance of lost or inaccurate data, and potentially reduce postage costs.

Forms that can be electronically submitted will have a Submit to CALGB button on the bottom of the last page, and they can be submitted with one click of the button.

### Coming Soon

#### Routine Adverse Events Reporting System

With the new Routine Adverse Events Reporting System, or RAERS (pronounced "rares"), CRAs will be able to submit study-required adverse event forms electronically, eliminating the need to mail or fax data. Using the new system, CRAs will easily specify adverse event codes because they will be supplied on the electronic form. In addition, grades and attributions can be selected from drop-down menus that are specific to the event being reported. There is immediate notification of common errors, which will reduce queries about invalid data.

After CRAs submit reports, Data Coordinators will use RAERS to approve them, sending them to the CALGB database. Data Coordinators may also request corrections and correct or amend database records of reports previously approved.

Data entry staff will use RAERS to create reports and submit them to the database. Statisticians will use RAERS to view adverse events records from the database.

Preliminary test results from CRAs and Data Coordinators indicate that the RAERS application report is easy to use and is considered an improvement over the current, paper-based system.

RAERS is undergoing live testing and should be available for general use this fall.

### System Update Specimen Tracking

Requirements for a new specimen tracking system to replace LabTrak have been developed by an internal cross-functional team composed of staff from the Central Office, Information Systems and repositories, including Data Coordinators, Statisticians and CRAs. The new system, when completed, will be web-based, intuitive and most importantly, will reduce the amount of effort required to log, ship and receive specimens. Also, logged specimen data will be searchable and retrievable. The system should be available mid-2008. Watch this column for future updates.

# CALGB GROUP NEWS

## STAFF UPDATES

### @ The Central Office

**Katherine Beckett** joins CALGB as a Database Analyst from Leo Burnett USA/Resources IT. Beckett will provide reports for the CALGB staff using Crystal Reports, Crystal Enterprise maintenance and administration, and Oracle database programming.

As Senior IT Analyst, **Benjamin Kleinman** will help develop CALGB system applications and software, maintain the CALGB Web site and protocol postings, and serve as the Central Office IT liaison to the Statistical Center. Kleinman comes to CALGB from IT units at SWOG and ECOG.

### @ The Statistical Center

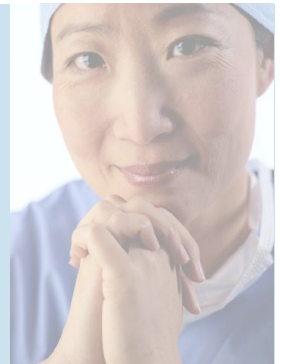
**Nimesh Patel** joins CALGB as a Java Developer from AT&T (Cingular) where he worked as an Application Developer Analyst. Patel will design and develop Java applications supporting cancer clinical trial operations, including the Query Tracker System.

As a Java Developer, **Rahul Sood** will work on the Institutional Per Case Payment Application (PCPA). Sood brings his software development expertise to CALGB from Asparity Decision Solutions and Carefirst Blue Cross Blue Shield.

## CANCER CARE continued from page 1

### Christiana Care Health Services, Inc.

The Delaware/Christiana Care Community Clinical Oncology Program (CCOP), located in Newark, DE, has a long history of participating in NCI cooperative group research that dates back to the early 1970s. Since its inception as a CCOP in 1987, Christiana Care has maintained one of the highest levels of patient participation in NCI-sponsored clinical trials, and in recent years, total trial participation reached more than 5,000. It is the major regional healthcare provider, providing service to areas in Maryland, Pennsylvania and New Jersey. Recently, the Helen F. Graham Cancer Center at Christiana Care was chosen by NCI as one of 14 cancer programs to pilot the NCI Community Cancer Centers Program (NCCCP), a strategic initiative to extend access to NCI-sponsored clinical trials around the country. Christiana Care will host its 20th Anniversary Gala on November 1, 2007 at the Hotel du Pont in Wilmington, DE. Stephen Grubbs, M.D., is the Principal Investigator, and Kandie Price, M.S., R.N., O.C.N., C.C.R.P., is Director of the Cancer Research Office.

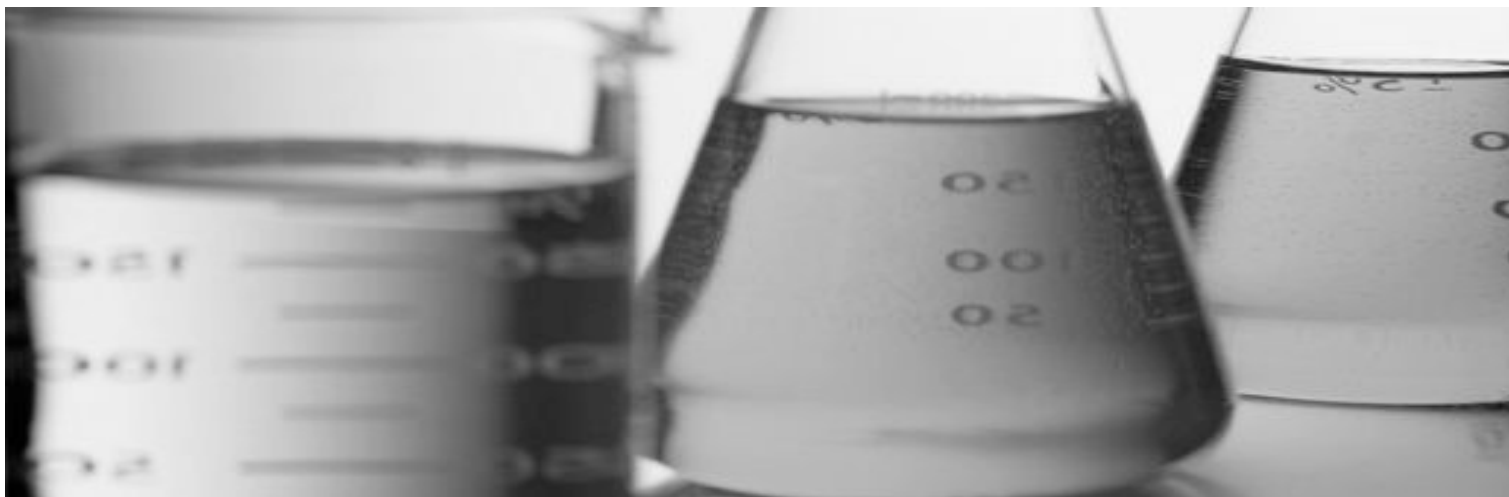


### Southeast Cancer Control Consortium, Inc.

In 1986, the concept for the Southeast Cancer Control Consortium (SCCC) was developed by Charles L. Spurr, M.D., a medical oncologist with Bowman Gray School of Medicine, with NCI funding granted in 1987. The SCCC is designed to treat adult oncology patients as well as deliver community-based cancer prevention/ control programs. Initially, eleven charter components participated; however, current participation has grown to 19 components. In 1993, Spurr relinquished leadership to James N. Atkins, M.D., a medical oncologist affiliated with Wayne Memorial Hospital in Goldsboro, NC. Currently, the SCCC has more than 100 physicians, including oncologists, surgeons, urologists and radiation oncologists, and a six-person operational office staff in Winston-Salem, NC, which oversees daily program operation. Since its inception in 1987, the SCCC has enrolled 10,321 patients/participants to clinical trials and provides access to about 180-200 clinical trials. The SCCC will host its 20th Anniversary Celebration on October 19, 2007 at the Grand Dunes Marriott Resort in Myrtle Beach, SC. James N. Atkins, M.D. is the Principal Investigator, and Susan Tuttle, R.N., C.C.R.P., is the CCOP Administrator.

### Mount Sinai Medical Center

Mount Sinai Community Clinical Oncology Program (MSCCOP), located in Miami Beach, FL, is the only NCI-funded research institution in South Florida. Its status allows it to direct cancer studies at other major hospitals and participate in about 60 clinical trials in cancer prevention and treatment. The nonprofit community-based program provides novel clinical research to cancer treatment patients and to healthy individuals who may be at risk for cancer. In recent years, the MSCCOP has entered about 300 patients onto clinical trials with more than 3,200 patients entered since its inception in 1987. The MSCCOP also has succeeded in making cancer research studies available to diverse economic and ethnic groups. It is a national leader in minority accrual, entering significant percentages of Hispanic and African American/Islander patients onto trials. Rogerio Lilenbaum, M.D., is the Principal Investigator, and Francine Minneau is the CCOP Administrator. The MSCCOP is currently developing plans to celebrate its 20th year.



## GI COMMITTEE

### OPENED

**CTSU—S0600:** PhIII ir+cet +/- bv col ca prog bv +FFX, OPMX or XLX

*Study Chair: L. Saltz*

### SUSPENDED

**80302—**Preop cis + CPT11 -> cis/CPT11/rt: loc adv esoph ca

*Study Chair: D. Ilson*

## LEUKEMIA COMMITTEE

### SUSPENDED

**10602—**Aza +/- MS-275 for MDS, CMML, and AML w/ multi dysplasia (E1905)

*Study Chair: J. Gabilove*

**CTSU—E2902:** R115777 in AML in 2nd or sub remission or ind failure

*Study Chair: R. Larson*

## RESPIRATORY COMMITTEE

### OPENED

**30601—**Phase II study of dasatinib in malig meso

*Study Chair: A. Dudek*

### CLOSED

**CTSU—R0214:** PCI vs OBS in locally advncd NSCLC

*Study Chair: J. Bogart*

# SUPPORT



The following have provided support to Cancer and Leukemia Group B research and educational programs in 2007. Thank you for your support.

Abbott Laboratories

Abraxis BioScience

Amgen, Inc.

AstraZeneca

Bayer HealthCare Pharmaceuticals

Breast Cancer Research Foundation

Bristol-Myers Squibb Oncology

Celgene Corporation

Eli Lilly

Enzon Pharmaceuticals

Genentech BioOncology

GlaxoSmithKline

GPC Biotech

Millennium Pharmaceuticals

Neopharm

Novartis Oncology

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# Give Today Get Away

Earn American Airlines®  
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when you give to the CALGB



Your generous gift will help fight cancer and bring you closer to the vacation of a lifetime. What's more, you'll earn 500 miles for every \$100 you give. Just include your AAdvantage number in the space provided and we'll take care of the rest.\*

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:

**Cancer and Leukemia Group B Foundation.**

*Thank you for your support.*

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

- In Memory of \_\_\_\_\_  Please use my gift where needs are greatest
- In Honor of \_\_\_\_\_  Please use my gift for \_\_\_\_\_
- Occasion \_\_\_\_\_
- Please send me information on how to include the Cancer and Leukemia Group B Foundation in my will or charitable trust.

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City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_

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

\* Gifts of \$1,000 or more earn 10 miles per dollar donated. Gifts of \$100-\$999 earn five miles per dollar donated. Gifts up to \$99 earn one mile per dollar donated.