



A PUBLICATION FOR MEMBERS OF THE NORTH CENTRAL CANCER TREATMENT GROUP

Group Chair Message



Jan C. Buckner, M.D.

We begin 2007 with a full agenda of research activities. In addition to our ongoing clinical trials and clinical study development, we have several important initiatives within the North Central Cancer Treatment Group (NCCTG).

- **Imaging Initiative** — A pilot project is under way to test the software that will be used to

transmit radiology images from NCCTG sites to the research base at Mayo Clinic. Several Mayo Health System sites are participating in this initial effort to improve transmission quality and ensure system security. In addition, an Imaging Committee is being created within NCCTG, consisting of experts in a full range of imaging techniques. Serving in an advisory capacity to all

NCCTG investigators and to community physicians, the committee will review clinical trial concepts and establish imaging standards.

- **Operations efficiency analysis** — NCCTG is partnering with the Mayo Clinic Research Infrastructure and Service Excellence Office in the department of Research Administrative Services to analyze current operations and improve efficiencies throughout the clinical trials development and administration process.
- **Enhanced informatics system for biospecimen collection** — A formal process analysis to identify the information technology needs of the NCCTG Biospecimen Resource has been completed. The goal of this effort is to enhance current capabilities and improve the efficiency and quality of biospecimen collection and translational research.

Several members of NCCTG are also participating in the National Cancer Institute (NCI) cancer Biomedical Informatics Grid (caBIG) project; these initiatives are aimed at restructuring the cancer research systems. The informatics objectives of the caBIG project are to enhance the clinical trials enterprise through a national, standards-based, informatics infrastructure. NCCTG participants include:

- Bradley Erickson, M.D., Ph.D., a radiologist at Mayo Clinic, will serve on the In Vivo Imaging Workspace.
- Christopher Chute, M.D., Dr.P.H., who works in biomedical informatics at Mayo Clinic, will serve on the Vocabularies and Common Data Elements Workspace.
- Jan C. Buckner, M.D., NCCTG group chair and an oncologist, and Sharon Elcombe, NCCTG systems coordinator, both at Mayo Clinic, will work on the Clinical Trials Management Systems Workspace.
- Wilma Lingle, Ph.D., a laboratory scientist at Mayo Clinic and director of the Mayo Clinic Cancer Center Biospecimen Accessioning and Processing Core Resource, will serve on the Tissue Banks and Pathology Tools Workspace.

Inside this issue:

NCCTG collaborates in international trial for breast cancer.....	2
Food and Drug Administration recommends label change for tamoxifen.....	5
Leadership update	5
NCCTG to lead international study for low-grade oligodendrogliomas.....	6
New Mayo Clinic Cancer Center Director addresses members.....	8
Patient Advocacy Committee expands outreach efforts.....	8
Nursing Board plays critical role in clinical trial development	9
NCCTG welcomes new membership and affiliates.....	9
Fall meeting highlights.....	10
Additional funding for colon cancer trial.....	10
NCCTG protocols opened in first quarter 2007.....	11
NCCTG meeting sponsors	12



continued from page 1

As we move forward on these initiatives, we will continue to update the NCCTG membership on how our progress will impact our clinical trials research and the work of our community sites.

For the October 27, 2006, issue of *The Cancer Letter*, I was asked to comment on the recent request by NCI leadership to all cooperative group chairs to prepare a budget with a 10% reduction in expenses for the coming year. As I stated in the article, as with other groups, NCCTG continues to look for supplementary sources of revenue through philanthropy, grants and contracts. In addition, we are always looking for ways to improve the efficiency of our operations so that we can make the most of our resources and continue to bring forward high-quality clinical trials. The prospect of having to reduce the number of clinical trials that we conduct serves as great motivation for all of our current efforts.

During the grant renewal process, NCI reviewers commented on the strong relationship between the NCCTG research base at Mayo Clinic and the NCCTG community members. More recently, John Kugler, M.D., chair of the NCCTG Executive Committee, cited interaction between an NCCTG investigator at the research base and a community oncology practice, emphasizing that this interaction is what makes NCCTG such a strong organization.

As we move forward with the new initiatives, NCCTG members' role in evaluating and implementing these programs will be critical. As always, we appreciate our members continued collaboration in conducting high-quality clinical research.

Sincerely,

Jan C. Buckner, M.D.
Group Chair

North Central Cancer Treatment Group collaborates in international trial for breast cancer

Developing and conducting large-scale clinical trials can provide definitive evidence about the effectiveness of tested therapies. This is the goal of the collaborators in the Adjuvant Lapatinib and/or Trastuzumab Treatment Optimisation (ALTTO) Trial, an international trial testing therapies for patients with (Human Epidermal Growth Receptor 2) HER2-positive breast cancer.

The ALTTO trial represents a worldwide collaboration among scientists, oncologists, academia and the pharmaceutical industry. NCCTG researchers have collaborated in the development of this trial with the Breast International Group, which will be leading the European portion of the study. Other collaborators include the National Cancer Institute and GlaxoSmithKline, which will be providing the drug therapies for the trial.

Investigators expect to enroll 8,000 patients for the trial — 4,000 patients from North America and 4,000 patients from the rest of the world.

Patients with early stage HER2-positive breast cancer receiving adjuvant chemotherapy will be randomized to one of four treatment arms — trastuzumab alone, lapatinib alone, trastuzumab followed by lapatinib and trastuzumab given in combination with lapatinib.

"One of our strategic research themes in the NCCTG Breast Committee is the development of novel targeted therapies to decrease recurrence and improve survival in early breast cancer," says Edith Perez, M.D., an oncologist at Mayo Clinic and principal investigator for the North American portion of the ALTTO trial. "This trial is the logical next step in our attempt to optimize blockade of the HER2 pathway, which started with the evaluation of trastuzumab and now extends to the inclusion of lapatinib. Translational research is also an integral part of this study."



Edith Perez, M.D.



“We anticipate brisk accrual and timely completion of this trial, as we collaborate with investigators worldwide, providing leadership and education. Our team is deeply committed to help patients and improve the biological understanding of breast cancer.”

Looking for better therapies

More than 30 years ago, the benefit of targeted therapy was discovered with the development of tamoxifen, an agent that antagonizes binding of estrogen to its receptor. Recently, targeted therapy for cancer patients has improved with the development of biological agents such as trastuzumab, a human monoclonal antibody directed against the extra-cellular domain of the HER2 receptor protein. This agent was approved for the treatment of metastatic breast cancer in 1998 and for the adjuvant treatment of early breast cancer in 2005 outside the United States and in 2006 within the United States.

Despite the impressive results obtained with trastuzumab both in the adjuvant and metastatic settings, some patients do not respond to the treatment and others will experience relapse of their disease. Therefore, new agents are clearly needed. Lapatinib is an orally-administered, small molecule, which inhibits both Epidermal Growth Factor Receptor and HER2 tyrosine kinases. In addition, it is effective for patients with HER2-positive breast cancer that is resistant to trastuzumab or recurs during or after trastuzumab treatment.

Lapatinib has additional advantages over trastuzumab including less risk of cardiotoxicity. Lapatinib can also cross the blood-brain barrier and shows some activity against brain metastases in patients previously exposed to trastuzumab.

These encouraging results point to the need for further trials to assess the efficacy of lapatinib in the adjuvant interventions for HER2 positive breast cancer. The goal of the ALTTO trial is to investigate these therapies further and compare the effectiveness of each treatment regimen.

Teamwork — within NCCTG and on a global scale

Every clinical trial starts with an idea. That idea needs to be translated into a clinical trial protocol that provides specific information about the study. Developing the ALTTO trial concept was a team effort, beginning with Dr. Perez and members of the nursing and operations staff at the NCCTG research base, Mayo Clinic.

“Once we have a hypothesis or a vision, we begin our planning,” says Fran Palmieri, a clinical nurse specialist at Mayo Clinic in Jacksonville, Fla. Palmieri works closely with Lynn Flickinger, the protocol development coordinator for the NCCTG Breast Program and a member of the clinical research office at Mayo Clinic in Rochester, Minn.



Fran Palmieri

“From the beginning of the clinical trial development process, we include the different groups that will play a role in the trial. This includes people from data management systems, quality control, regulatory affairs, statistics, nursing and pathology,” says Flickinger. “We then give all NCCTG members the opportunity to review the clinical trial protocol.”



Lynn Flickinger

NCCTG statisticians also play a major role in the trial. They collaborate in the development of the statistical plan for the trial and will participate in the interim and final data analyses.

“We worked to reduce the amount of patient data that needed to be collected for this trial,” says Amylou Dueck, Ph.D., a statistician at Mayo



Amylou Dueck, Ph.D.

continued on page 4



continued from page 3

Pathology to play key role in ALTO trial

Pathologists and geneticists within NCCTG have collaborated to play an important role in the trial. Before a patient can be enrolled in the study, a diagnosis of HER2-positive breast cancer must be confirmed. To meet the challenge of processing tissue from 4,000 patients, NCCTG pathologists have developed a plan to efficiently prepare and review patient specimens.



Marie Christine Aubry, M.D.

“We need to determine the HER2-positive status of these patients quickly, so that they can be enrolled in the study and begin receiving treatment,” says Marie Christine Aubry, M.D., a Mayo Clinic pathologist and director of the NCCTG Biospecimen Resource.

Slides will be prepared and then scanned using virtual microscopy to create a digital image of the specimen in the Tissue and Cell Molecular Analysis (TACMA) lab at Mayo Clinic in Rochester. Slides can then be reviewed electronically by Ann McCullough, M.D., a Mayo Clinic pathologist based in Arizona.



Wilma Lingle, Ph.D.

“This method allows us to review a large number of slides quickly,” says Wilma Lingle, Ph.D., director of the TACMA lab and co-chair of the Biospecimen Resource. “With this system, we avoid having to ship slides to Arizona, a process that would take additional time and risk damage to the specimens. We also create a permanent record of each slide for use in future translational research.”

Robert Jenkins, M.D., Ph.D., a geneticist and associate director for translational research at the Mayo Clinic Cancer Center, will also conduct fluorescent in situ hybridization analysis on tissue specimens for the study.

Clinic in Rochester and lead statistician for the NCCTG Breast Program. “We reduced the patient information from over 300 pages to just over 60 — only essential data will be collected from each patient.”

Because this is an international trial, the NCCTG team works closely with their counterparts in the Breast International Group. “We all spend a lot of time on teleconferences ensuring that every aspect of the trial is coordinated — from enrolling the patients, to administering the study, to then analyzing the results,” says Flickinger. “This collaboration is essential if we are going to definitely identify the best therapy for these patients.”

Learn more about the ALTO trial at the spring 2007 NCCTG Clinical Research Associate (CRA)/Nursing Board meeting

At the spring NCCTG CRA/Nursing Board Workshop to be held in Rochester, Minn., on April 17–28, 2007, NCCTG members will have the opportunity to learn more about the ALTO trial. The workshop will feature a panel discussion led by Edith Perez, M.D. The study design, research protocol and trial administration will be discussed.

The workshop presentation will also highlight many unique materials that have been developed for physician and patient education, including webcasts explaining the clinical trial protocol and treatment regimens.

For more information on the spring 2007 CRA/Nursing Board Workshop, visit the NCCTG Web site at <http://ncctg.mayo.edu>.



Food and Drug Administration panel recommends label change for tamoxifen



Matthew Goetz, M.D.

Mayo Clinic and North Central Cancer Treatment Group (NCCTG) researchers recently delivered evidence to the Food and Drug Administration (FDA) that points to the importance of a critical enzyme, CYP2D6, necessary for the activation of tamoxifen.

As many as 10% of people inherit a deficient form of CYP2D6, and a larger percentage of people have genetically normal levels of the enzyme but are co-prescribed drugs that inhibit CYP2D6. Matthew Goetz, M.D., an oncologist at Mayo Clinic, conducted a retrospective analysis of NCCTG clinical trial 89-30-52 to evaluate the impact of CYP2D6 enzyme levels on breast cancer patients being treated with tamoxifen. Results of the study were recently published in *Breast Cancer Research and Treatment*. Researchers found that women treated with tamoxifen and who were CYP2D6 poor metabolizers (either genetically or as a result of drug-induced enzyme inhibition) were three times more likely to experience breast cancer recurrence compared to women with normal CYP2D6 enzyme levels who were not co-prescribed CYP2D6 inhibitors.

Dr. Goetz presented these research results to the FDA in October 2006 where an advisory panel recommended a change to the tamoxifen label to include a warning related to the increased risk of breast cancer recurrence for women with altered CYP2D6 metabolism.

“Mayo and the NCCTG were the first to demonstrate the importance of CYP2D6 metabolism as it relates to breast cancer outcomes in women treated with tamoxifen,” says Dr. Goetz. “The FDA warning will include language stating that women,

with either genetically decreased metabolism or who are prescribed medications that inhibit CYP2D6, have a higher risk of breast cancer relapse when prescribed tamoxifen for the treatment of breast cancer.”

The CYP2D6 tamoxifen research was the result of collaboration among numerous Mayo researchers including James Ingle, M.D., the principal investigator of the original tamoxifen study, and the laboratories of Matthew Ames, Ph.D., and Richard Weinsilboum, M.D. In addition, other Mayo researchers contributing to the study included Stacey Knox, M.D.; Vera Suman, Ph.D.; Stephanie Safgren; Carol Reynolds, M.D.; Fergus Couch, Ph.D., and Wilma Lingle, Ph.D., all in Rochester, Minn.; and Edith Perez, M.D., in Jacksonville, Fla.

David Flockhart, M.D., Ph.D., and Zeruesenay Desta, Ph.D., both from Indiana University, as well as James Rae, Ph.D., and Daniel Visscher, M.D., from the University of Michigan, also collaborated in the research. Dr. Flockhart presented data to the FDA demonstrating the importance of CYP2D6 as it relates to the plasma levels of the most important tamoxifen metabolite, endoxifen.

The label change was put forward by the Food and Drug Administration Center for Drug Evaluation and Research, Advisory Committee for Pharmaceutical Science (ACPS), Clinical Pharmacology Subcommittee (CPSC). The actual official FDA label change usually follows four to six months after a panel’s recommendation. The CYP2D6 genetic test has recently become available through most reference laboratories including Mayo Medical Laboratories.

The study was funded by the National Institutes of Health the Commonwealth Cancer Research foundation and the Breast Cancer Research Foundation.

NCCTG Leadership Update

Axel Grothey, M.D., is the new vice chair for NCCTG. Dr. Grothey has served as director for the NCCTG Cancer Treatment Program and co-chair of the NCCTG Gastrointestinal Cancer Committee. Dr. Grothey replaces Alex Adjei, M.D., Ph.D., who has joined Roswell Park Cancer Institute in Buffalo, N.Y. Dr. Adjei will retain his role as chair of the NCCTG Lung Committee.

Monica Reinholz, Ph.D., is the new associate director for the NCCTG Biospecimen Resource, replacing Wilma Lingle, Ph.D. Dr. Lingle will continue her work to develop informatics support for biospecimen collection and as a laboratory scientist with the NCCTG Breast Cancer Committee.



North Central Cancer Treatment Group to lead international study in the treatment of low-grade oligodendrogliomas

There is increasing evidence suggesting that anaplastic (high-grade) oligodendrogliomas (AO) are responsive to treatment. Unlike most gliomas, response rates up to 70% have been observed following radiotherapy. In past research, attempts have been made to correlate genetic markers to response rates. In particular, data suggest that 1p and 19q loss of heterozygosity may be predictive of superior outcomes.

Recently, the chairs of the neuro-oncology committees of the North Central Cancer Treatment Group (NCCTG), Eastern Cooperative Oncology Group (ECOG) and other U.S., Canadian and European cooperative groups met to consider clinical trials that would answer the most important questions relative to treatment of AO.



Kurt Jaeckle, M.D.

Based on previous study results, there will be collaboration in two clinical trials involving the United States, Canada and Europe to further evaluate treatments for oligodendrogliomas. The 1p and 19q deletion will be used as a genetic marker to determine which treatment patients should receive. NCCTG will lead clinical trial N0577, which will evaluate

treatment for those patients with the 1p and 19q deletion. Kurt Jaeckle, M.D., a neuro-oncologist at Mayo Clinic in Jacksonville, Fla., and chair of the NCCTG Neuro-oncology Committee, will be the principal investigator for the study.

The second trial will be led by the European Organization for Research and Treatment of Cancer (EORTC) and will evaluate treatments for those patients who do not have the 1p and 19q deletion. This multiple trial design is in recognition that these two groups of patients have different outcomes, regardless of therapy.

These trials represent one of the first international efforts in brain cancer research within the cooperative group setting. In addition to NCCTG, the following groups will participate in the collaboration:

- Radiation Therapy Oncology Group (RTOG)
- Eastern Cooperative Oncology Group (ECOG)
- European Organization for Research and Treatment of Cancer (EORTC)
- National Cancer Institute of Canada (NCIC)
- NCI Clinical Trials Studies Unit (CTSU)

The primary objectives of N0577, a Phase III trial for newly diagnosed patients with AO, include:

- Determine whether there is a survival advantage for those who receive concomitant temozolomide and radiotherapy followed by adjuvant temozolomide over that observed in patients treated with radiotherapy alone
- Determine whether there is a survival advantage for those who receive temozolomide alone over that observed in patients treated with radiotherapy alone
- Determine whether there is a survival advantage of temozolomide alone over radiotherapy with concomitant and adjuvant temozolomide
- Determine whether there are differences in quality of life and neurocognition by treatment arm

Several key translational correlative studies are incorporated into this study, including association of outcomes endpoints 1p/19q status, downstream signaling events, other candidate gene expression profiles and determination of methylguanine methyltransferase (MGMT) gene promoter methylation status. Additional analysis will include:

- Evaluation of CEP1/19p12 fusion and the t(1;19)q10:p10 translocation will be correlated with 1p and 19q deletions and outcomes endpoints
- Ongoing assessment and comparison of quality of life and neurocognitive status as a function of treatment arm



Previous research on oligodendrogliomas leads to current study design

In the early 1990s, many physicians began treating anaplastic oligodendroglioma (AO) patients with procarbazine, lomustine (CCNU) and vincristine (PCV) chemotherapy, despite the lack of evidence in effectiveness. To study this issue in the United States, clinical trial R9402 was initiated by the Radiation Therapy Oncology Group (RTOG). R9402, a prospective, randomized, Phase III study, was an intergroup effort involving RTOG, the North Central Cancer Treatment Group (NCCTG), Southwest Oncology Group (SWOG) and Eastern Oncology Cooperative Group (ECOG).

The trial randomized AO patients, following surgical resection or biopsy of their neoplasm, to either radiation therapy (RT) alone or RT + PCV chemotherapy. The main objective of the study was to determine if there was evidence of a survival advantage when PCV chemotherapy was added to radiotherapy in initial treatment, and to explore the predictive value of certain molecular markers, specifically 1p and 19q deletion. Study results provided no clear evidence of superior survival of patients receiving RT + PCV as compared to patients who received RT alone. However, those patients with co-deletions for 1p and 19q had significantly longer progression-free survival and overall survival over those with one or no deletions, regardless of treatment arm. This study did not randomize patients based on 1p and 19q deletion.

A similar Phase III study with a slightly different design was also initiated by the European Organization for Research and Treatment of Cancer (EORTC). Study 26951 showed similar results to those of the RTOG study. This study compared RT alone to RT followed by adjuvant PCV chemotherapy for AO patients. No differences in survival were observed between the two treatment arms. As in R9402, patients with 1p and 19q deletion had significantly longer overall survival and progression-free survival than those patients without the deletion.

In 2006, Robert Jenkins, M.D., Ph.D., conducted a retrospective analysis of NCCTG clinical trial 94-72-52. Researchers found that as with high-grade oligodendrogliomas, those patients with low-grade oligodendroglioma who had the 1p and 19q deletion had better survival than those patients without the 1p and 19q deletion. In this study, investigators grew tumor cells and were able to identify the nature of the 1p and 19q translocation. Chromosomes 1p and 19q were not missing but were in fact attached to each other. This study opens the door to further research into the cause of the translocation, and potentially, the cause of the disease.

In addition to Dr. Jaeckle, other NCCTG researchers will play important roles in the conduct of the two international trials including:

- NCCTG Statistics and Data Center will coordinate the data analysis for N0577.
- NCCTG Biospecimen Resource will serve as the coordinator of specimen collection for the United States and Canada for both clinical trials.
- Caterina Giannini, M.D., a research pathologist at Mayo Clinic and co-chair of the NCCTG Pathology Committee, will coordinate central pathology review for both studies.

- Robert Jenkins, M.D., Ph.D., a geneticist at Mayo Clinic and co-chair of the NCCTG Translational Research Coordinating Committee, will coordinate the 1p/19q testing for the United States and Canada for both studies.

“With this trial, not only is the scientific question important,” says Jan C. Buckner, M.D., NCCTG group chair and a co-investigator on the study. “The development of a collaborative worldwide network to study brain tumors is also an important achievement that will impact this study and future research efforts. NCCTG is extremely pleased to a part of this effort.”



Continuing a strong partnership — New Mayo Clinic Cancer Center Director addresses North Central Cancer Treatment Group membership at fall 2006 meeting



Robert B. Diasio, M.D.

Robert B. Diasio, M.D., the new Mayo Clinic Cancer Center director, is very familiar with the research activities of NCCTG. Dr. Diasio has served as a member of the NCCTG External Advisory Board for the past several years and participated in the recent grant renewal preparation and site visit.

In September 2006, Dr. Diasio spoke to NCCTG members at the group's semiannual meeting. "In coming to Mayo Clinic, a very strong attribute and positive attraction was the opportunity to work with NCCTG," says Dr. Diasio. "The organization functions well as a cooperative group. In addition, NCCTG operates efficiently and effectively with the Mayo Clinic Cancer Center, which continues to provide an administrative infrastructure for the group."

"As new Mayo Clinic Cancer Center director, I am interested in continuing and strengthening this relationship. Two important initiatives for both Mayo Clinic and NCCTG are the use of information

technology in tracking and processing biospecimen collection and the imaging research programs."

Dr. Diasio came to Mayo Clinic from the University of Alabama School of Medicine in Birmingham, where he was associate director of the Comprehensive Cancer Center, chairman of the Department of Pharmacology and Toxicology, and director of the Division of Clinical Pharmacology. Nationally known as an expert in cancer pharmacogenomics, Dr. Diasio plans to continue research on methods to maximize the effectiveness of chemotherapy for cancer patients.

"I am very excited about the opportunity that has been given to me as the director and as a participant in NCCTG — especially in the area of novel therapeutics and GI oncology, an area of long-standing interest for me," says Dr. Diasio.

"We are delighted with Dr. Diasio's move to Mayo Clinic," says Jan C. Buckner, M.D., NCCTG group chair. "He has great enthusiasm and support for NCCTG, both as the Mayo Clinic Cancer Center director and as an investigator."

Patient Advocacy Committee develops initiatives to expand outreach efforts

The Patient Advocacy Committee continues to play a critical role in clinical trial development within the North Central Cancer Treatment Group (NCCTG). Patient advocates work with each scientific and modality committee and provide the patient perspective during the clinical trial development process. In addition, they develop programs within communities to educate patients about clinical trial participation.

The 2007 initiatives for the Patient Advocacy Committee are:

- Establish a Web site for enhanced communication and outreach efforts
- Enhance clinical trial participation of underserved populations
- Evaluate effectiveness of current patient education programs

The annual NCCTG Patient Advocacy Symposium will be held June 11–13, 2007, at the Radisson Plaza Hotel in Rochester, Minn. The symposium is facilitated by Mayo Clinic staff and brings together patient advocates from NCCTG and other cancer programs. Attendees have the opportunity to learn more about the clinical trials development process and gather helpful educational tools for conducting community outreach programs. Advocates also have the opportunity to network with each other and learn about effective advocacy programs from participants around the country.

For more information on the NCCTG Patient Advocacy Committee or the Patient Advocacy Symposium, visit the NCCTG Web site, <http://ncctg.mayo.edu> or contact the committee at canceradvocacy@aol.com.



Oncology Nursing Board plays critical role in clinical trial development

The North Central Cancer Treatment Group (NCCTG) consists of 40 memberships and more than 375 treatment locations. Our geographical area ranges from metropolitan facilities to sites in a comparatively rural setting. Within these diverse treatment settings, nurses take on multiple roles, including clinical, research and management tasks. The role of the NCCTG Oncology Nursing Board is to provide expertise for protocol development and implementation and education to nurses and patients to assist with protocol conduct.

The biannual NCCTG meetings provide a forum for the Oncology Nursing Board to convene and provide information on clinical trials administration. At these meetings, board members also discuss issues relating to current NCCTG clinical trials development and implementation.

For each disease area, a member of the Nursing Board serves as a resource nurse to assist in the development of clinical trial protocols prior to study activation and then provide feedback once a trial is opened. These liaisons bring their experience in implementing clinical studies to the research development process. Nursing Board liaisons assist in the development of treatment studies and Cancer Control trials. Three nursing leaders at Mayo Clinic, NCCTG's research base, play a critical role in leading these efforts — Debra Barton, Ph.D., R.N.; Lisa Kottschade, R.N., M.S.N., C.N.P.; and Susan Thompson, R.N., M.S.N.

The Nursing Board is chaired by two members. Kottschade is the appointed Research Base Nurse, and the elected Community Nurse is Wanda DeKrey, R.N., OCN. As critical issues arise, ad hoc committees are formed to deal with short-term concerns. Long-term goals are also identified by the board and addressed by committees. Ongoing nursing projects include:

- The development of a mentoring program to foster the involvement of new member sites in the research process
- The creation of a nursing questionnaire to identify grade 2 adverse events associated with new targeted agents and their impact on the patient

The role of the Oncology Nursing Board has evolved over the years as nurses at the NCCTG treatment sites take on more responsibility in patient care and clinical trials administration. NCCTG benefits from the experience, knowledge, ideas and energy of nurses at each member site. Nurses throughout NCCTG are encouraged to continue their efforts and contribute to the clinical research process.

For more information about the NCCTG Oncology Nursing Board, visit the NCCTG Web site, <http://ncctg.mayo.edu/member.html>.

NCCTG welcomes new membership and affiliates

Membership

- **Virginia Mason Community Clinical Oncology Program, Seattle, Wash.**

Affiliates

- **Woodbury and Maplewood, Minn.** — Metro Community Clinical Oncology Program (CCOP) component
- **St. Mary's Hospital, Grand Junction, Colo.** — Colorado CCOP component
- **Mary Rutan Hospital, Bellefontaine, Ohio** — Columbus CCOP component
- **Roswell Park Cancer Institute, Buffalo, N.Y.** — Mayo Clinic Rochester affiliate
- **Mt. Sinai School of Medicine, New York, N.Y.** — Mayo Clinic Rochester affiliate
- **Baptist Hospital, Jacksonville, Fla.** — Mayo Clinic Jacksonville affiliate
- **Abben Cancer Center, Spencer, Iowa** — Sioux City component
- **Exempla Lutheran Medical Center, Wheat Ridge, Colo.** — Colorado CCOP component
- **Alegent Health Lakeside Hospital, Omaha, Neb.** — Missouri Valley CCOP component
- **Oncology Hematology Associates, Kewanee, Ill.** — Peoria CCOP component
- **Howard University, Washington, D.C.** — Mayo Clinic Rochester affiliate
- **Fredericksburg Oncology Inc., Fredericksburg, VA** — Toledo CCOP component



Fall 2006 NCCTG meeting highlights



Robert B. Diasio, M.D., the new director of the Mayo Clinic Cancer Center, addresses the NCCTG membership.



Bradley Erickson, M.D., Ph.D., a radiologist at Mayo Clinic and coordinator of the NCCTG Imaging Initiative, addresses the NCCTG membership.

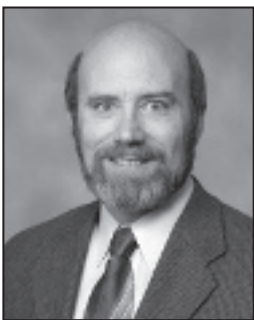


Neal Meropol, M.D., a medical oncologist and director of the Gastrointestinal Cancer Program at Fox Chase Cancer Center in Philadelphia, Pa., speaks on pharmacoeconomics issues at the fall symposium.



Passing the baton — Sharon Elcombe (right) turns over the role of NCCTG operations coordinator to Kelly Paulson. Elcombe will continue to serve as NCCTG systems coordinator.

Additional funding received for trial providing adjuvant therapy for colon cancer



Steven Alberts, M.D.

BristolMyersSquibb has generously provided additional funding for each patient enrolled in clinical trial N0147, a Phase III North Central Cancer Treatment Group (NCCTG) trial for patients with resected Stage III colon cancer. For each patient enrolled in the study, investigators will receive an additional \$2,000 to cover

the cost of data management and clinical trial administration.

“N0147 remains a trial of critical importance in our national effort to improve the outcomes for patients undergoing potentially curative resections for stage III colon cancer,” says Steven Alberts, M.D., an oncologist at Mayo Clinic and principal investigator for the trial. “We hope that the additional \$2,000 will help to more adequately

defray the costs for participation in this important trial.”

N0147 is designed to evaluate the benefit of adding the epidermal growth factor receptor (EGFR)-directed monoclonal antibody cetuximab (C225, Erbitux) to FOLFOX in the adjuvant treatment of colon cancer. Previous research indicates that cetuximab enhances response to both initial chemotherapy and chemotherapy for refractory metastatic colorectal cancer. Using this monoclonal antibody in adjuvant therapy may better target micrometastatic disease prior to the development of tumor-related angiogenesis.

The study opened in August 2005, and to date, 750 patients have enrolled. Total accrual is projected to be 2,300. For further information on N0147, including the clinical trial protocol and eligibility criteria, visit the NCCTG Web site, <http://ncctg.mayo.edu>.



NCCTG Protocols Opened In The First Quarter 2007

Clinical Trial Number

Title

Breast

N0537	Phase II Trial of VEGF Trap in Patients with Metastatic Breast Cancer Previously Treated with Anthracycline and/or Taxane
N0539	Phase II Trial of Fulvestrant and Bevacizumab in Patients with Metastatic Breast Cancer Previously Treated with an Aromatase Inhibitor
N063I	Changes in Breast Density and Plasma Hormone Levels After One Year of Aromatase Inhibitor Therapy

CNS

N057N	Response to Pre-Radiation Chemotherapy as a Predictor of Survival in Patients with Newly Diagnosed Malignant Astrocytoma
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GI

N0543	A Phase II Trial of Pharmacogenetic-Based Dosing of Irinotecan, Oxaliplatin, and Capecitabine as First-Line Therapy for Advanced Small Bowel Adenocarcinoma
N064E	Use of Data from NCCTG Trial N0148 for the Purposes of Illustration of Statistical Methods

Lung

N0528	A Randomized Phase II Study of Gemcitabine and Carboplatin With or Without AZD2171 as First-Line Therapy in Advanced Non-Small Cell Lung Cancer
N0626	A Phase II Randomized Study of Pemetrexed Combined With Sorafenib Versus Pemetrexed Alone as Second-Line Therapy in Patients With Advanced Non-Small Cell Lung Cancer

Melanoma

N0679	A Meta-analysis of Individual Data From Phase II Clinical Trials in Malignant Melanoma to Explore Alternative Clinically Meaningful Endpoints
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Other

N03C9	Phase III Trial of Honey for the Treatment of Radiation- or Combination Therapy-Induced Stomatitis
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NCCTG wishes to thank the following pharmaceutical companies for their support of the Spring 2007 Group meeting:

Platinum Level Sponsors

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Pfizer
sanofi aventis
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NCCTG Administration

Jan C. Buckner, M.D., *group chair*

Axel Grothey, M.D., *group vice chair*

Charles L. Loprinzi, M.D., *cancer control program director*

Randolph S. Marks, M.D., *data monitoring committee chair*

Paula J. Schomberg, M.D., *radiation quality control director*

Barbara Pockaj, M.D., *surgery coordinator*

Marie Christine Aubry, M.D., and
Caterina Giannini, M.D., *pathology coordinators*

Daniel Sargent, Ph.D., *group statistician*

Kelly Paulson, *operations coordinator*

Sharon Elcombe, *systems coordinator*

Steven Evans, *administrator*

Future Meeting Dates

April 16–19, 2007
Sept. 24–27, 2007

April 7–10, 2008
Oct. 20–23, 2008

NCCTG Insights

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