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CALGB Fall Group Meeting To Be Held in New Orleans



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November 20–22, 1998 Hilton New Orleans Riverside

Register now for CALGB's fall 1998 group meeting. Regular committee meetings begin Friday, Nov. 20.

You can now register for the meeting by fax using your credit card. The deadline for meeting registration and hotel room reservations is Oct. 22.

For more details and registration forms, see the special Fall Meeting Section beginning on page 11.

Cancer and Leukemia Group B

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MESSAGE FROM THE GROUP STATISTICIAN

Revisions To Follow-up Reporting Requirements on CALGB Studies



Stephen L. George, Ph.D.
Group Statistician

As part of the overall effort in data reduction and procedural simplification, the CALGB Executive committee recently approved a new policy on the long-term follow-up reporting requirements for CALGB studies.

Previously, all patients entered on CALGB treatment

studies were required to be followed for the lifetime of the patient with regular reporting to the CALGB Data Management Center (DMC).

The new policy requires the specification of a fixed length of time (the 'truncation' time T) for each study, beyond which no further follow-up reporting is required. This study-specific value T is the time in years from the date of patient registration until truncation of follow-up reporting. It will be given in the statistical section of each protocol and will be based on the particular objectives of the study. Note that T is both the minimum time period for which full information on a patient is required to be submitted to the DMC as well as the maximum time period, beyond which no further information is required to be submitted. In addition to specification of T in the protocol, it is

also possible to terminate all follow-ups on a particular study, regardless of the follow-up status of individual patients on the study.

For study concepts in development, this new policy will be applied immediately. For all active or closed studies, the statisticians have been reviewing with the study chairs the need either to specify a truncation time T or to terminate follow-up reporting altogether. This review will be completed soon and a list of all affected studies will be distributed shortly thereafter.

It should be emphasized, if it isn't obvious from the above, that such truncation or termination of follow-up refers only to reporting to the CALGB Data Management Center. The primary rationale is that follow-up reporting longer than that required to meet the objectives of the study is unnecessary

and wasteful of limited CALGB resources. But continued follow-up to meet institutional or other requirements may be necessary or desirable even though the CALGB reporting requirement is completed. In addition, there is an exception: If a second malignancy is detected, even after the truncation time, it

should be reported to the DMC as required by NCI guidelines.

Finally, remember that complete reporting up to T is required according to the protocol-specified data submission rules regardless of the actual survival time. Thus, surviving beyond T does not obviate the need for full reporting up to T.

Studies will be assigned a fixed length of time ("T") for patient follow-up reporting. The clock starts on the patient's registration date and ends at elapsed time T. This is both the minimum and the maximum time period for submitting full patient follow-up information to the CALGB Data Management Center.

CALGB GROUP NEWS

New Patient Issues Committee Formed

Barriers to participation in cancer clinical trials from the patients' perspectives will be the focus of a new CALGB committee — the Patient Issues Committee — announced by CALGB chair Richard L. Schilsky, M.D.

"We've gained a lot of insight over the last few years about patients' concerns from patient advocates on many of our committees," said Schilsky. "We've also come to realize the value of addressing in a more unified way the obstacles to patient participation which cut across diseases and treatment modalities."

Co-chairs of the new committee are James N. Atkins, M.D. of the Southeast Cancer Control Consortium CCOP, and Deborah Collyar, founder of Patient Advocates in Research. Collyar has been involved on CALGB committees

"Many patients fear that joining a clinical trial means they won't receive the best treatment for their disease"

since 1995, and is currently serving as patient advocate on four CALGB disease and modality committees.

"Patients don't always see clinical trials the same way that physicians do," said Collyar. "Or they aren't aware of the possibility of clinical trials at all, due to a lack of information. Many patients fear that joining a clinical trial will mean they won't receive the best treatment for their disease. They also have to deal with insurance companies who may refuse to reimburse for the new treatments involved in clinical trials."

Atkins said that the new committee will try to determine what barriers exist in allowing patients access to clinical trials, then investigate remedies. "Some barriers, such as insurance issues, may be outside of the scope of the committee's abilities to resolve. There are, however, educational issues pertinent to physicians and patients that we can address. There are mindsets that need to be changed, and some of this will probably have to be done at the grass roots level."

The committee hopes to have input into consent form issues, amount of laboratory tests needed, and examining doctor/patient relationships.

The first meeting of the Patient Issues committee will be a closed core meeting, to be held at the fall group meeting in New Orleans, Sunday Nov. 22 at 8 a.m.

For more information, contact Deb Collyar at collyar@worldnet.att.net.

Breast Cancer Therapy Breakthrough Discussed in Nation-wide Live Satellite Symposium.

Promising interim results of a CALGB trial of paclitaxel to treat node positive breast cancer was the focus of a live satellite symposium sponsored by CALGB and the University of Chicago on September 10.

I. Craig Henderson, M.D., University of California-San Francisco, presented the abstract on CALGB 9344 which was first presented in May at the annual ASCO meeting.* Over 500 people participated both in Chicago and at 25 remote satellite sites around the country. Larry Norton, M.D., Memorial-Sloan Kettering Cancer Institute, and Edith A. Perez, M.D., Mayo Medical School, offered commentary as well.

The program included discussions led by Norton and CALGB Chair Richard L. Schilsky, M.D. Audience members at each site had the opportunity to ask questions and discuss current developments.

"The event came off extremely well," said Schilsky. "It was a very informative session with a lot of good questions from various audiences."

CALGB 9344 is the first major randomized intergroup study to demonstrate improved overall and disease-free survival in node-positive primary breast cancer with the addition of paclitaxel to the standard adjuvant regimen of doxorubicin/cyclophosphamide. The text of the abstract was also reprinted in the summer edition of the *Cal•Gab*.

The symposium was supported by an unrestricted educational grant from Bristol-Myers Squibb Oncology.

*I.C. Henderson, D. Berry, G. Demetri, C. Cirincione, L. Goldstein, S. Martino, J.N. Ingle, M.R. Cooper, G. Canellos, E. Borden, G. Fleming, J.F. Holland, S. Graziano, J. Carpenter, H. Muss, L. Norton. Improved disease-free and overall survival from the addition of sequential paclitaxel (T) but not from the escalation of doxorubicin (A) dose level in the adjuvant chemotherapy of patients with node-positive primary breast cancer. (*Proc ASCO 17:390a, 1998*)



Richard L. Schilsky, M.D.

New Staff

CALGB Data Management Center

Robert Rose, Analyst/Programmer II, began at CALGB on June 29, 1998. Bob comes from the Navy where he served 16 years in the recruiting field with an emphasis in Information Systems. He joins the development staff and will assume responsibilities for application development and enhancement of the CALGB Information Systems client application.

Central Office

Benjamin Adair has been named User Support Specialist at the Central Office. He comes from Wooster, Ohio, where he earned his B.A. in Computer Science from The College of Wooster and completed a year-long internship in the Academic Computing Services department. Ben will be providing user support and training services for the CALGB Central Office. He can be reached at (773) 702-6731, email: badair@midway.uchicago.edu.

QARC News

QARC Looks to Electronic Image Transfer

The Quality Assurance Review Center (QARC) has begun Phase I of a project to exchange image data electronically. Just recently they have ordered the equipment to upgrade their computer system and establish a high-speed network between QARC-Providence and Mass Radiation Oncology in Worcester. Phase I is expected to be completed this year. Next steps will include piloting the receipt of image data electronically from participating institutions. Investigators interested in piloting this phase with QARC are encouraged to contact Dr. T.J. FitzGerald at QARC.

Amgen Inc. to Sponsor CALGB Clinical Research Award

A new Clinical Research Award program for oncology fellows at CALGB institutions will be introduced at the Fall Group Meeting in New Orleans, according to CALGB Chair Richard L. Schilsky, M.D. The award will be sponsored by Amgen Inc. of Thousand Oaks, CA. Details about the award level, eligibility and award criteria will be announced in New Orleans. Schilsky said the award program will be similar to the CALGB-Janssen Clinical Research Award program, unveiled at the Summer Group Meeting in Fort Lauderdale. "Our goal is to provide research support for fellows at CALGB institutions. The future of our cooperative group depends heavily on cultivating and supporting talented young investigators participating in CALGB research activities," he said.

New Cancer Journal Invites Manuscripts from CALGB Investigators



Cancer Therapeutics, a new peer-reviewed journal published by Lippincott Williams & Wilkins, is inviting papers to be considered for publication. The bi-monthly journal, which focuses on practical and state-of-the-art care for cancer patients, published its first issue in March, 1998. *Cancer Therapeutics* is the official journal of the Coalition of National Cancer Cooperative Groups.

Recent articles featured in the journal have included an article by CALGB authors on genetic testing in breast cancer clinical trials, and a report on the results of CALGB 9160—a phase III trial of amifostine as a chemoprotective agent. The May/June issue included an article by Rod A. Hummerickhouse, M.D. and CALGB Chair Richard L. Schilsky, M.D. on thymidylate synthase inhibitors in clinical development.

The journal's editor, William N. Hait, M.D., Ph.D. of the Cancer Institute of New Jersey, has made rapid review time a priority. He has committed to responding with publication decisions within six weeks of submission.

The editorial board includes associate editors Schilsky, Karen Antman, M.D., Robert L. Comis, M.D., Ross Donehower, M.D., Theodore S. Lawrence, M.D., Ph.D., Edison T. Liu, M.D., Dan L. Longo, M.D., Anna T. Meadows, M.D., Raphael E. Pollock, M.D., Ph.D., T.S. Ravikumar, M.D., and Daniel D. Von Hoff, M.D.

Further information about the journal, including instructions for authors and article specifications, is available on the journal's web site at www.wilkins.com/cancertherapeutics, or from the editorial office at Cancer Therapeutics, The Cancer Institute of New Jersey, 195 Little Albany St., New Brunswick, NJ 08901, 732-235-8373; fax 732-235-8374.

“Thank You” To Organizations Supporting CALGB During 1998

The following organizations have generously supported CALGB research, educational programs, publications, and data resources during 1998:

Alza Pharmaceuticals
 Amgen, Inc.
 Arrow International
 Berlex Laboratories
 Breast Cancer Research Foundation
 Bristol-Myers Squibb Oncology
 Cellcor, Inc.
 Chiron Therapeutics
 Genetics Institute
 Glaxo Wellcome Oncology
 Immunex Corporation
 Impact Communications
 Janssen Pharmaceutica Research Foundation

Lederle International / Wyeth Ayerst Laboratories
 Leukemia Clinical Research Foundation
 Lilly Oncology
 Nexstar Pharmaceuticals
 Novartis Oncology
 Ortho Biotech Inc.
 Pfizer Inc.
 Pharmacia & Upjohn Co.
 Rhône-Poulenc Rorer Pharmaceuticals, Inc.
 Schering Corporation
 SEQUUS Pharmaceuticals, Inc.
 SmithKline Beecham
 T.J. Martell Foundation for Leukemia, Cancer and AIDS Research
 Vysis, Inc.

CALGB–Janssen Clinical Research Award

Applications are still being accepted for the CALGB Janssen Clinical Research Award, a \$25,000 research grant for novel clinical or translational studies by oncology fellows in the area of signal transduction. The award program, offered by the CALGB Foundation with support from Janssen Pharmaceutica, was announced at the CALGB Summer 1998 Group Meeting in Fort Lauderdale, Florida.

Research grant applications should focus on elucidating the importance of signal transduction pathways in the biology of human cancer, on assessing prognosis, or on determining response to therapy. Clinical trials of novel signal transduction inhibitors are also appropriate.

Applicants must have at least one year of training remaining after June, 1999, when the award recipient will be announced. Physicians at CALGB main member or affiliate institutions who have completed at least one year of clinical oncology training but do not have a faculty appointment are eligible. Clinical or translational studies supported by this grant should ideally be conducted within CALGB.

The one-time, one-year funding, to begin by July 1, 1999, can be augmented by up to \$2,500 to the recipient's institution for overhead expenses.



Applications must be submitted by January 15, 1999. Send an original plus 6 copies to:

Mary Sherrell, M.A., Treasurer
 CALGB Foundation
 208 S. LaSalle St., Suite 2080
 Chicago, IL 60604-1104
 Phone: 773-702-9856
 e-mail: msherrel@midway.uchicago.edu

Application Checklist

Applications must include the following:
Research Proposal (10 pages or less, plus references)

- Specific objectives
- Background and rationale
- Preliminary data
- Research methods
- Statistical considerations
- Description of patient population (if appropriate)
- References
- Appendix: Draft of clinical trial protocol (if a therapeutic clinical trial is proposed)

Additional documentation:

- Applicant CV
- Summary of other research support
- Letters of support from department chair and research mentor
- Budget with justifications

GASTROINTESTINAL COMMITTEE NEWS

Molecular Markers of Response and Resistance in Gastrointestinal Cancer

The ability to assess molecular-genetic parameters of an individual tumor may allow oncologists to more selectively determine which patients will benefit from specific therapies in both adjuvant and disseminated disease settings. The level of thymidylate synthase (TS) expression in particular has been found to indicate significant differences in response and prognosis. A pending prospective trial correlating intratumoral expression of TS, p53, DPD and TP with responses to chemotherapy will help establish the importance of molecular expression for predicting prognosis and determining optimal therapy.

*C. Gail Leichman, M.D.
Roswell Park Cancer Institute*

A number of retrospective studies relating molecular parameters to clinical outcome in gastrointestinal malignancies have appeared in the literature in recent years; fewer trials prospectively examining these questions have been conducted. Among the molecular markers of interest in GI malignancies are DCC, p53, thymidylate synthase (TS), *ERCC-1*, *K-ras*, thymidine phosphorylase (TP), dihydropyrimidine dehydrogenase (DPD), and microsatellite instability (MSI). Available data for a number of these parameters was reviewed at the GI Committee session of the summer group meeting in Fort Lauderdale.

In disseminated colorectal cancer, a phase II clinical trial from the University of Southern California (USC) prospectively correlated intratumoral expression of TS, as measured by PCR and expressed as a ratio with β -actin, with response to protracted infusion 5-fluorouracil. A cut-point for TS expression was identified above which tumors did not respond to 5-FU. A similar correlation was observed in primary gastric cancer treated pre-operatively with infusional 5-FU and cisplatin, although the level of expression was different. In this setting, the expression of *ERCC-1*, which may predict for platinum resistance, when added to TS expression was more informative for response and resistance of the gastric primary.

In the USC population, additional analyses for DPD and TP were done retrospectively. Each of these para-

meters was found to have a level of expression which was predictive for response/resistance. While there was not complete overlap of favorable prognostic expression levels for these parameters, the addition of each to TS was more predictive. Combining all three molecular parameters of response/resistance can be an even more powerful correlative tool. Evaluation of other molecular parameters is expected to add further to our prognostic abilities. For TP, which is a bifunctional gene, the optimal level of expression is not known, and may differ for 5-FU and a drug such as capecitabine which requires TP for activation.

The expression of TS within the primary tumor also has been demonstrated to correlate with survival for patients with stages II and III colorectal cancer. In a large retrospective analysis of tumor blocks from patients treated on NSABP R-01, immunohistochemical methodology was used to demonstrate that patients with rectal cancers having a high TS expression had a worse outcome overall, but achieved more benefit from adjuvant therapy. In a population of untreated stage II colon cancer, high TS also predicted for a higher risk of relapse. Likewise, the presence of overexpressed (mutated) p53 predicted for a worse outcome; TS and p53 status together were more strongly predictive for recurrence of disease.

The independent role of p53 as a prognostic predictor in colorectal cancer remains uncertain. In a multivariate analysis of stage II and III colon cancer patients entered by SWOG on INT-0035, Ahnen et al. found p53 overexpression to be associated with a favorable prognosis. Among those patients with wild-type p53, those receiving combination adjuvant chemotherapy (5-FU and levamisole) had a better survival. For *K-ras*, however, those with wild-type expression had better survival, while survival was improved with combination adjuvant therapy for both wild type- and mutated *K-ras*.

In the setting of emerging molecular-genetic tools for predicting individual response and survival, we are designing a trial, CALGB 89801, for disseminated colorectal cancer in which the predictive value of intratumoral TS will be prospectively stratified and addressed in a randomized fashion. Additionally, all tumors will be assayed for expression of p53, DPD and TP to gather further information regarding their association with response/survival for use as future response predictors.

CANCER CONTROL COMMITTEE NEWS

Grants Awarded for Studies in Breast Cancer Survivorship Issues and Prostate Cancer Prevention.

Two innovative Cancer Control Committee studies were awarded federal grants, announced this summer. The National Institute on Aging awarded \$370,000 over three years to fund research on issues facing long-term breast cancer survivors. The U.S. Department of Defense recently approved funding for a multi-site prostate cancer prevention study investigating soy as a chemopreventive agent.

Cancer Control Committee chair Electra Paskett, Ph.D. served as principal investigator for both grant awards. She will be study chair for the pending breast cancer survivorship issues study, CALGB 79804, which will be based at Wake Forest University School of Medicine.

Funding details from the Department of Defense Prostate Cancer Research Program for the pending prostate study, CALGB 79806, were not available at press time. Robert W. Lee, M.D., Wake Forest, will chair the study, which will be conducted at four sites: Wake Forest, the University of California-San Francisco, the University of Illinois-Chicago and Christiana Health Care Corporation.

Long-term Survivorship Issues for Breast Cancer Patients

The subjects for the breast cancer survivorship study will be disease-free survivors who participated in CALGB 8541 — a phase III CAF dose-intensity study of patients with stage II node positive breast cancer. 400 survivors who are 8-13 years post-diagnosis will be randomly selected from the three treatment arms of the study.

Dr. Paskett said, "We know very little about the life consequences that long term survivors of breast cancer face. This study provides one of the first opportunities to examine these issues in the unique setting that CALGB 8541 provides for us.

"As advances are made in the treatment of cancer, the number of patients surviving 5 years or more from the time of diagnosis will increase. Issues of survivorship are especially important in breast cancer due to the increased use of mammography and the increasing number of younger women being diagnosed. Breast cancer survivors face issues related to spiritual, physical, economic, and psychosocial well-being. These issues have not been well-studied in terms of incidence, duration, and impact on overall health-related quality of life (HRQL) as a survivor. Half of the women in this study were pre-menopausal at diagnosis, which will allow us to look at reproductive and menopausal issues as well."

Other areas of interest include: osteoporosis, pain, cosmesis, lymphedema, patterns of resource utilization, employment changes, insurance changes, social support, depression, anxiety, sexuality, body image, and sleep disturbance.

These areas will form the bases of the content of a telephone counseling intervention that will be developed and pilot tested during a second phase. The results will be used to further develop and test intervention studies aimed at reducing physical, psychosocial, spiritual and economic consequences of breast cancer diagnosis and treatment on the HRQL of long-term breast cancer survivors.

Prostate Cancer Prevention Study of Soy Protein Products

Dr. Paskett stated, "While prostate cancer is the single most common cancer in adult males, the science is still unsettled on issues of treatment and screening. We also haven't identified any clearly superior chemopreventive agents. On the flip side we do have strong evidence of lower prostate cancer death rates among men in Japan and Pacific Rim countries where soy products are a much larger part of the normal diet.

"Alternative health foods are becoming an important part of Americans' lives. We need to do a careful study to find out if soy has any impact at all on this major cancer. This study affords us the opportunity to do this in a scientific fashion."

Soybeans and other legumes contain large quantities of plant estrogens known as isoflavones. Specific isoflavones found in soy (genistein and daidzein) have been implicated in reducing breast, colon and prostate cancer risk in both laboratory-based studies and epidemiologic observational studies.

This randomized double-blind clinical trial will test whether an isoflavone-rich soy protein dietary supplement can reduce prostate cancer risk in older men. 160 men (80 white and 80 African-American) aged 55 years or older with high PSA levels but normal prostate biopsies will be randomized into one of two groups: soy protein or casein protein supplementation. Changes will be measured in clinical (PSA levels and prostate volume) and biologic (Ki-67, apoptosis, sex-steroid receptors, angiogenesis, antioxidant enzyme expression) markers of prostate cancer risk. The study will also assess soy protein effects on hormone levels, plasma lipids/lipoproteins and blood pressure, and changes in health-related quality of life, including urinary symptoms and sexual functioning. If positive results are obtained in this trial, soy supplementation may provide an important tool for the prevention of prostate cancer.

PET COMMITTEE NEWS

Selected Pharmacology & Experimental Therapeutics Studies on Taxane Population Pharmacology

Three studies by the PET committee are noteworthy because

- they are open group-wide,
- they are not disease-specific, and
- they require only one cycle of treatment on protocol.

These three studies are highlighted so that investigators may select the appropriate patients who have an indication for treatment with paclitaxel or docetaxel. These are unique studies in that they ask pharmacologic questions in specific patient populations, but are not directed against certain diseases. Protocol-specific questions should be directed to the study chairs who would be happy to hear from you.

CALGB 9762 — Clinical Pharmacology of Paclitaxel in Relation to Patient Age

Study Chair: Stuart M. Lichtman, M.D.

North Shore University Hospital, Manhasset, NY

As the American population as a whole gets older, we should pay more attention to how age affects outcome of chemotherapy. The objective is to determine if there is a relationship between aging and paclitaxel pharmacokinetics and toxicity. Patients age 55 and older are eligible if they have a documented non-hematologic malignancy. Only one prior chemotherapy regimen and no prior paclitaxel therapy are allowed. Paclitaxel is administered as a single dose for one cycle only at 175 mg/m² over three hours. All further treatment is at the discretion of the treating physician. Blood is drawn on day 1 of cycle 1 only. The sampling times are before the start of infusion and then at 1, 6, and 7 hours from the start of the infusion. As always, details of eligibility and treatment can be found in the protocol. It is worth noting that data and follow-up requirements are kept to a minimum because the pharmacology is only studied in cycle 1.

CALGB 9763 — Prospective Evaluation of Body Surface Area (BSA) as a Determinant of Paclitaxel Pharmacokinetics/Pharmacodynamics in Women with Solid Tumors

Study Chair: Antonius A. Miller, M.D.

Veterans Affairs Medical Center, Memphis, TN

Mark Ratain posed the question "Body-Surface Area as a Basis for Dosing of Anticancer Agents: Science, Myth or Habit?" in an editorial in the *Journal of Clinical Oncology* in July 1998. The objective of our CALGB study is to evaluate how BSA, pharmacokinetics and toxicity of paclitaxel are interrelated. Women with documented cancer, in whom single-agent paclitaxel is appropriate therapy, are eligible. Only one prior chemotherapy regimen and no prior paclitaxel therapy are allowed. Paclitaxel is administered at a fixed total dose of 360 mg (not normalized for BSA) in cycle 1 over 3 hours. In cycle 2, the paclitaxel dosage is at the discretion of the physician. Blood is drawn in cycle 1 only. Sampling times are prior to treatment and then at 1, 6, and 24 hours from the start of the infusion. Data collection is required for only 2 treatment cycles. Please review the protocol for details of treatment and follow-up.

CALGB 9871 — A Study of the Population Pharmacokinetics of Docetaxel (Taxotere) in Caucasian and African-American Cancer Patients

Study Chair: Lionel D. Lewis, M.D.

Dartmouth Medical School, Lebanon, NH

The hypothesis of this trial is that there are ethnic differences in the phenotype of cytochrome P450 (CYP3A4) resulting in increased metabolism and clearance of docetaxel in African-American compared to Caucasian patients. The objective is to study the pharmacokinetics and toxicity of a single dose of docetaxel in relation to ethnic background. Caucasian or African-American patients with a non-hematologic malignancy suitable for docetaxel therapy are eligible. Up to 2 prior chemotherapy regimens, but no prior docetaxel therapy are allowed. Docetaxel is administered as a single-agent for 1 cycle only over 1 hour. The dose (100 mg/m² or 75 mg/m²) depends on the patient's pre-study SGOT (AST). All further treatment is at the discretion of the physician. Blood samples are taken on day 1 of cycle 1 only. The sampling times are before the docetaxel infusion, and then at 55 minutes and 6 hours after the start of the infusion. Data submission is required for only 1 cycle of treatment.

ONCOLOGY NURSING

Generating Accruals With a Computerized Tool

The University of Alabama-Birmingham Comprehensive Cancer Center has developed a web-based tool to aid in generating accruals to CALGB and other cooperative group protocols. Minimal patient profile information is compared against a database of potential clinical trials. The results are given to physicians for consideration at the initial patient consultation. By encompassing all incoming patients at a clinical or outpatient setting, and giving physicians information on available trials when they meet with patients, the program has successfully increased faculty enrollments onto clinical trials. The system can centralize screening, enrollment, and patient and protocol information.

*Ellen Frederick, R.N., B.S.N., O.C.N.
University of Alabama at Birmingham*

Oncology clinical trials are designed to identify the pharmacokinetics and maximum tolerated dose (MTD) of new agents (Phase I), as well as the efficacy of new agents (Phase II), and determine the most effective treatment for specific tumor types that lead to improved survival rates for patients (Phase III). Conducting clinical trials in this changing health care environment can be challenging.¹ Clinicians, clinical investigators, nursing staff and clinical research associates are finding that the patient screening process and patient enrollment onto clinical trials can be time-consuming and often complicated. The accrual of patients onto clinical trials is hampered by failure to recruit eligible patients.²

Although complete data is not available, currently it is recognized that only about 10–30% of potentially eligible adult patients are actually placed on cooperative group protocols.³ Oncology trials typically fare much worse: 5–8% by some estimates. Because the problem is complex, it is not susceptible to simple solutions.

Clinical Trials Informatics Program (CLINTRIP) is a web browser-driven "computerized tool" developed at The University of Alabama at Birmingham (UAB) Compre-

hensive Cancer Center in an attempt to promote and encourage the participation of all faculty now entering patients onto clinical trials, including CALGB trials. CLINTRIP provides an automated computer-driven program to have a convenient way to screen and ultimately enroll patients on protocols. In addition, the program offers a central and convenient data storage to retrieve protocol and patient information.

When CLINTRIP is activated at all five oncology divisions, it will enhance recruitment on protocols active within a division and enhance interdivisional clinical investigational efforts.

Presently the CLINTRIP program has been beta-tested to provide quick and easy protocol screening for all new patients who come to the Hematology/Oncology outpatient clinic. The program links patients to applicable clinical trials from the entire database of nearly 75 protocols and requires minimal patient characteristics for this automated screening. The data entry, which takes approximately five minutes, is performed by a nurse prior to the patient being seen by the physician and is derived from information from medical records. The physician is then presented with a printout of applicable protocols (usually 2-3 protocols) at the time of first patient contact. Thus, at the time of initial patient consultation, each patient may be offered specific clinical trial options. Since initiation of CLINTRIP, there has been an increased number of faculty enrolling patients onto clinical trials, thereby increasing accrual rate.

CLINTRIP has provided additional information besides the original purpose for instantaneously identifying relevant clinical protocols for patients at time of initial physician contact. CLINTRIP will also be used to analyze demographics, clinical characteristics and clinical trial options of all new patients entering medical, surgical and chemoprevention divisions at UAB.

For the successful outcome of clinical investigations, adequate and timely patient accrual is critical. All clinical trials need to be completed in a certain time frame so that the trial will have a clinical relevance.⁴ CLINTRIP can be a useful tool to expedite trial accrual and enhance timely trial completion.

CLINTRIP

- Requires minimal data entry
- Encompasses all patients seen at the clinic
- Enforces participation of all faculty
- Screens patients for all active clinical trials and can be accessed via the Internet

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3. Conti CR, 1998. Finding Patients for Clinical Trials. *Clinical Cardiology*, 21(3):176.
4. Wittes RE, Friedman MA. 1988. Accrual to Clinical Trials. *Journal of the National Cancer Institute*, 80(12):884-885.

PROTOCOL NEWS

Protocol Update

NEW STUDIES:

August 15, 1998

19801—A Phase II Study of 506U78 in Patients with Refractory or Relapsed T-Lineage Acute Lymphoblastic Leukemia (ALL) or Lymphoblastic Lymphoma (LBL)
Study Chair: Ted Szatrowski, M.D.

9865—Tumor Replication Error (RER) Status and Outcome in a Colon Cancer Adjuvant Chemotherapy Trial
Study Chair: Monica Bertagnolli, M.D.

September 15, 1998

9871—A Study of Population Pharmacokinetics of Docetaxel (Taxotere) in Caucasian and African American Cancer Patients
Study Chair: Lionel D. Lewis, M.D.

39803—Pre-Resectional Minimally Invasive Surgical Restaging Of Stage III (Mediastinal Node Positive) Non-Small Cell Lung Cancer (NSCLC)
Study Chair: Malcolm DeCamp, M.D.

89805—Phase II Chemoradiation Trial Using Gemcitabine in Patients with Locoregional Adenocarcinoma of the Pancreas

Study Chair: Margaret A. Tempero, M.D.

119801—Telephone Monitoring: Early Identification of Psychological Distress in Cancer Patients 65 or More Years Old During Active Treatment

Study Chair: Alice Kornblith, Ph.D.

CLOSURES:

September 29, 1998

9365— Pharmacogenetics of 5-FU Fluorouracil
Study Chair: Robert Diasio, M.D.

October 1, 1998

9794/SWOG 9445 — Prognostic Factor Panel to Predict Preferred Therapy for Node Positive Postmenopausal Breast Cancer Patients (CAF vs. Tamoxifen) (A Companion Protocol to SWOG-8814 [INT-0100, CALGB-9194, ECOG-4188, NCCTG-883051, NCIC-MA.9])
Study Chair: Daniel F. Hayes, 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, consult the "Study Funding List" on the CALGB website ("members only" Financial section). You may also contact Mary A. Sherrell, Financial Officer at (773) 702-9856.

9170 Hospital vs Early Discharge Therapy of Low-Risk Patients with Fever and Neutropenia. Multi-Center Phase III Study.

9270 Colorectal Adenoma Chemoprevention Trial Using Aspirin. Phase III Study.

9334 Sclerosis of Pleural Effusion by Talc Thoracoscopy vs. Talc Slurry. Phase III Study.

9335 Video-assisted Wedge Resection + Radiotherapy for High Risk T1 NSCLC. Phase II Study.

9380 Thoracoscopic Staging for Esophageal Cancer. Phase II Study.

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.

9484 Linkage of Molecular and Epidemiological Breast Cancer Investigations with Treatment Data. Specialized Registry.

9490 Does an Oral Analgesic Protocol Improve Pain Control for Patients with Cancer? (ECOG E4293)

9499 Chemoprevention Trial to Prevent Second Primary Tumors with Low-Dose 13-CIS Retinoic Acid in Head and Neck Cancer. (MDACC DM90-094)

9581 Adjuvant Immunotherapy with Monoclonal Antibody 17-1A after Resection for Stage B2 Colon Adenocarcinoma. 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)

9670 Barriers to Participation of Older Women with Breast Cancer in Clinical Trials. Pilot Study.

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)

9780 A Phase II Study of Docetaxel, Estramustine, and Low Dose Hydrocortisone in Men with Hormone Refractory Prostate Cancer

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

FALL GROUP MEETING

New Orleans Offers Great Food, Great Music, and a Great Place for a Group Meeting.

Hilton New Orleans Riverside Hotel

The European Queen of the Mississippi, the Crescent City, the Mardi Gras capital of the world...these are all synonyms for New Orleans (pronounced "N'Awlins" by the natives), site of CALGB's Fall Group Meeting.

The Hilton, New Orleans' largest hotel, is located on the Mississippi's Riverwalk, an area with more than 140 shops and restaurants.

Known the world over for its exotic cuisine (and dining so diverse that culinary items must be dignified by the word "cuisine"), New Orleans offers a variety of dining experiences to satisfy even the most discriminating palate. Cajun and Creole are the two most famous culinary traditions in New Orleans. Cajun cooking is country cooking with a robust and hot-peppery taste. Cajun cooks use a variety of sausages, duck, chicken, pork as well as a variety of seafood in a mixture of fat and flour that adds body and flavor. Developed by the French and Spanish, Creole cooking is best exemplified by its sauces. The region's bayous, marshlands and waterways produce an abundance of sea creatures that turn up on tables throughout the city. The Louisiana oyster is one of the best in the country.

A trip to New Orleans is not complete without a visit to the famous French Quarter. Cobblestone streets lead visitors to a potpourri of restaurants, entertainment spots and shops filled with anything from Mardi Gras memorabilia to some of the finest antiques money can buy. Music is heard everywhere in the French Quarter — the Crescent City is best known for jazz. Rhythm and blues music also continues to thrive in New Orleans.

Jackson Square is the hub and heartbeat of the French Quarter. You will find artists working in the Square along with musicians, mimes, acrobats, fire-eaters and tarot card readers. Horse carriage rides are available in Jackson Square.

Meeting Registration

Group Meetings are open to the membership of the CALGB, as well as to invited guests.

Deadline and Fees:

\$40 (for registrations received before October 22); \$65 (on-site). Registration fees are nonrefundable.

Substitutions:

If you are unable to attend the meeting, substitutions are permissible, providing, however, you inform the Central Office in writing by October 22. After this date, we will be unable to accept substitutions.

CALGB Reception

Saturday 7 – 10 pm

Get ready to cruise with your colleagues aboard the famous Creole Queen Paddlewheeler docked right outside the Riverside Building of the Hilton Hotel on the Riverwalk. A delectable array of New Orleans cuisine will be served during the cruise. We will cruise the Mississippi for about an hour. Boarding will begin at 7 pm with a 7:30 pm departure time, returning to the dock at approximately 9 pm. The reception will continue dockside until 10 pm.

Genetics Education Workshop

Friday, 3 – 6 pm

This special workshop on the role of genetics in clinical cancer research, endorsed by the American Society of Clinical Oncology, offers new and updated information useful to a wide range of CALGB members. Oncology health care professionals including physicians, nurses, genetic counselors, project managers and researchers all can benefit. Participants will learn how to identify individuals at risk for inherited cancer and how to guide patients through the genetic testing process using the new ASCO Cancer Genetics Curriculum. Issues related to clinical outcomes and insurance reimbursement will be discussed. In addition, participants will learn how to enroll patients on genetic studies sponsored by CALGB and other cooperative groups. All CALGB members are encouraged to take advantage of this workshop.

Agenda:

Overview of Cancer Genetics

Funmi Olopade, M.D., University of Chicago

Update on recent developments in Cancer Genetics

F. Olopade

Cancer Risk Assessment and Cancer Genetic Counseling

Shelly Cummings, MS, University of Chicago

Inherited Colon Cancer Syndromes and Genetic Testing

F. Olopade

Breast/Ovarian Syndromes and Genetic Testing

Marie Wood, M.D., Vermont Cancer Center

Quantitative Genetics: Berry/Parmigianni model

Don Berry, Ph.D., CALGB Statistical Center

Case studies/CALGB protocols

D. Berry; O. Ross McIntyre, M.D., Dartmouth Medical School

Workshop Fee:

\$20 in advance or on-site. (You are strongly encouraged to pre-register in the event the workshop becomes full.)

To enroll in the workshop, place a checkmark in the box for the Genetics Education Workshop on the CALGB Group Meeting Registration form on page 13 of this newsletter. Send it to the Central Office along with your \$20 workshop registration fee. Sorry, but we cannot accept cancellations.

CALGB Fall Group Meeting Schedule

November 20-22, 1998 • Hilton New Orleans Riverside Hotel • New Orleans, Louisiana

(schedule as of 10/1/98)

FRIDAY, NOVEMBER 20

7 am – 5 pm	Registration
8 – 9 am	Constitution Committee*
10 am – Noon	CALGB Data Base Training*
11 am – 1 pm	Thoracic Surgery Subcommittee
1 – 7 pm	CALGB Data Base Hands-on Training (6 one-hour sessions)*
3 – 6 pm	Genetics Education Workshop**
5 – 7 pm	Oncology Nursing Committee
8 – 10 pm	Data Audit Committee*

SATURDAY, NOVEMBER 21

7 am – 5 pm	Registration
8 – 9 am	Institution Performance Evaluation Committee*
8 – 9 am	Surgical CRA Workshop
8 – 9:30 am	Melanoma Working Group
8 – 9:30 am	GI Surgery Subcommittee
8 – 10 am	Cancer in the Elderly Working Group
8 – 10 am	Cancer Control Committee
8 – 10:30 am	Respiratory Committee
8 – 11 am	Lymphoma and Lymphoma Correlative Sciences Committees
8 am – Noon	Prostate Solid Tumor Correlative Sciences *
9:30 am – Noon	Surgery Committee
10 am – Noon	CCOP Committee*
10 am – Noon	CRA Committee
11 am – Noon	Leukemia and Leukemia Correlative Sciences Committees Part I
Noon – 1 pm	Health Outcomes Research Council*
Noon – 1 pm	Conflict of Interest Committee*
1:30 – 4 pm	PLENARY SESSION
4 – 5 pm	Membership Committee*
4 – 6 pm	PET Committee
4 – 6 pm	Breast Surgery Subcommittee
4 – 6 pm	Prostate Surgery Subcommittee
4 – 6:30 pm	Leukemia and Leukemia Correlative Sciences Committees Part II
4 – 6:30 pm	CRA Continuing Education Workshop
4 – 6:30 pm	Solid Tumor Correlative Sciences Committee
4 – 6:30 pm	GI Committee
4 – 6:30 pm	Psycho-Oncology Committee
7 – 10 pm	Reception

SUNDAY, NOVEMBER 22

7 – 11 am	Registration
7 – 10 am	Board of Directors*
8 – 10 am	Patient Issues Core Committee*
10 am – Noon	Pathology Committee
10 am – Noon	Prostate Committee
10 am – 12:30 pm	Breast Committee
10 am – 12:30 pm	Psycho-Oncology Core Committee*

* Closed meeting ** Additional registration fee required

ATTENDEE INFORMATION

NAME _____ SOCIAL SECURITY # _____
 INSTITUTION _____ PHONE # _____
 ADDRESS _____ FAX # _____
 _____ E-MAIL _____
 CITY _____ STATE _____ ZIP _____

REGISTRATION

ADVANCE REGISTRATION DEADLINE IS OCT. 22, 1998 - *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 |
|---|--|
| <input type="checkbox"/> GROUP MEETING
<i>(Fee includes Agenda Book)</i> | \$40 advance/
\$65 after Oct. 22 |
| <input type="checkbox"/> GENETICS EDUCATION WORKSHOP*
<i>(Friday, Nov. 20, 3-6 p.m.)</i> | \$20 |
| <input type="checkbox"/> AGENDA BOOK ONLY
<i>(Order by Oct. 22 to guarantee availability)</i> | \$30 |
| <input type="checkbox"/> DONATION TO CALGB FOUNDATION <i>(Optional)</i>
I wish to make a tax-deductible donation in the following amount:
<i>You will receive an acknowledgment from the Foundation by mail.</i> | |

	REG. DATE:
FEE	CHECK #
\$ _____	# _____
\$ _____	# _____
\$ _____	# _____
\$ _____	# _____
TOTAL DUE	
\$ _____	# _____

CENTRAL OFFICE USE ONLY

*NOTE: Advance registration is required for the Genetics Education Workshop.

PAYMENT

- PAYING BY CHECK:** You may pay for all items with one check.
 Make your 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 October 22, 1998.

AGENDA BOOKS
 The registration fee for the meeting includes the Agenda Book. However, we cannot guarantee that Agenda Books will be available if you register after October 22.

REGISTER BY FAX
 For credit card payment, you may fax this form to CALGB Central Office, fax #312-345-0117.

REGISTER BY MAIL
 Return this form with your payment to: CALGB Registration, 208 S. LaSalle, Suite 2000, Chicago, IL 60604-1104.

Continuing Medical Education Credits

M.D., Ph.D., D.O., and P.A.s

The University of Chicago has approved co-sponsorship of CALGB's Fall Group Program. The University of Chicago is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to sponsor continuing medical education for physicians. Approval of approximately 14.0 credit hours in Category I of the Physician's Recognition Award of the American Medical Association has been granted.

R.N., O.C.N., and A.R.N.P.s

The Illinois Nurses Association has approved Continuing Education Credit (approximately 16.0 contact hours) for nurses.

C.C.R.A.s

The Society of Clinical Research Associates has approved Continuing Education Credit (approximately 5.0 hours) for clinical research associates or nurses.

CME and CEU forms and instructions will be available at the information table at the Group meeting located at CALGB registration area.

NOTE: Continuing education credits are NOT granted for attendance at Core sessions (which are closed), only committee sessions.

Transportation

Discounted meeting air fare to the Fall Group Meeting in New Orleans, Louisiana

CALGB has appointed I.T.S. as the official air travel coordinator for our 1998 meeting. I.T.S. provides attendees with personalized, unbiased airline reservations and ticketing at the lowest available fare with one easy toll-free call, 1-800-621-1083. Fly on the official carrier and save!

Meeting discounts on Delta Airlines

Special guaranteed zone fares which do not require a Saturday night stay are available. Or get a 10% discount off unrestricted coach fares or 5% discount off lowest applicable fares, including first class. For Delta Airlines Reservations, use file number 121558A.

In addition, I.T.S. will provide:

- Guaranteed lowest available air fare
- Full mileage credit for all frequent flyer club members
- Easy payment by all major credit cards

CALL I.T.S.

Toll-Free: 1-800-621-1083

Monday - Friday, 8:00 a.m. - 5:00 p.m. (Central Time)

Ground Transportation

Airport Shuttle provides the easiest method of transportation to the Hilton (about 30-35 minutes from the airport). Airport Shuttle information desks (staffed 24 hours a day) are located outside the baggage claim area. Transportation cost is \$10 one-way. Passenger vans arrive at and depart from the airport every 15 minutes.

Taxicab fare is a flat \$21.00 for up to 3 passengers; \$8.00 for each additional passenger.

Hotel Reservations

Guest rooms have been reserved at the Hilton New Orleans Riverside Hotel located on the Mississippi River on Poydras Street.

Rates

House

\$109 single occupancy

\$139 double occupancy

Towers

\$144 single occupancy

\$174 double occupancy

Check-in time: 3:00 pm

Check-out time: 12:00 Noon

Room rates are exclusive of 11% sales tax and a \$3 occupancy tax per room per night.

Reservations Procedures

Guests may either fax a copy of the Hotel Reservation Form included in this newsletter to the hotel or telephone the hotel.

Deadline

All reservations must be received by the hotel(s) no later than October 22, 1998. Room reservations will be available on a first-come, first-served basis until the CALGB hotel block is filled. Hotel will continue to accept reservations after the cutoff date on a space-available basis at the group rates based on availability in the CALGB block.

Deposits

A first-night's **NON-REFUNDABLE** deposit will be required when securing your reservation.

Phone Reservations

Reservations can be made by calling the Hilton New Orleans Riverside Hotel's Reservations Department at (504) 584-3999. Be sure to identify yourself as a Cancer and Leukemia Group B attendee in order to receive the special convention rate and have credit card information available at the time of your call.

Fax Reservations

(504) 584-3979. Fax the completed copy of the Hotel Reservation Form from this Newsletter directly to the Hilton New Orleans Riverside Hotel. Be sure to include your credit card information on the form along with expiration date for first night's **non-refundable** deposit.

Reservations by Mail

Send the completed Hotel Registration Form from this newsletter directly to the Hilton. If using the mail-in method, be aware of your mailing date.

Hilton New Orleans Riverside Hotel
Reservations Department
Poydras at the Mississippi River
New Orleans, LA 70140

CALGB CALENDAR

Fall '98 Group Meeting	Nov. 20–22, 1998	New Orleans, Louisiana— <i>Hilton New Orleans Riverside Hotel</i>
REGISTRATION DEADLINE	Oct. 22, 1998	(Meeting Registration and Hotel Reservations)
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Summer '99 Group Meeting	June 25–27, 1999	Toronto, Ontario, Canada— <i>Sheraton Centre</i>

ABSTRACT DEADLINES

Abstracts reporting on CALGB studies must be submitted to the Central Office for review at least two weeks prior to the submission deadline.

	ABSTRACTS DUE AT CENTRAL OFFICE	SUBMISSION DEADLINE	MEETING DATE	LOCATION
AACR American Association for Cancer Research	Oct. 23	Nov. 6	April 10–14, 1999	Philadelphia, PA
ASCO American Society of Clinical Oncology	Nov. 19	Dec. 3	May 15–18, 1999	Atlanta, GA



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