THE CAL:GAB

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QUARTERLY NEWSLETTER OF THE CANCER AND LEUKEMIA GROUP B

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June 9–11, New Orleans, Louisiana. Registration Deadline May 31.
There's still time to register! Registration form, hotel reservation form, updated meeting schedule and meeting highlights inside.

Cancer and Leukemia Group B
Central Office of the Chair
208 S. LaSalle St., #2000
Chicago, IL 60604-1104
(773) 702-9171
www-calgb.uchicago.edu

Everything you always wanted to know about Urologic Cancers

Mary Elshamy ARNP, AOCN
Dartmouth Hitchcock Medical Center

It's not just prostate cancer anymore. The renamed GU Cancer Committee of the CALGB now includes other urologic cancers within its research scope. This article presents a brief review of bladder and renal cell cancers, the staging systems used for these diseases, and an introduction to proposed concepts for CALGB research. The GU Committee will also begin research in testicular cancer--a similar overview will be presented in a future CALGAB. Prostate cancer will continue to be an area of significant research within the GU Committee, focusing on early to late stage disease interventions and novel approaches.

Bladder Cancer

It is estimated that in the year 2000 there will be 53,200 new cases of bladder cancer diagnosed in the United States. An additional 1,100 cases of cancer of the ureter and other urinary organs is estimated. Deaths from bladder cancer in 2000 are anticipated to reach 12,200 with an additional 500 deaths from cancer of the other urinary organs. The incidence of cancer of the bladder is four times higher in men than in women and the rate among whites is double the rate among blacks. The incidence of mortality has significantly declined in the US since the 1970s from a relative 5-year survival rate of 73% to a rate of 81% in the 1990s. This decrease in mortality may be in part due to early diagnosis. Currently 70% of new cases of bladder cancer are diagnosed in the superficial stage.

Smoking is a risk factor for the development of bladder cancer: smokers' risk is double that of non smokers. Smoking is responsible for 47% of bladder cancer deaths in men and 37% of bladder cancer deaths among women. Other environmental and occupational risk relationships are noted, with increased incidence in urban areas and among workers in dye, rubber or leather industries. Hematuria (blood in the urine) is the most common presenting symptom of bladder cancer. Diagnosis is then made utilizing urine cytology and cystoscopy. There are no effective screening tools for bladder cancer yet.

Transitional cell cancer (TCC) accounts for 95% of the pathology of bladder cancer. Squamous cell cancers are rare, from 2% to 5% of cases. Adenocarcinoma is very rare, seen in 0.5% to 2% of cases. Several other rare subtypes have been reported. Patient survival ranges greatly according to the stage of disease at diagnosis. Five-year survival for minimal disease is about 82%. However 5-year survival rates for a patient with metastatic disease fall to the range of 39%.

Renal Pelvis, Ureter and Urethral Cancers

Cancers of the urethra, ureter and renal pelvis are rare cancers of the urothelium. They are often included in bladder cancer clinical trials as their pathology mimics that of bladder cancer. The pathology of cancer of the renal pelvis differs from the usual pathology of renal cell carcinoma (RCC) or kidney cancer. The majority (80%) of cancers of the renal pelvis are TCC, similar to the pathology

Urologic Cancers
continued on page 4

MESSAGE FROM THE CHAIR

As I begin my second term as CALGB Chairman, it is worthwhile to reflect on the many changes that have occurred in the Group during the past 5 years. Our major focus has been on rejuvenating the scientific leadership of CALGB and on judiciously expanding into new areas of scientific opportunity. We have installed new leadership in most of our scientific committees by replacing sixteen committee chairs and by encouraging significant turnover in committee membership. We have appointed working groups in Melanoma and Cancer in the Elderly and have expanded the Prostate Committee to become a GU Committee. We have established a new Pathology Coordinating Office that has brought significant new technology and expertise to the Group and have created a coordinated research activity in Cancer Control and Health Outcomes. In the past few years, several major institutions have joined CALGB as main members including Ohio St. University, the University of Nebraska, Georgetown University, the Medical University of South Carolina and Memorial Sloan Kettering Cancer Center and nine new institutional PIs now serve on the Board of Directors. Our membership categories have been restructured to permit physician practices as well as hospitals to join CALGB and to allow larger affiliates and CCOPs to participate directly in Group activities and governance as At-Large members. Our funding programs have, likewise, been re-organized to insure that all institutions in the Group are reimbursed directly and at the same rate for the work they do on behalf of CALGB. We have worked vigorously to establish international collaborations with the Cancer Research Campaign Clinical Trials Unit in the United Kingdom, the EORTC and other organizations as a means of enhancing accrual to some of our studies. In addition, we have reached out to the pharmaceutical industry to partner with them in bringing new drugs and diagnostic tests to market for the American people and to develop studies with many exciting new agents. A very gratifying change has been the recruitment of patient advocates to serve on CALGB committees to provide their perspective on the needs, fears and desires of patients with cancer and to recommend changes in protocol design to enhance accrual.

Richard L. Schilsky, M.D.

We have done these things while, at the same time, re-designing the database that supports the work of the Group, implementing an aggressive data reduction policy to reduce the workload at institutions, introducing on-line registration for CALGB studies, re-designing and expanding the use of the CALGB web site and cooperating actively with the National Cancer Institute in the re-design of the national cancer clinical trials program.

To be sure, these many accomplishments are not the work of one person and there are many to thank for all that has been accomplished. I have been fortunate to have an outstanding, dedicated and loyal staff at the Central Office, knowledgeable and creative Executive Officers, a wonderful colleague and friend in Steve George, a superb group of statisticians, data coordinators and computer programmers at the Statistical Center, wise and consistent counsel from Mark Green, the CALGB Vice Chair, strong support from the Executive Committee and the Board of Directors and, of course, remarkably dedicated colleagues at CALGB institutions everywhere.

The many changes that have occurred have produced tangible results in CALGB. We now have 90-95 protocols actively accruing at any point in time. Annual accrual to therapeutic studies has increased from about 3,300 in 1995 to nearly 4,000 in 1999; and overall accrual has gone from 4,588 in 1995 to almost 6,400 last year. CALGB investigators continue to lead the way in correlative science studies and have been successful in obtaining eight investigator-initiated NIH grants, as well as support from non-profit foundations to support this work since 1997.

Where do we go from here? We have worked hard to rejuvenate the scientific leadership of the Group, to enhance the infrastructure necessary to develop and conduct studies efficiently, to develop incremental resources and to encourage the participation of patients in our work. This is, without doubt, the most exciting time ever to be engaged in cancer research. The science is breath-taking, there are more new agents in development for cancer treatment than ever before, the tissue resources of the Group provide extraordinary opportunities to enhance our understanding of predictive and prognostic factors in cancer treatment. The stage is set in CALGB for great progress in the next 5 years. Keep the ideas coming!

The *CAL•GAB* is published quarterly by the Cancer and Leukemia Group B and is distributed free to the CALGB active membership. Suggestions for articles are encouraged. The next copy deadline is July 5, for the Summer 2000 edition. Articles and correspondence should be sent to: Robert Blount-Lyon, CALGB Publications Coordinator; 208 S. LaSalle St., Suite 2000, Chicago, IL 60604-1104
e-mail: rblountl@midway.uchicago.edu
Voice: (773) 702-9479 Fax: (312) 345-0117

PLEASE NOTE:
While we make every effort to provide accurate dosing information in the CAL•GAB, you should always check the appropriate drug dosages before prescribing and/or administering any medication.

CALGB GROUP NEWS

CALGB Central Office Staff News

Christopher Ryan, M.D., University of Chicago, will be replacing **Ann Mauer, M.D.** on CALGB Central Office staff as **CALGB Executive Officer** July 1. Dr. Mauer will return to full-time practice and clinical research at the University of Chicago Medical Center. Dr. Ryan will be assigned to the same committees as Dr. Mauer, with the exception that David Grinblatt, M.D. will assume responsibility for the Respiratory Committee and Dr. Ryan will be assigned to the GU Committee.

Heather Becker joined the **Protocol Editor** team at the Central Office in March 2000. She will function as the Protocol Editor and Study Coordinator for two new pharmaceutical company sponsored breast trials. Heather has previous experience as an IRB Coordinator, Study Coordinator and Data Manager.

CALGB Main Member News

Michael Schuster, M.D. is new **Principal Investigator** at Weill Medical College of Cornell University in New York City. Dr. Schuster replaces **Ted Szatrowski, M.D.**

CALGB Statistical and Data Management Center Staff News

Tasha Carmon was hired as a permanent CALGB employee in February. She has been the CALGB registrar since November 1999.

Ken Tan was named Deputy Director of CALGB Information Systems. Tan will hold the temporary position of CALGB IS Director after June 1 when Michael Moloney and Rick Preston leave CALGB for new opportunities. Recruitment is under way for a permanent Director of Information Systems—Moloney and Preston will be assisting throughout the process of the CALGB IS transition to new leadership.

Cancer Trials Support Unit (CTSU) will open enrollment to CALGB and other Cooperative Groups in July.

There will be 17 protocols available through the CTSU beginning July, 2000. Five protocols (one breast, two lung, one colorectal, and one leukemia) on the CTSU menu of trials are sponsored by CALGB, and CALGB members are eligible to enroll patients through the usual process. CALGB members will be eligible to enroll patients on the 12 remaining protocols sponsored by other Cooperative Groups through the CTSU.

As of July, 2000, members of CALGB, ECOG, NCCTG, RTOG, NSABP, NCIC, SWOG, GOG, and ACOSOG will be able to access protocols on the CTSU menu, print protocols, sample consent forms, and CRFs, and complete the site registration process through the online system. Educational materials about the CTSU and the protocols will also be available online.

CTSU staff members will conduct educational seminars on how to access and utilize the online system and other CTSU functions at the June, 2000 CALGB Meeting in New Orleans. CALGB members are encouraged to stop by the CTSU display for more information.

The CTSU is a pilot project sponsored by the National Cancer Institute (NCI) for the support of a national network of physicians and patients to participate in NCI-sponsored phase III cancer treatment trials.

CRA Committee News: Mentors needed for new CRAs

The CRA Committee initiated a pilot mentoring program last fall for attendees of the 1999 CRA Beginner's Workshop. The mentoring program is still being evaluated; experienced CRAs are needed to participate as mentors for attendees of the upcoming 2000 Beginner's Workshop—August 11–13 in Durham, NC.

Mentoring is one way to provide additional support to CRAs working on CALGB studies at CALGB institutions. While many new CRAs work in large research offices with other staff members to advise on CALGB data requirements, policies and resources, a number of new CRAs work in smaller medical groups, or in specialties for which CALGB studies are only a small component of their workload. For these or other reasons, some new CRAs may feel "out of the loop" with respect to CALGB activities. Mentoring can help provide a bridge to those individuals, and create opportunities to exchange information that may improve job satisfaction and may even affect the quality of data collection.

At many research sites, the burden of training new CRAs falls on Senior CRAs who may already have full workloads. Mentors may be able to help by providing another resource for a trainee to consult when problems arise related to CALGB protocols or procedures. A mentoring program offers the opportunity to address individual questions and concerns, and may also provide insight on general Group issues. Mentoring sessions can be tailored to the needs and experience level of the participants, an effective learning method not possible through study of policies and procedures documents. This offers a unique opportunity to build on the skills of an individual and provide support that isn't available from other sources.

Experienced CRAs who are interested in mentoring will be included in the planning process for the 2000 program. New CRAs who attend the Beginner's Workshop will be given information about the mentoring program, and will receive follow-up interim phone calls from mentors throughout the year. All conversations between the mentor and participant are kept confidential. Individuals who are interested in serving as a mentor may contact Jean Roark, chair of the CRA committee at (314) 996-5569 or Laurie Smith at (314) 747-1194.

Urologic Cancers *continued from page 1*

of bladder cancer. Males are three times more likely than females to have cancer of the renal pelvis, and over twice as likely to have cancer of the ureter. The majority of cancers of the ureter are also TCC.

Urethral cancer is extremely rare and accounts for 0.1% of GU tumors. It is seen more frequently in females than males by a 3:1 ratio. And, importantly, the pathology of urethral cancers can vary. In females, squamous cell carcinoma (SCC) accounts for 40% of the cases and these occur in the distal portion of the female urethra. Adenocarcinoma accounts for about a third of female urethra cancers. Transitional cell cancer (TCC) is seen in 21% of female urethral cancers and these occur in the proximal portion of the urethra, closest to the bladder. In males, SCC accounts for more than half of the cases.

Transitional cell cancers of the bladder, renal pelvis, ureter, and urethra are usually treated with the same chemotherapy regimens. Although surgical and radiation interventions differ due to anatomy and physiology, the transitional cell tumors respond similarly to chemotherapy.

Treatment of transitional cell cancers:

Superficial bladder cancers are most often managed with transurethral resection (TUR) of the bladder tumor. Another common intervention that may prevent recurrence of tumor is intravesical therapy: instillations of chemotherapy or immunotherapy into the bladder. Invasive bladder cancer (stage 2) will require more aggressive surgical interventions: from resection to partial or radical cystectomy.

In some patients radiation therapy may be utilized as primary therapy or in combination with chemotherapy and sometimes surgery. In general, radiation may be given to patients with localized disease who are not surgical candidates or who decline surgery. And radiation may be administered combined with chemotherapy in a bladder conservation approach.

Patients with metastatic bladder cancer require combination chemotherapy for treatment of their disease. The four-drug combination MVAC (methotrexate, vinblastine, doxorubicin, cisplatin) has been considered the standard of care over time. New agents and new combinations continue to be tested in comparison to the MVAC regimen. ECOG has an open study comparing MVAC with carboplatin and paclitaxel. CALGB will begin opening studies for TCC by joining the ECOG study. Other chemotherapy agents that are likely to be seen in upcoming CALGB studies include drugs such as ifosfamide, paclitaxel, cisplatin, doxorubicin and gemcitabine. Use of antibodies such as Herceptin and new agents such as arsenic are also among potential study drugs. And the concept of adjuvant therapy in high-risk patients is one of interest to the group and is likely to be a population studied in CALGB.

Renal Cell Cancer

It is estimated that there will be 31,200 new cases of renal cell cancer (RCC) in the United States this year. 11,900 people in the U.S. are expected to die in 2000 due to renal cell cancer. RCC is recognized as the ninth most common tumor in men and thirteenth most common in women, with the cancer affecting males twice as frequently as females. The incidence of this cancer peaks in a person's sixth to seventh decade. However, it may occur in children—about 150 cases have been reported.

Risk factors include a possible correlation with smoking and some possible occupational risks including exposure to fuels, asbestos and other substances. No other clear relationships have been made. Familial clustering of RCC has been noted and Von Hippel-Lindau Disease, an inherited disorder, may predispose a person to kidney cancer.

Renal cell carcinoma (RCC) accounts for 90% of kidney cancers. Within RCC there are several types: clear cell (75%), chromophilic (10%), as well as chromophobic, Bellini duct, oncocytic, metanephroid, and neuroendocrine.

Relative 5-year survival has improved significantly recently. In the 1970s the overall survival rate was 52%. By the 1990s it has reached 60%. Five-year survival by staging demonstrates the remarkable differences between early and late diagnoses. Stage I disease has 85% to 90% five year survival with Stage II at 75% to 85%; a large drop to 58% for Stage III and only 10% to 15% five-year survival for Stage IV disease.

Surgical excision of RCC is the most important approach to management of this disease. Radical nephrectomy can be a complex surgical intervention with prolonged recovery in the age range (60 and 70 years) at highest risk for the disease. A sentinel study by SWOG, reported in the plenary session of this year's ASCO meeting, shows a slight survival advantage for cytoreduction nephrectomy in metastatic renal cancer. Survival following radical nephrectomy is also dependent on the stage of disease.

Partial nephrectomy is another approach in select populations. Surgery in the metastatic setting is usually reserved for palliation of symptoms. Surgical excision of the tumor burden may, however, enhance response to immunotherapy. Radiation therapy has a limited role in the preoperative RCC setting, but may contribute to local control postoperatively. Radiation is most useful in the palliative setting for symptoms associated with primary tumor as well as metastatic sites, especially bone and brain metastases.

Chemotherapy, whether as a single agent or in combinations, produces very limited response in RCC. Multidrug resistance may contribute to this low efficacy, as studied in CALGB 9163. The reversal of the mechanism continues to be elusive.

Immunotherapy is currently the treatment approach of choice for management of RCC, particularly in the metastatic setting. Interferons and interleukins, utilized as single agents as well as in combination, are the current approved standards of care for management of Stage IV RCC. Vaccines and gene therapies may also hold promise for improved response, with new agents entering clinical trial. Immunotherapy in combination with chemotherapy is an approach that will continue to be explored.

The GU committee will pursue novel approaches to treatment of renal cell carcinoma. CAI is a new agent under study opening through the PET committee and is a protocol that will be open for patients who have previous-

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ly failed immunotherapy. Additionally, other antiangiogenic agents are of interest for RCC trials. Another novel immunologic approach for patients with RCC is stem cell transplant, which is likely to be the basis for another CALGB study. Non marrow ablative, or "mini" allogeneic stem cell transplant is designed to elicit an immune response by graft against RCC, rather than the usual transplant approach of overcoming chemotherapy resistance with high-dose chemo followed by transplant. The use of new immunotherapy agents, such as IL-12, is in discussion in collaboration with the Melanoma Working Group, another disease in which immunotherapy seems to have a role. Discussion regarding a trial of chemotherapy agents in combination, Gemcitabine and 5FU, is ongoing.

References

American Cancer Society. (2000). *Cancer Facts & Figures 2000*. Atlanta: Author.

Droller, M. J. (1998). Bladder Cancer: State-of-the-art care. *CA Cancer Journal for Clinicians,* 48 (5), 269-284.

Ernstoff, M. S., Heaney, J. A., & Peschel, R. F. (Eds.) (1997). *Urologic Cancer.* Cambridge: Blackwell Science.

Klein, E. A., Bukowski, R. M., & Finke, J. H. (Eds.) (1993). *Renal Cell Carcinoma: Immunotherapy and cellular biology.* New York: Marcel Dekker, Inc.

STAGING GROUPS

<table>
<tr><th></th><th></th><th>BLADDER CANCER</th><th>RENAL PELVIS AND URETER</th><th>CANCER OF THE URETHRA</th><th>RENAL CELL CANCER</th></tr>
<tr><td>Stage 0a</td><td rowspan="3">Super-ficial B.C.:</td><td colspan="3">Ta / N0 / M0</td><td></td></tr>
<tr><td>Stage 0is</td><td colspan="3">Tis / N0 / M0</td><td></td></tr>
<tr><td>Stage I</td><td colspan="4">T1 / N0 / M0</td></tr>
<tr><td rowspan="2">Stage II</td><td rowspan="6">Deep B.C.:</td><td colspan="4">T2 / N0 / M0</td></tr>
<tr><td>T3a / N0 / M0</td><td colspan="3"></td></tr>
<tr><td rowspan="5">Stage III</td><td colspan="2" rowspan="2"></td><td colspan="2">T1 / N1 / M0</td></tr>
<tr><td colspan="2">T2 / N1 / M0</td></tr>
<tr><td rowspan="2">T3b / N0 / M0</td><td colspan="2">T3 / N0 / M0</td><td>T3a / N0, N1 / M0</td></tr>
<tr><td></td><td>T3 / N1 / M0</td><td>T3b / N0, N1 / M0</td></tr>
<tr><td rowspan="4">Metastatic B.C.:</td><td>T4a / N0 / M0</td><td colspan="3"></td></tr>
<tr><td rowspan="3">Stage IV</td><td>T4b / N0 / M0</td><td></td><td colspan="2">T4 / Any N / M0</td></tr>
<tr><td colspan="2">Any T / N1-3 / M0</td><td colspan="2">Any T / N2, N3 / M0</td></tr>
<tr><td colspan="4">Any T / Any N / M1</td></tr>
</table>

GU CANCER STAGING: AJCC TNM STAGING

<table>
<tr><th></th><th>BLADDER CANCER</th><th>CANCERS OF THE RENAL PELVIS AND URETER</th><th>CANCER OF THE URETHRA</th><th>RENAL CELL CANCER</th></tr>
<tr><td colspan="5">Primary Tumor (T):</td></tr>
<tr><td>TX</td><td colspan="3">Tumor not accessable</td><td>Minimum requirements cannot be met</td></tr>
<tr><td>T0</td><td colspan="4">No evidence of primary tumor</td></tr>
<tr><td>Ta</td><td colspan="2">Noninvasive papillary carcinoma</td><td></td><td></td></tr>
<tr><td>Tis</td><td colspan="3">Carcinoma in situ</td><td></td></tr>
<tr><td>T1</td><td colspan="3">Invasion of subepithelial connective tissue</td><td>Tumor ≤ 2.5 cm in greatest dimension, limited to the kidney</td></tr>
<tr><td>T2</td><td>Invasion of superficial muscle (inner half)</td><td>Tumor invasion of the muscularis</td><td>Tumor invasion of corpus spongiosum or the prostate or the periurethral muscle</td><td>Tumor > 2.5 cm in greatest dimension, limited to the kidney</td></tr>
<tr><td>T3</td><td>Invasion of deep muscle or perivesical fat</td><td>Renal pelvis: tumor invasion of peripelvic fat or renal parenchyma, Ureter: tumor invasion of periureteric fat</td><td>Tumor invasion of corpus cavernosum or beyond the prostate capsule, or the anterior vagina or bladder neck</td><td>Tumor extends into major veins or invades adrenal gland or perinephric tissues but not beyond Gerota;s fascia</td></tr>
<tr><td>T3a</td><td>Invasion of deep muscle (outer half)</td><td colspan="2"></td><td>Tumor invades adrenal gland or perinephric tissues but not beyond Gerota's fascia</td></tr>
<tr><td>T3b</td><td>Invasion of perivesical fat</td><td colspan="2"></td><td>Tumor involving renal vein or vena cava</td></tr>
<tr><td>T4</td><td>Tumor invasion of other adjacent organs</td><td>Tumor invasion of adjacent organs or through kidney into perinephric fat</td><td>Tumor invasion of other adjacent organs</td><td>Tumor invades beyond Gerota's fascia</td></tr>
<tr><td>T4a</td><td>Invasion of prostate, uterus, vagina</td><td colspan="3"></td></tr>
<tr><td>T4b</td><td>Invasion of pelvic wall or abdominal wall</td><td colspan="3"></td></tr>
<tr><td colspan="5">Regional Lymph Nodes (N):</td></tr>
<tr><td>NX</td><td colspan="3">Lymph nodes not assessable</td><td>Minimal requirements cannot be met</td></tr>
<tr><td>N0</td><td colspan="3">No regional lymph node metastasis</td><td>No evidence of involvement of regional nodes*</td></tr>
<tr><td>N1</td><td colspan="4">Metastasis in a single node, ≤ 2 cm in greatest dimension</td></tr>
<tr><td>N2</td><td colspan="4">Metastasis in a single node, size 2-5cm; or multiple nodes, none > 5cm</td></tr>
<tr><td>N3</td><td colspan="4">Metastases in a lymph node > 5 cm in greatest dimension</td></tr>
<tr><td colspan="5">Distant Metastasis (M):</td></tr>
<tr><td>MX</td><td colspan="3">Nonassessable presence of distant metastasis</td><td></td></tr>
<tr><td>M0</td><td colspan="4">No distant metastasis</td></tr>
<tr><td>M1</td><td colspan="4">Distant metastasis</td></tr>
</table>

* (Note: regional lymph nodes are hilar, abdominalr para-aortic and paracaval nodes.)

CALGB IS DEPARTMENT

The 'I' stands for Information—finding your way around the CALGB IS Client

Jennifer Margeson, CALGB IS Help Desk Coordinator

The CALGB Information Systems Application (known to the user community as "The I.S. Application" or "the Client") runs from a large database housed at the Statistical Center at Duke University, in Durham, NC. It is most known for hosting the on-line Patient Registration Application, which permits Clinical Research Associates at CALGB institutions to register patients to certain trials at any time. Currently there are 10 studies that permit on-line registration, and this information is updated regularly and available on the Statistical Center Web Site. When the Information Systems Group updates the server resources at the Statistical Center, access to the database will become more available to the membership at large.

Current IS Application users have been receiving a **Tip of the Week** email since early January 2000. Tips include how to use the hidden hot-link and wild card features, how to create mailing labels, how to generate a list of all active protocols at your institution, and general overviews on the different applications or "modules" available within the IS Application. Training has been offered since June 1997. The Tip of the Week email, combined with demo sessions at the Group meetings provides a quick and easy learning opportunity for system users to advance their knowledge.

The remainder of this article briefly reviews different features of the IS Application, including Drugs, Reports, and information searches.

Drugs Application

The Drugs Application was released in early 2000. It displays the drug ID and name as well as the pharmaceutical company and its generic name.

To find information using the Drugs Application, type in the Brand Name in the name field and press the FIND button on the tool bar. The information stored in the database will be displayed in the available fields.

Reports

The IS Application offers many different types of reports, and these are available in many of the different modules. Some of the most popular reports include mailing labels in the Participant Application, IRB Tickler Report in the Institutions Application, and the Study Network Accrual Report in the Study Application. These reports offer IS Application users useful information in a time saving format.

Information Searches

Because the database stores a great deal of information, it can be tricky to retrieve it. The use of the wild card character is one tip to help the search along. For example, you know my name is Jennifer but you don't know how to spell my last name, and you need my email address. Rather than type in only "JENNIFER" in the first name field of the Participant Module, you can type in what you know of my last name and use the wild card character (the star key [SHIFT + 8]) as the replacement. Your search will look like this: "Jennifer" "Mar*" on the first tab, and then click on the ADDRESS tab and select "CALGB" as the Group and "Data Management Center" as the Institution, and press the FIND key on the tool bar, and there I am! Remember, the more information in your search, the better!

Database, Patient Registration & Lab-Trak Training at Summer Group Meeting

Database and Lab-Trak Training:
Fri., June 9: 3 –4 p.m.; Sat., June 10: 10:15 – 11:15 a.m.

Patient Registration Training: *Sat., June 10: 9 – 10 a.m.*

Walk-In Database Demonstrations: *Sat., June 10: 4 – 6 p.m.*

The CALGB Information Systems staff will conduct special hands-on training sessions for Lab-Trak, on-line patient registration, and database access. Space is limited—you must register in advance for the training sessions.

PROTOCOL NEWS

NEW STUDIES

February 2000

79806—Prostate cancer prevention using dietary soy supplements
Study chair: Robert W. Lee, M.D.

March 2000

59902—Randomized phase III study in low grade lymphoma comparing cyclophosphamide/fludarabine to standard therapy followed by maintenance anti-CD20 antibody
Study chair: Stanley R Frankel, M.D.

99813—A phase II study of docetaxel/estramustine/carboplatin/GCSF in men with hormone refractory prostate cancer
Study chair: William K. Oh, M.D.

April 2000

39901—Phase II study of weekly dose-dense paclitaxel in extensive small-cell lung cancer
Study chair: Mark A. Socinski, M.D.

309801—Determination of utilities for control of chemotherapy-induced nausea or vomiting
Study chair: Steven M. Grunberg, M.D.

CLOSED STUDIES

February 2000

9251—High intensity, brief duration chemotherapy for diffuse small non-cleaved cell lymphoma and the L-3 subtype of ALL: a pilot study of a multidrug regimen
Study chair: Carl E. Freter, M.D.

9671—Long-term psychosocial adaptation of survivors of breast cancer treated by adjuvant chemotherapy fifteen years ago: companion to CALGB 7581
Study chair: Alice B Kornblith, Ph.D.

March 2000

9781—Prospective randomized phase III trial comparing trimodality therapy (cisplatin, 5-FU, radiotherapy, and surgery) to surgery alone for esophageal cancer
Study chair: Mark J. Krasna, M.D.

9870—Quality of life and cost analysis companion to CALGB 9781
Study chairs: David G. Pfister, M.D., Marcy List, Ph..D.

9621—Phase I study of MDR modulation with PSC-833 (NSC #648265) with a pilot study of cytogenetic risk-adapted consolidation followed by a phase II pilot study of immunotherapy with rIL-2 (NSC #373364) in previously untreated patients with AML < 60 years
Study chair: Jonathan E Kolitz, M.D.

9661—Pilot study of low-dose interleukin-2 plus recombinant human anti-her2 monoclonal antibody in solid tumors
Study chair: Gini Fleming, M.D.

9740—A cross-sectional study to estimate the incidence of endometrial pathology in women receiving tamoxifen on SWOG S9313 (INT 0137, CALGB 9394, NCCTG 93-50-51)
Study chair: Larry Norton, M.D.

April 2000

59902—Randomized phase III study in low grade lymphoma comparing cyclophosphamide/fludarabine to standard therapy followed by maintenance anti-CD20 antibody
Study chair: Stanley R Frankel, M.D.

CALGB STUDY FUNDING

Support is available to qualifying institutions for participation in these studies. Payments are made through the main member institution. For more information, visit the CALGB website or contact Mary A. Sherrell, Financial Officer at (773) 702-9856.

9473 – Omega-3 Fatty Acids for Cancer Cachexia. Phase I/II Trial.

9481 – Hepatic Artery Floxuridine, Leucovorin, and Dexamethasone vs Systemic 5-FU and Leucovorin as Treatment for Hepatic Metastases from Colorectal Cancer. Phase III Study.

9581 – Adjuvant Immunotherapy with Monoclonal Antibody 17-1A after Resection for Stage B2 Colon Cancer. Phase III Randomized Study.

9594 – Intermittent Androgen Deprivation in Patients with Stage D2 Prostate Cancer. Phase III Study. (SWOG 9346)

9596 – Vincristine, Doxorubicin, and Dexamethasone with or w/o PSC-833 in Patients with Relapsing or Refractory Multiple Myeloma. Phase III Study. (ECOG E1A95)

9682 – Prognostic Significance of Endorectal MRI in Predicting Outcome After Combined Radiation and Androgen Suppression for Prostate Cancer. Prospective Phase II Study.

9730 – Taxol vs. Taxol + carboplatin for advanced NSCLC. Randomized Phase III Study.

9770 – High-Dose vs Conventional Dose Octreotide Acetate vs Loperamide in the Treatment of Chemotherapy-related Diarrhea in Patients with Colorectal Cancer. Randomized Trial. (ECOG E1295)

9782 – Phase II trial of potency-sparing hormonal therapy in patients with elevated serum PSA after radiation therapy or radical prostatectomy for prostate cancer.

9872 – Activated protein C resistance and tamoxifen-associated thrombosis

19801– A Phase II Study of 506U78 in Patients with Refractory or Relapsed T-Lineage Acute Lymphoblastic Leukemia (ALL) or Lymphoblastic Lymphoma (LBL)

19803–Randomized phase II trial of oral topotecan given twice a day for 5 days vs. 1x/day for 10 days to patients with myelodysplastic syndromes

39802 – Video-assisted lobectomy for peripheral (3 cm or less) N0, non-small cell lung cancer – a phase II feasibility study

39803 – Pre-resectional minimally invasive surgical restaging of stage III (mediastinal node positive) non-small cell lung cancer (NSCLC)

39804 – Phase III randomized prospective trial of open versus minimally invasive, video-assisted resection of pulmonary metastases

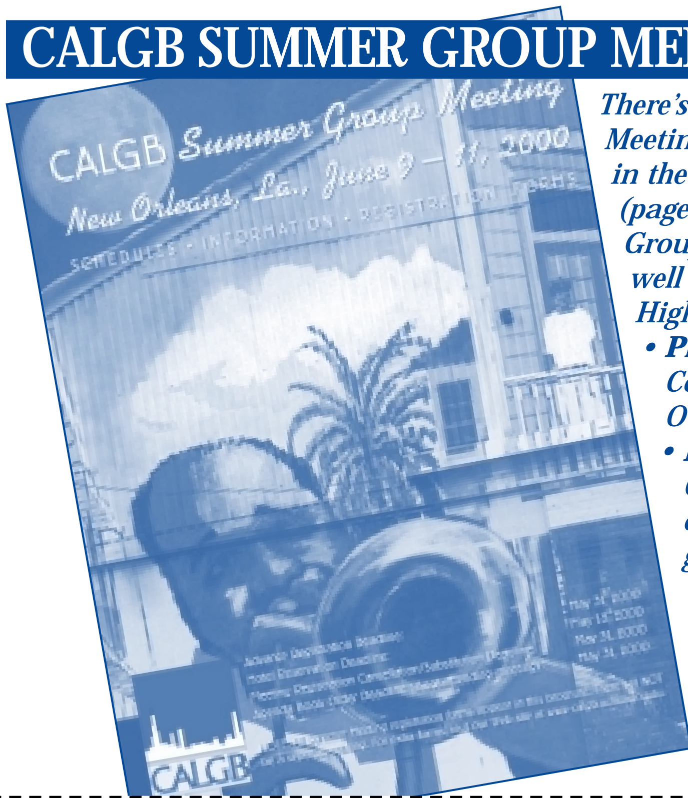
49805 – Phase III randomized double blind study of letrozole versus placebo in women with primary breast cancer completing five or more years of adjuvant tamoxifen

79806—Prostate cancer prevention using dietary soy supplements.

89804–Randomized phase III trial of 3 different regimens of CPT-11 plus 5-FU and leucovorin compared to 5-FU and leucovorin in patients with measureable advanced adenocarcinoma of the colon and rectum.

99808—Estramustine and docetaxel versus mitoxantrone and prednisone for advanced prostate cancer

CALGB SUMMER GROUP MEETING – SPECIAL SECTION



There's still time to register for the CALGB Summer Group Meeting. If you didn't receive your Meeting Invitation brochure in the mail last month, we've included a registration form (page 10), and hotel reservation form (below) in this issue. Group meetings are open to the membership of the CALGB, as well as invited guests.

Highlights of this summer's group meeting include:

- ***Plenary Scientific Session** organized by the CALGB Cancer Control & Health Outcomes committee on "Health Outcomes: The Future of Cancer Research"*
- ***HER2–Fest:** Special meeting of the Solid Tumor Correlative Sciences Committee focusing on state-of-the-art clinical and prognostic implications of human epidermal growth factor receptor. (see article on page 9)*
- ***Cancer Information Booths**: Outreach and advocacy resources from the Cancer Information System; also info from the Clinical Trial Support Unit staff (see p. 3).*
- ***Patient Issues Open Forum:** presentations and discussion of timely topics including the ethics of cancer clinical trials and improving protocol design.*

CALGB 2000 Summer Group Meeting
June 9–11, 2000

Hotel Reservation Form

New Orleans, Louisiana
Fairmont Hotel

ROOM RESERVATION DEADLINE: May 18, 2000. *Please print or type.*

NAME______________________________ PHONE # ________________

ADDRESS____

____

CITY ____________________ STATE__________ ZIP ____________

NO. OF PERSONS IN ROOM:________ ARRIVAL: ________________ *(Date/Time–check-in time is 4:00 p.m.)* DEPARTURE:________________ *(Date/Time–check-out time is 1:00 p.m.)*

❏ Non-Smoking Room ❏ Handicapped-accessible room. *(Please describe handicap:* ____________________*)*

RATES:

❏ **Single** $109 ❏ **Double** $149

Room rates are in effect for the entire duration of your stay, based on space and rate availability. Rates do not include state and local taxes of 11% plus $2.00 occupancy tax per room per night. Additionally, should you depart earlier than your scheduled departure date, you will be assessed a $50 early check-out fee. **These fees will not be CALGB's responsibility.**

ALL RESERVATIONS MUST BE ACCOMPANIED BY FIRST NIGHT'S NON-REFUNDABLE DEPOSIT.
Room reservations will be available on a first-come, first-served basis until CALGB's hotel block is filled. Rooms reserved after the cutoff date—**May 18, 2000**—are subject to hotel availability and prevailing hotel rates.

❏ **PAYING BY CHECK:** Make your check for first night's <u>non-refundable deposit</u> payable to Fairmont Hotel New Orleans.

❏ **PAYING BY CREDIT CARD:** Please provide credit card information below to guarantee your reservation. I understand my credit card will be immediately charged for my first night's deposit. **Room deposits are <u>non-refundable.</u>**

❏ VISA ❏ MASTERCARD ❏ AMERICAN EXPRESS ❏ DISCOVER

CARDHOLDER'S NAME *(Please print):* ____________________________

CARD NUMBER__________________________ EXP. DATE____________

CARDHOLDER'S SIGNATURE ______________________________

MAIL OR FAX RESERVATION FORM TO: ATTN: Reservations, Fairmont Hotel New Orleans, 123 Baronne Street, New Orleans, Louisiana 70112. Fax: 504-529-4764

CALGB SUMMER GROUP MEETING SCHEDULE

Friday, June 9

8 – 11 am	Patient Issues Committee*
8 am – noon	Extended Executive Committee*
8 am – noon	SoCRA Certification Exam
9 am – 1 pm	Leukemia & Leukemia Correlative Sciences
11 am – 1 pm	Advocate Working Group*
Noon – 1:30 pm	Data Audit Committee*
1 – 4 pm	Radiation Oncology Committee
1 – 4 pm	CRA Committee
1 – 4 pm	Solid Tumor Correlative Sciences
3 – 4 pm	CALGB Data Base/Lab-Trak Training**
4 – 6 pm	CCOP Committee
4 – 6 pm	Cancer Control & Health Outcomes Steering Committee*
4 – 7 pm	CRA Continuing Education Workshop
4 – 7 pm	Lymphoma & Lymphoma Correlative Sciences
4 – 7 pm	Pathology Committee
4 – 7 pm	PET Committee

Saturday, June 10

7 – 9 am	Foundation Board of Trustees*
7 – 9 am	CALGB 309801 for CRAs
8 – 11 am	Surgery Committee
9 – 10 am	CALGB Patient Registration**
9 – 11 am	Institution Performance Evaluation Committee*
9 am – noon	Transplant Committee
9 am – noon	GI Committee
9 am– noon	Cancer Control & Health Outcomes Committee
9:30 am – 1:30 pm	Data & Safety Monitoring Board*
10:15 – 11:15 am	CALGB Data Base/Lab-Trak Training**
11 am – 1 pm	Membership Committee*
11:30 am – 12:30 pm	CALGB Patient Registration**
Noon – 1 pm	Constitution Committee*
Noon – 1:30 pm	Solid Tumor Correlative Sciences Steering Committee*
Noon – 1:30 pm	Pharmacy Core Committee*
1:30 – 4 pm	**Plenary Session**
4 – 6 pm	CALGB Walk-In Data Base Demonstrations
4 – 6 pm	Melanoma Working Group
4 – 6 pm	Membership Committee*
4 – 7 pm	Breast Committee
4 – 7 pm	Joint Nursing/Pharmacy Committees
6 – 7 pm	Conflict of Interest Committee*
7 – 10:30 pm	**Reception**

Sunday, June 11

7 – 10 am	Board of Directors*
8 – 10 am	Surgery Quality Assurance Review Committee*
8 – 11 am	Patient Issues Committee
8 – 10 am	Cancer in the Elderly Working Group
9 am – noon	Respiratory Committee
9 am – noon	GU Committee

**closed meeting   **training booked through Central Office*

HER2-Fest at STCSC Meeting in New Orleans

Friday, June 9, 1–4 p.m.

The Solid Tumor Correlative Sciences Committee will focus its committee meeting at this summer's Group Meeting on a single topic of broad interest to all CALGB members: HER2, also known as human epidermal growth factor receptor.

CALGB researchers are widely recognized as leaders in the science of HER2 testing, according to STCSC Chair Daniel Hayes, M.D., of Georgetown University. HER2 plays a role in prognosis or treatment of solid tumor cancers studied by CALGB's Breast, GI, GU and Respiratory Committees as well. Herceptin, a monoclonal anti-HER2 antibody, is the investigational agent in several current CALGB studies.

The STCS Committee meeting is presenting this in-depth discussion of HER2 in order to enhance understanding of the biological activity of HER2 as well as other epidermal growth factor receptors, their ligands, and the downstream pathways; and the importance of these pathways in solid tumors. Highlights of the meeting include:

- Overview of HER2 biology presented by Dr. Mark Slikowski (staff scientist from Genentech): "The biological ramifications of erbB-2 in human malignancies."
- A committee member from each of the solid tumors represented in CALGB (Breast, GI, GU, and Respiratory) will discuss the state-of-the-art of HER2's clinical status as a prognostic and predictive factor in his/her respective disease, including interactions with classic therapies; and whether HER2 itself can be the target of therapy (looking specifically at immunotherapy using monoclonal anti-HER2 antibodies).
- Lynn Dressler, M.S., co-chair of the STCSC, will discuss methods of testing for HER-2, including quantitative polymerase chain reaction (PCR), immunohistochemistry (IHC) and flourescence in situ hybridization (FISH). CALGB researchers have unique expertise in HER2 testing, and Ms. Dressler will present the most current analyses of their relative strengths, and whether any one is preferable or complementary to another.
- "Open mike" discussion, open to all CALGB members in attendance, on where the field stands and where CALGB is or should be going.

Dr. Hayes encourages CALGB members from every discipline and disease area to attend: the meeting will be interesting, useful and valuable to basic and clinical scientists and clinical investigators interested in solid tumors.

CALGB 2000 Summer Group Meeting **Registration Form** June 9–11, 2000, New Orleans

ATTENDEE INFORMATION

NAME & TITLE ______________________ SOCIAL SECURITY # ______________________

INSTITUTION ______________________ PHONE # ______________________

ADDRESS ______________________ FAX # ______________________

______________________ E-MAIL ______________________

CITY ______________________ STATE ________ ZIP ______________________

REGISTRATION

ADVANCE REGISTRATION DEADLINE IS MAY 31, 2000 – *Forms must be postmarked by deadline to receive discount.*
Please check off your selections, enter the appropriate fees, and fill in your total below.

	COST
❑ **GROUP MEETING** *(Fee includes Agenda Book)*	**$40** advance/ **$65** after May 31
❑ **AGENDA BOOK ONLY** *(Order by May 31 to guarantee availability)*	**$30**
❑ **DONATION TO CALGB FOUNDATION** *(Optional)* I wish to make a tax-deductible donation in the following amount: *You will receive an acknowledgment from the Foundation by mail.*	

REGISTRATION DATE:

PAYMENT AMOUNT	CHECK #
$ ________	# ________
$ ________	# ________
$ ________	# ________
TOTAL DUE	
$ ________	# ________

CENTRAL OFFICE USE ONLY

WORKSHOP REGISTRATION

Advance registration is required for the following workshops. Check your selections and **circle your preferred dates and times*** where applicable. There are no extra fees for workshop attendance. If you are submitting your registration via mail, you may fax this form separately to the CALGB Meetings Manager, 312-345-0117, to reserve your spot(s).

❑ **CALGB Database and Lab-Trak Training**
Fri. June 9: 3 – 4 pm; ***Sat. June 10:*** 10:15–11:15 am

❑ **CALGB On-line Patient Registration Training**
Sat. June 10 9 – 10 am

*Space will be assigned on a first-come basis. CALGB will assign you to a session. We will send you your schedule via mail.

PAYMENT

❑ **PAYING BY CHECK:** You may pay for all items with one check. Make check(s) payable to University of Chicago/CALGB

❑ **PAYING BY CREDIT CARD:** You may use Visa or MasterCard

CARDHOLDER'S NAME ______________________ ❑ Visa ❑ MasterCard

CARD NUMBER ______________________ EXP. DATE ______________

CARDHOLDER'S SIGNATURE ______________________

IMPORTANT

CANCELLATIONS AND SUBSTITUTIONS

Regretfully, we are unable to issue refunds for meeting cancellations. If your registration has been processed and you cannot attend the meeting, you may send a substitute provided we receive your request in writing by May 31, 2000.

AGENDA BOOKS

The registration fee includes the Agenda Book. However, Agenda Books may not be available if you register after May 31.

REGISTER BY FAX OR MAIL

For credit card payment, you may fax this form to CALGB Central Office, fax # 312-345-0117. You may also mail this form with your payment to: CALGB Registration, 208 S. LaSalle, Suite 2000, Chicago, IL 60604-1104.

Thank you to organizations supporting CALGB in 2000

The following organizations have provided assistance to support CALGB research activities this year:

Agouron Pharmaceuticals
Alza Pharmaceuticals
Amgen, Inc.
Arrow International
Berlex Laboratories
Breast Cancer Research Foundation
Bristol-Myers Squibb Oncology
Gilead Sciences
Glaxo Wellcome Oncology
Genentech BioOncology/IDEC Pharmaceuticals
Immunex Corporation
Impact Communications
Lilly Oncology
Millennium Pharmaceuticals
Novartis Oncology
Ortho Biotech, Inc. and the Janssen Research Foundation
Pfizer, Inc.
Pharmacia & Upjohn
Roche Pharmaceuticals
Sanofi Lilly Oncology
Sanofi-Synthelabo
Schering Corporation
SmithKline Beecham
T.J. Martell Foundation for Leukemia, Cancer and AIDS Research
Wyeth-Ayerst Pharmaceuticals

Your donation will do a world of good and take you a world away

NOW YOU CAN EARN AMERICAN AIRLINES AADVANTAGE MILES WHEN YOU GIVE TO THE CALGB FOUNDATION. Your generous gift will help us and will bring you closer to the vacation of a lifetime. Earn up to 10 free miles for every dollar you give,* in addition to the satisfaction you'll get from knowing your gift made a difference.

*Gifts of $1000 or more earn 10 miles per dollar donated. Gifts of $100–$999 earn 5 miles per dollar donated. Gifts up to $99 earn 1 mile per dollar donated.

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

NAME ______________________________ AA FREQUENT FLYER #: ______________

ADDRESS ______________________________ PHONE ______________

CITY ______________________________ STATE ______________ ZIP ______________

Send to:

CALGB Foundation, AA Miles Program
208 S. LaSalle St., Suite 2000
Chicago, IL 60604-1104

For information about this program, or more information about major gift opportunities, assistance regarding gifts of securities, other gifts of appreciated property, or gifts-in-kind, please contact: Mary A. Sherrell, M.A., Treasurer, (773) 702-9856

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CALGB CALENDAR

Summer 2000 Group Meeting	June 9–11	New Orleans, Louisiana—*Fairmont Hotel*
Hotel Reservation Deadline	May 18	
Meeting Registration Deadline	May 31	
CRA Beginners' Workshop	August 11–13	Durham, NC—*Washington Duke Inn*
Fall 2000 Sequential Cores Meeting*	September 8-10	Chicago, IL—*Westin O'Hare Hotel (in Rosemont near O'Hare Airport)*
Fall 2000 Group Meeting	November 10-12	Chicago, IL—*Chicago Hilton & Towers*
Winter 2001 Sequential Cores Meeting*	March 2–4, 2001	Chicago, IL—*Fairmont Hotel Chicago*
Summer 2001 Group Meeting	June 22-24, 2001	Ottawa, Ontario, Canada—*Westin Hotel and Chateau Laurier/Fairmont Hotel*

NOTE: CALGB will no longer hold a Combined Core/Group Meeting in November as in previous years. CALGB will now hold four meetings per year as follows:

March:	Sequential Core Committee meetings* (closed sessions)
June:	Group meeting (open sessions)
September:	Sequential Core Committee meetings* (closed sessions)
November:	Group Meeting (open sessions)

**closed meetings open to cadre members of core committees and invited guests*

Cancer and Leukemia Group B Central Office
at the University of Chicago
208 S. LaSalle St., Suite 2000
Chicago, IL 60604-1104

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