



Group chair message



Jan Buckner, M.D.

Congratulations to all NCCTG researchers and members for strong representation at the 2009 American Society of Clinical Oncology meeting held in June. NCCTG had 31 abstracts accepted to the meeting (see NCCTG Abstract Listing on page 14 with several studies being highlighted with oral presentations (see ASCO Highlights on page 2).

NCCTG continues our commitment to streamline research operations. Recently recognized for their efforts to reduce the time required for protocol development, the Mayo Clinic Cancer Center Research Operations office will soon broaden their effort to reduce inefficiencies from the concept stage to patient enrollment for Mayo Clinic and NCCTG clinical trials.

NCCTG principal investigators have played a key role in this process and have helped identify other areas for improvement such as the difficulty of reviewing minor adverse event reports that are not directly related to NCCTG trials (see article on page 12). NCCTG also continues to be active on a national level in improving research efficiencies, with several NCCTG researchers and operations staff serving on the National Cancer Institute Operations Efficiency Working Group.

In this issue of Insights, we provide an update on the exciting work under way in quality of life (QOL) research. The NCCTG QOL Committee is taking the next step in bringing patient-reported outcomes to the forefront of toxicity reporting and clinical practice. Learn about a new pilot study evaluating real-time QOL assessment and clinical pathways and how NCCTG is collaborating with an international consortium to identify genetic factors that influence a patient's QOL during cancer treatment.

We also highlight several new studies, including three trials in three different disease areas using the same treatment and collaborative laboratory testing to provide even more definitive results (see article on page 17).

Each of these new efforts, whether they involve QOL research or biomarker identification, are made possible by our members' efforts, including assisting patients in completing QOL questionnaires and tracking these results and submitting tissue and blood specimens for analysis. As always, our members' collaboration makes it possible for us to achieve our mission of improving cancer care.

Jan Buckner, M.D.

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The following section is a summary of three NCCTG clinical studies presented at the American Society of Clinical Oncology (ASCO) meeting held in June 2009.

Two Targeted Therapies Likely Better Than One in Patients with Aggressive Lymphoma, Mayo Clinic Researchers Say

When combined with a cocktail of chemotherapy drugs, two monoclonal antibodies, instead of one, appear to offer superior results in patients with diffuse large B-cell lymphoma, according to Mayo Clinic researchers working with the North Central Cancer Treatment Group (NCCTG). These results were presented at the annual meeting of the American Society of Clinical Oncology (ASCO).

Researchers say that adding the targeted therapy epratuzumab to a regimen known as R-CHOP resulted in an overall 12-month survival of 88 percent in 78 patients. While they call that a very good outcome, the researchers were especially encouraged because the survival rate was 85 percent in patients with high-risk disease.



Ivana Micallef, M.D.

“These results are very good and very promising, and hopefully will be an important advance over treatment now being offered to patients with this cancer,” says the study’s lead author, Ivana Micallef, M.D., a Mayo Clinic hematologist. “But we cannot yet say that is so, since the two different regimens haven’t been tested head to head.

“Still, we are eager to do a randomized, Phase III study because when we compare our results to some other studies of R-CHOP, our findings do look better,” she says. In general, those studies showed a 12-month progression-free survival (PFS) of 67 to 79 percent.

The NCCTG multi-institutional research network is planning a clinical trial that will randomize patients with high-risk diffuse large B-cell lymphoma

to either this regimen, known as ER-CHOP, or to R-CHOP, the standard treatment. R-CHOP includes a combination of chemotherapy drugs (cyclophosphamide, doxorubicin, and vincristine), the steroid drug prednisone, and rituximab, a monoclonal antibody.

Diffuse large B-cell lymphoma is one of the most common and aggressive forms of non-Hodgkin lymphoma, a cancer of the B-lymphocyte white blood cells.

The researchers are the first to study the addition of epratuzumab to R-CHOP in newly diagnosed, untreated patients. Both epratuzumab and rituximab are monoclonal antibodies that attach to proteins commonly found on the outside surface of B cells — CD20 for rituximab and CD22 for epratuzumab. They are also used as immunosuppressive agents to treat certain autoimmune diseases where B cells produce antibodies that attack a person’s own cells. “These drugs are designed to shut down B cells, whether they are involved in autoimmunity or are malignant,” Dr. Micallef says.

Rituximab is approved for use by the Food and Drug Administration, while epratuzumab is not. That means ER-CHOP treatment cannot be used outside of a clinical trial.

In addition to the results on overall survival, the researchers found an 82 percent PFS in the group. The 39 high-risk patients had a 77 percent PFS, and, for the 39 low-risk patients, PFS was 88 percent. Patients are deemed high risk if they have three or more poor prognostic factors, such as age (60 years or older), elevated LDH (a blood test), advanced disease stage, disease outside of lymph nodes and poor physical performance status.

Dr. Micallef says that the treatment, which is given every 21 days, was well tolerated by patients. The study drug, epratuzumab, was provided by Immunomedics, Inc. The research was funded by NCCTG.



Mayo Clinic Researchers Say Agent Provides Treatment Option for Women with Hot Flashes

A pill used for nerve pain offers women relief from hot flashes, Mayo Clinic researchers reported at the annual Meeting of the American Society of Clinical Oncology (ASCO).

They say the agent, pregabalin, decreased hot flash severity and frequency about 20 percent more than did a placebo agent. Thus, pregabalin appears to offer about the same benefit as gabapentin, an older, related drug, as well as newer classes of antidepressants.



Charles Loprinzi, M.D.

“Hot flashes are a major problem in many women, and for those who opt not to take hormonal therapies or antidepressants, pregabalin appears to be another treatment option,” says the study’s lead author, Charles Loprinzi, M.D., a medical oncologist at Mayo Clinic in Minnesota.

While pregabalin offers about the same benefit as gabapentin, women who use it only need to take two pills a day, versus three for gabapentin, he says. Side effects can occur with the use of either drug. However, in this study, they were not severe enough that participants stopped using the active study drug any more often than did patients who were taking placebos, researchers say.

Dr. Loprinzi has pioneered the field of nonhormonal hot flash therapy, which he began researching decades ago to help breast cancer patients using tamoxifen, an anti-estrogen treatment that creates symptoms of menopause. He is the first researcher to test the use of antidepressants, compared to placebo treatment, for hot flashes.

Gabapentin, an agent that has long been on the market to treat pain caused from injury to nerves, has been shown to decrease hot flashes more than do placebos. This drug is approved by the U. S. Food and Drug Administration to treat diabetic peripheral neuropathy and for shingles. Anecdotal evidence suggested that menopausal women who used it had a reduction in hot flashes, Dr. Loprinzi says. Multiple placebo-controlled studies have since demonstrated that this drug decreases hot flashes.

Gabapentin and a variety of antidepressants are now commonly prescribed for treatment of hot

flashes, although these agents are not specifically approved by the FDA for such use.

Pregabalin is a newer version of gabapentin. “We thought it might also relieve hot flashes and thus was worth testing,” Dr. Loprinzi says.

So, using grant funds from the National Cancer Institute, Dr. Loprinzi and colleagues set up a 207-participant study conducted by the North Central Cancer Treatment Group (NCCTG). The study was a Phase III double-blinded, placebo-controlled randomized trial, testing three different treatment arms: a placebo versus daily doses of 150 milligrams (mg) of pregabalin (75 mg twice a day) and 300 milligrams (150 mg twice a day). Patients getting pregabalin started off with lower doses which were increased weekly to the eventual full dose.

Participants, who reported having at least 28 hot flashes a week, kept a “hot flash diary” in which they recorded the number and severity of hot flashes they had each day while taking their study drug — the content of which was unknown to them.

In the study group, 34 percent were using anti-estrogen therapy — either an aromatase inhibitor, raloxifene, or tamoxifen — to help prevent the recurrence of estrogen-sensitive breast cancer.

The researchers found that for the 163 patients for whom information was available, both doses of pregabalin reduced hot flashes to about the same degree, but that toxicities, such as cognitive dysfunction, were increased at the higher dose. Other reported side effects included weight gain, sleepiness, dizziness, coordination troubles, concentration troubles, and concerns regarding vision changes.

They found that after six weeks of treatment women using a placebo agent reported about a 50 percent decrease in their hot flash score (severity), but the change was greater for those who used a 75 mg twice daily dose of pregabalin (65 percent decrease) and a 150 mg twice daily dose (71 percent decrease). The declines in hot flash frequency were 36 percent for placebo users, 58 percent in women who used lower-dose pregabalin, and 61 percent in women given the higher dose.

“All in all, this study demonstrates that we have another agent to add to the list of medications that offer benefit against hot flashes, even in women using anti-estrogen therapies,” Dr. Loprinzi says.

Pfizer, the company that manufactures pregabalin, donated both the drug and placebo tablets for this study.



Chemo Combo Outcomes Differ for Older, Younger Colon Cancer Patients

The combination of chemotherapies 5FU and oxaliplatin compared to 5FU alone after surgery for colon cancer decreases colon cancer recurrence and promotes longer survival for patients under 70 — but not for those who are older, according to Mayo Clinic and Dana-Farber Cancer Institute scientists who presented their findings at the American Society for Clinical Cancer (ASCO) annual meeting in June.

“By combining information about many patients from a collection of studies, our analysis determined that the more aggressive combination chemotherapy does not benefit older colon cancer patients as it does for those who are younger,” says Nadine Jackson McCleary, M.D., Ph.D., Dana-Farber gastrointestinal oncologist and the lead author on the study. Dr. Jackson-McCleary is the recipient of a 2008–2009 ASCO Young Investigator’s Award.

Adding oxaliplatin to chemotherapy treatment with 5FU reduces the risk of recurrence among patients less than 70 years of age who have had their primary cancer removed, the study determined. This finding was expected based on the results of previous individual trials. Patients under 70 who were treated with 5FU and oxaliplatin had improved disease free survival, with the addition of oxaliplatin relatively reducing the risk of recurrence or death by approximately 15 percent. Those patients aged 70 and older who were treated with the combined drug therapy, however, did not have improved outcomes compared to patients who received 5FU alone.



Daniel Sargent, Ph.D.

“We found that adding chemotherapy agents to the standard 5FU regimen in older patients after surgery did not provide the benefits that younger patients see,” Daniel Sargent, Ph.D., Mayo Clinic, a collaborator on the study, agrees. “For the older patient, this means that it is appropriate to choose the better tolerated treatment strategy of 5FU alone.”

The benefit of post-surgical treatment for both young and older colon cancer patients with 5FU was documented in a study by Dr. Sargent and colleagues published in the *New England Journal of Medicine* in 2001. By 2003, however, oxaliplatin was approved for use in combination with 5FU because the combination boosted the impact of 5FU on extending disease free survival after colon cancer surgery. While the combined treatment carried additional risk of side effects, physicians prescribed the treatment strategy to patients of all ages. Initially, studies that examined age-related impact of the aggressive chemo combo did not indicate a difference in survival or recurrence related to a patient’s age.

The current study presented at the ASCO annual meeting includes a large enough patient base to powerfully discern differences related to age that are due to treatment regimen. “The younger patients do get an additional boost from both drugs used together,” Dr. McCleary notes. “Older patients don’t benefit from that combination of treatment.”

The findings arise from analysis of combined data collected within an expanded database by the Adjuvant Colon Cancer End Points (ACCENT) Group, a consortium of scientists. The ACCENT database includes data from more than 33,500 patients from the United States, Canada, Australia and Europe. ACCENT is supported by the North Central Cancer Treatment Group (NCCTG). Dr. Sargent is chair of ACCENT.

“At this point we can only speculate as to why older patients do not benefit from combined chemotherapies,” Jeffrey Meyerhardt, M.D., M.P.H., of Dana-Farber and co-investigator on the trial says. “Perhaps the toxicity of the combination is too great a burden leading to more chemotherapy dose reductions and delay. We do know that a higher number of older patients have to stop the drug before completing the full six-month prescribed course of treatment.”

“These studies add to the knowledge base that defines how to choose treatment strategies for every individual patient,” Dr. Sargent says. “Age is as important a consideration as genetics when defining individual medical options for colorectal cancer patients.”



Approximately half of all colon cancer patients are older than 70. While about half of the colon cancer patients over 70 will live for five years, those with recurrence typically develop additional tumors within three years. The disease is diagnosed in a million people worldwide every year. In the United States, colorectal cancer accounts for 10 percent of new cancer cases, as well as 10 percent of cancer-related deaths every year.

Drs. Jackson McCleary, Meyerhardt, and Sargent conducted the analysis on the expanded database in concert with an international team of scientists participating in ACCENT, including E. Green, M.A., G. Yothers, Ph.D., A. DeGramont, M.D., E. Van Cutsem, M.D., M. O'Connell, M.D., C. Twelves, M.D. and L. Saltz, M.D.



A rich experience — the 2009 NCCTG Patient Advocate Symposium

By Cynthia Chauhan
Co-chair, NCCTG Patient Advocate Committee

“A rich experience.” “A consistent level of excellence.” “AWESOME!!” These are some of the many positive comments we received on the 2009 North Central Cancer Treatment Group (NCCTG) Patient Advocate Symposium. Thirty-five advocates came from nine states to Rochester, Minn., to attend our seventh annual symposium. This meeting, sponsored and funded by NCCTG, is an opportunity for community advocates to come together to learn about the role of NCCTG in bringing cancer clinical trials to the community as well as about the latest advances and NCCTG clinical trials in breast, brain, gastrointestinal, lung and melanoma cancers, quality of life, novel therapeutics and cancer control.

In addition to trials information, the 2009 symposium included updates on the importance of genomics, pharmacogenomics, pathology and statistics in the treatment of cancer as well as a panel presentation offering insight into the role and work of the bench researcher. A special highlight of this year’s symposium was a presentation from the Mayo Clinic Health Policy Center on reforming health care in America.

The symposium provides an opportunity for attending advocates to network with each other, to learn about the work each advocate has done in the their community, including alliances each advocate has formed and problems they have encountered. The rich diversity of experience provides excellent, intentional learning and sharing opportunities for the attendees. This is further enriched not only by the expertise of the Mayo physicians and scientists

who present but also by their approachability and caring. The depth of their caring expressed through their passionate dedication inspires the attendees, renewing and strengthening our commitment to our work in the communities.



Nasser Hanna, M.D.

A unique highlight of this year’s symposium was the inclusion of researchers from Hoosier Oncology Group (HOG), a cancer research organization. Nasser Hanna, M.D., chair of HOG, and other researchers from the group presented an overview of the group’s activities, including an update on their lung and gastrointestinal trials. We

welcome and are enhanced by the participation of HOG, which has modeled their community advocacy program after the NCCTG Patient Advocate Community Advocacy Program.

In summary, as one participant noted on the evaluation form: “It has been a rich experience, and I greatly appreciate all that has gone into making it so good.”

To view agendas and presentations from the 2009 NCCTG Patient Advocate Symposium and to learn more about NCCTG Patient Advocates, visit <http://ncctgpatientadvocates.org>.



Taking the next step — NCCTG's Quality of Life Committee brings cancer patients' perspectives to the forefront of clinical research and patient care

Keeping patients as the focus of quality of life research



Jeff Sloan, Ph.D.

Since the inception of the North Central Cancer Treatment Group (NCCTG) Quality of Life (QOL) Committee in 1992, the research team has focused on the best methods to obtain and utilize the patient's perspective, also known as patient-reported outcomes. "From the beginning, we have developed patient survey tools with rigorous scientific review," says Jeff Sloan, Ph.D., biostatistician at Mayo Clinic Cancer Center in Rochester, Minn., and the research base co-chair of the NCCTG QOL Committee. "Thanks to Dr. Michael O'Connell and Dr. Jan Buckner along with the NCCTG scientific leadership, every QOL research project has been evaluated to insure that survey tools will elicit important information about the patient's experience as he or she undergoes treatment."



Paul Schaefer, M.D.

In addition, feedback from NCCTG members has played a critical role in the development of the QOL program. "As a physician in the community setting, I am interested in participating in studies where the survey tools can be completed easily by the patient," says Paul Schaefer, M.D., an oncologist at the Toledo membership and community co-chair of the NCCTG QOL Committee. "It is essential to have the patient be the focus of the research. If the questionnaire is too long or difficult to complete, community practices will not want to use it. We have limited time and resources. On the other hand, a well-designed, brief questionnaire can give us important feedback on how a patient is tolerating treatment. We can then use this information as we evaluate the overall benefits of new therapies."

Tools for the trade

The NCCTG QOL Committee has been a leader in developing and refining survey tools to obtain QOL

data. Clinical trial N9741, a groundbreaking trial for colon cancer treatment was the first large-scale trial within NCCTG to incorporate a QOL component. Researchers included patient survey questions that would provide important feedback about the patients' well-being as they underwent treatment.

With the data from N9741 and other trials since that time, Mayo Clinic and NCCTG researchers have discovered critical relationships between QOL data and patient survival that provide important information for patient care. Some of these tools include:

- Changes in a patient's QOL scores that are a half standard deviation or more are clinically significant
- Patients who score five or less on a scale from zero to 10 when rating fatigue are more likely to do poorly
- Scores for QOL attributes should be evaluated individually and then combined for the best prognostic analysis
- Use of a one question QOL assessment can provide important feedback on patient well-being

Each of these tools has been incorporated into clinical trials and has helped researchers evaluate toxicity and treatment benefits for a wide range of cancer therapies. "We now have identified the tools that can provide clinically significant QOL data," says Dr. Sloan. "Our next step is to apply these tools in the clinical setting so that physicians can identify patients experiencing diminished QOL earlier and provide intervention sooner."

NCCTG plays a critical role in creating patient-reported outcomes for toxicity

Perhaps one of the biggest changes in the use of QOL research is the incorporation of patient-reported outcomes in toxicity evaluation. In the past, clinicians used the Common Terminology Criteria for Adverse Events (CTCAE) to rate the level of toxicity experienced by patients. Several past studies that have examined the effectiveness of these criteria found that the clinician's evaluation vastly differed from the patient-reported outcomes for toxicity.

NCCTG researchers, along with colleagues at Memorial Sloan Kettering, MD Anderson, Duke University and the University of Pennsylvania,



were awarded a contract by the National Cancer Institute to develop a patient-reported outcomes questionnaire that will be adopted and used along with the clinician's CTCAE.

The research team has already completed the development of the patient-reported outcomes questionnaire, which is undergoing validation testing with small patient populations. A large-scale validation study is scheduled to begin in the fourth quarter of 2009 and the final version of the survey should be completed before the end of 2010.

"This project takes a tremendous step forward in utilizing patient-reported outcomes in evaluating toxicity," says Dr. Sloan. "In less than two years, we will have developed a tool that, when combined with the clinician's CTCAE results, will help identify toxicity earlier and provide intervention sooner to patients undergoing all types of cancer treatments."

Pilot study to use real time QOL data in patient care



Michele Halyard, M.D.

How can clinicians utilize patient-reported QOL data in the clinical setting? A new pilot study under way is designed to answer that question. Mayo Clinic researchers are conducting the first study using real-time QOL assessment in a radiation oncology clinical practice setting. The researchers will provide clinician with

suggested symptom management pathways at the time patients are seen for on-treatment visits.

"We want to measure the value of providing real-time QOL assessment data along with symptom management pathways to clinicians as they see patients for their treatment visit," says Michele Halyard, M.D., a radiation oncologist at Mayo Clinic in Arizona and the principal investigator for the study. "Our initial pilot study involves more than 130 patients in Arizona and another study will open soon at Mayo Clinic in Rochester, Minn. and at several Mayo Health System locations. We plan to eventually move the study into NCCTG memberships."

For the study in Arizona, patients receiving radiation treatment in head, neck, lung and

gastrointestinal cancers will be divided into two groups. Each group will complete a 12-question survey on their current QOL, including questions on fatigue, pain and overall well-being, at week 1, week 3, week 5 and at the end of treatment. For the first group of patients, clinicians will not see this QOL data prior to seeing the patient for their treatment appointment. The study carried out at Mayo Rochester and the health system will involve neuro-oncology patients.



Angelina Tan

For the second group of patients, clinicians will be able to view the QOL information prior to seeing the patient for their treatment visit. "We have worked with Angelina Tan, a statistician at Mayo Clinic in Rochester, to develop a Web-based computer system that provides the patient's QOL scores on all 12 attributes over the course of treatment,"

says Halyard. "The system highlights any changes in QOL status and also provides links to the National Comprehensive Cancer Network clinical guidelines so that clinicians can immediately receive information about suggested interventions."

Researchers anticipate that this study will be the beginning of utilizing QOL data in the radiation oncology setting. "We hope that this type of real-time QOL data review along with suggested clinical pathways will be applied to all types of clinical settings for cancer patients," says Dr. Halyard. "We would welcome inquiries about this study from NCCTG members and look forward to testing these systems in the community setting."

Incorporating QOL in all aspects of cancer care



Barbara Pockaj, M.D.

Many previous QOL studies have been in the medical oncology setting. Yet researchers are continuing to expand QOL research to be included in every modality. Dr. Halyard's pilot study will bring the use of QOL to the forefront of radiation therapy. Similarly, the NCCTG Surgery Committee believes a patient's



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well-being should be considered when evaluating the benefit of surgical intervention.

“Surgery and its outcome not only impact overall survival but also a patient’s QOL,” says Barbara Pockaj, M.D., a surgeon at Mayo Clinic in Jacksonville, Fla., and the co-chair for the NCCTG Surgery Committee. “Surgeons, patients, and now other regulatory organizations consider post surgical QOL when considering surgical intervention. By combining the NCCTG Surgical Committee’s expertise with those of the disease site and QOL committees, we hope to advance our understanding of the influence of QOL. All of our upcoming protocols, especially those evaluating metastectomy in stage IV disease, will have a QOL component so we can better understand the ramifications of our surgical treatment and determine where improvements can be made.”

A new frontier – QOL and genetics

In February 2009, Mayo Clinic and NCCTG researchers hosted the first Genetic Disposition and Patient-Reported Quality of Life Outcomes symposium. More than 100 participants — statisticians, psychologists, clinicians and geneticists — gathered to spearhead research examining the relationship between genetic characteristics and quality of life attributes. Previous studies in twins indicate that up to 50 percent of a person’s feelings of well-being can be attributed to genetic factors.

“The ultimate goal of this research is to identify genetic factors that will impact a patient’s quality of life while undergoing treatment for cancer,” says Jeff Sloan., Ph.D. “As a first step, we have defined and published our research objectives in finding genetic

factors that influence a person’s positive (happiness) and negative (depression and anxiety) psychological status, fatigue level and pain experience.”

As a result of this first symposium, many researchers are reviewing their own data and preparing grant requests to meet these initial research objectives.

The QOL Team

Since the NCCTG QOL program began, the team for completing this research has included statisticians and researchers at the research base, along with all of the physicians and nurses at the member sites. The research base participants now include more than 30 people — from statisticians to psychologists to principal investigators and nurses. The community member sites work closely with the researchers to design and then administer the patient questionnaires and then submit survey results back to the research base.

“We have more than 94 percent compliance with submission of patient-reported data,” says Dr. Sloan. “This shows the commitment of our members to carrying out this research. Our members’ participation is critical to our success. Because of their efforts to help patients complete surveys, answer questions about the studies and then compile and submit the data, we have excellent data quality that leads to meaningful results.”

The NCCTG QOL team is now extended even further by the collaboration with researchers at other institutions to develop a new patient-reported outcomes tool for toxicity and the initiation of the QOL and genetics research efforts.

NCCTG Quality of Life Liaisons from Disease Committees

Neuro-oncology

Paul Brown, M.D.

Gastrointestinal cancer

Axel Grothey, M.D.

Joleen Turja, M.D.

Breast cancer

Michele Halyard, M.D.

Amylou Dueck, Ph.D.

Lung cancer

Nina Garces, M.D.

Nathan Foster

Melanoma

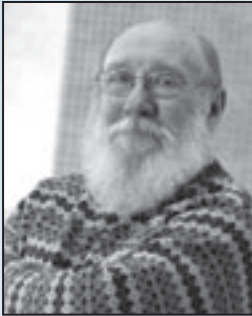
Barbara Pockaj, M.D.

Svetomir Markovic, M.D., Ph.D.



Patient perspectives on the importance of QOL research

Three NCCTG patient advocates offer their views on the value of quality of life research:



Wayland Eppard

Wayland Eppard, co-chair of the NCCTG Patient Advocacy Committee

“Fixing a patient’s cancer often takes the patient to the ‘edge of life.’ Many times during this process the patient wonders if staying on the ‘life’ side of that edge is worth it. The research done by the NCCTG QOL committee provides an insight into cancer research that optimizes the eventual standard of care towards keeping the patient more upbeat and functional during the treatment process. Fewer patients will entertain the ‘dark side of that edge.’”



Cynthia Chauhan

Cynthia Chauhan, co-chair of the NCCTG Patient Advocacy Committee

“A significant advance in cancer research has been the recognition of the importance of quality of life issues to patients. From that understanding, a scientific approach has developed that provides clinicians with better tools to, first, identify quality of life issues, and, second, to intervene in meaningful ways when patients are experiencing poor quality of life. This means that I, as a patient, am approached and understood as a whole person and am given the supportive measures to sustain what is good in my life, while offering tools to deal with what is problematic. Quality of life research provides my treatment team with tools to better understand and communicate with me, ultimately enhancing my care.”



Mary Lou Smith

Mary Lou Smith serves as a member of NCCTG Patient Advocacy Committee, co-chair of the Radiation Therapy Oncology Group Patient Advocate Committee, co-chair of the Eastern Cooperative Oncology Group Patient Representative Committee and member of the Symptom Management QOL Steering Committee for NCI.

“From a patient’s perspective, QOL research is going to become more and more important. The new targeted drugs being tested offer more options to patients. Patients will need to understand the impact of all available treatments on QOL so that they can make informed decisions about their treatment.”

Currently, only 3 to 5 percent of cancer patients enroll in clinical trials. If there were more QOL and symptom management studies, more patients would seek out these trials.

The work that NCCTG has done in this area is so important. Studies like Dr. Halyard’s real-time QOL data evaluation in the clinical setting will help physicians and nurses understand the patient’s experiences during treatment.”



First Recipient Named for North Central Cancer Treatment Group (NCCTG) Junior Faculty Academic Community Partnership Award



Bret Friday, M.D. Ph.D., of the Duluth, Minn., membership will work with Mayo Clinic and other NCCTG researchers in the development and conduct of neuro-oncology clinical trials.

The first recipient of the North Central Cancer Treatment Group (NCCTG) Junior Faculty Academic Community Partnership was named at the spring 2009 NCCTG meeting held May 13–15, 2009 in Rochester, Minn. Bret Friday, M.D., Ph.D., an oncologist at the Duluth Clinic, received the award, which is funded through a grant from Millennium Pharmaceuticals, Inc. Dr. Friday's award funds three years of research to pursue cancer treatments.

"The goal of the NCCTG Junior Faculty Academic Community Partnership is to improve cancer patient outcomes by strengthening the capacity and continuity of community-based cancer clinical research," says Jan Buckner, M.D., group chair of NCCTG and an oncologist at Mayo Clinic's Rochester campus. "That goal will be achieved through a systematic program of recruitment, training, mentorship, and support for select junior-level physician oncologists who will, in turn, become research leaders within their local community practices."

The award program will support two clinicians in their first two or three years at NCCTG member sites, as they establish clinical research careers. These junior-level faculty members will be trained and mentored throughout the award period. As the first recipient, Dr. Friday will be trained in project years 2009–2011. The second recipient will be trained in project years 2011–2013.

Mentoring cancer research leadership in the community setting

Clinical oncology research demands extensive community-level study over a broad and diverse patient population. Community practices serve as the backbone for such research, offering a wide spectrum of study opportunities while sharing the same structured approach as at major medical research institutions. Such research, however, is difficult to stimulate on the local level without a clinical research oncologist on site — a leader who can move the process forward, guide patients and engage staff and fellow clinicians.

Clinical research requires time for activities such as protocol setup, patient enrollment, and data collection. That time and associated cost pose a significant challenge to participation for community-level clinical oncologists. This is especially true for junior-level physicians since they already face numerous challenges as they develop their community practice.

Moving beyond chemotherapy — NCCTG Upper Gastrointestinal Cancer Clinical Trial Update

Several recently-opened trials as well as others in development by the NCCTG Gastrointestinal Cancer Committee are testing targeted therapies that, if proven effective, will provide patients with an alternative to chemotherapy. "Our goal with these trials is to evaluate targeted therapies aimed at specific biological activities that affect tumor growth," says Steven Alberts, M.D., an oncologist at Mayo Clinic in Rochester, Minn., and co-chair of the NCCTG Gastrointestinal Cancer Committee. "With these studies, we hope to identify patient populations that will benefit from these treatments and therefore have an alternative to undergoing chemotherapy which can have more severe side effects than targeted agents."

Following is a summary of these trials:

Clinical trial N0745

N0745 is a Phase II trial evaluating the effectiveness of bevacizumab and sorafenib in the treatment of hepatocellular carcinoma. This trial is being conducted in collaboration with clinical trial N0776 for recurrent glioblastoma multiforme and clinical trial N054C for metastatic colorectal cancer. (See article on page 17 for more information.) Dr. Alberts serves as the principal investigator for this study.

Clinical trial N054B

George Kim, M.D., an oncologist at Mayo Clinic in Jacksonville, Fla., is the principal investigator for this Phase II trial for patients with pancreatic cancer. This trial is combining the standard treatment for pancreatic cancer, gemcitabine, with two targeted



Conversely, local clinical research, which is persistently needed throughout all aspects of cancer research, provides an exceptional opportunity for the junior clinician to establish a research career and become an active participant — and leader — in the field.

The program will be carried out through NCCTG, a national clinical research group sponsored by the National Cancer Institute. The group's research and administration are based at Mayo Clinic. NCCTG consists of cancer specialists at more than 375 community clinics, hospitals and medical centers in the United States and Canada. The group is dedicated to bringing clinical trials with promising new cancer therapies to communities where patients live.

Clinical research training will enhance patient care in the community

The NCCTG Junior Faculty Academic Community Partnership Award enables Dr. Friday to continue participating in clinical research as a community oncologist. "I have an extensive background in basic science and clinical research," says Dr. Friday. "During my oncology fellowship at Mayo Clinic, I completed the clinical investigator training program. This award will allow me time to continue to develop my clinical research skills. Through my research efforts, I hope to make a meaningful contribution towards advancing the goals of NCCTG and improving treatment for cancer patients."

Dr. Friday says the NCCTG Junior Faculty Academic Community Partnership Award will directly benefit patients. "Clinical trials often are the best treatment option for cancer patients," says Dr. Friday. "Since a large number of cancer patients enrolled in clinical trials are primarily taken care of by community oncologists, it makes sense to have community oncologists knowledgeable and trained in clinical research. I hope to develop new protocols that will specifically offer new and exciting treatment approaches to my patients."



Evanthia Galanis, M.D.

Evanthia Galanis, M.D., an oncologist at Mayo Clinic in Rochester, will serve as Dr. Friday's research mentor through the award period. "Dr. Friday has an outstanding laboratory background and prior experience in protocol development," says Dr. Galanis. "One of the concepts he developed and tested in the laboratory during his oncology fellowship has resulted in an active NCCTG clinical trial for recurrent glioma patients."

"During this award period, he will be mentored on protocol development, clinical trial design and conduct, and he will be actively participating in the activities of the NCCTG Neuro-oncology Group," says Dr. Galanis. "We hope that this award will foster the development of community-based clinical research leaders, thus both enhancing NCCTG's research base and benefiting the affiliated community oncology practices."

agents, panitumumab and erlotinib. Researchers hope to enhance the effectiveness of gemcitabine with the targeted agents. Panitumumab targets the epidermal growth factor receptor (EGFR) on the surface of the cancer cell and erlotinib targets the EGFR receptor by getting inside the cancer cell. This trial is scheduled to enroll 88 patients.

Clinical trial N0747

Aminah Jatoi, M.D., an oncologist at Mayo Clinic in Rochester, is the principal investigator for this Phase II trial for elderly or poor performance status patients with metastatic esophageal cancer. This trial is meant for patients who are too sick to receive standard chemotherapy. In this study, patients receive an oral form of chemotherapy, capecitabine, with or without sunitinib, a targeted agent. This study is important because it offers treatment options for older patients or those who are too

sick to receive standard treatment. In addition, if this treatment is shown to be effective, it may become an option for younger patients. This trial is scheduled to enroll 98 patients.

Esophageal cancer trial in development

Harry Yoon, M.D., an oncologist at Mayo Clinic in Rochester, is the principal investigator for a trial being developed for patients with metastatic cancer of the esophagus or stomach. At this time, most studies for this type of cancer involve chemotherapy alone. This study proposes to test a targeted agent, 1121B, used in conjunction with FOLFOX, versus FOLFOX alone. The agent 1121B is an antibody that binds to the ErbB family of receptors on the surface of the cancer cell. These receptors play a major role in tumor growth in many types of cancer.



TIMEOUT! — NCCTG reviews the adverse event reporting process and eliminates unnecessary activity, reducing the workload for principal investigators and member sites



Terre McJoynt

In an effort to streamline the clinical research process, the Mayo Clinic Cancer Center and North Central Cancer Treatment Group (NCCTG) research operations offices began examining all phases of clinical trial development and implementation more than two years ago. By interviewing principal investigators at Mayo Clinic,

NCCTG's research base, one issue became apparent — the time devoted to addressing more than 200 adverse event reports received each month.

“Our principal investigators were receiving adverse event reports about minor or expected events that took place as part of other studies, using different drug combinations,” explains Terre McJoynt, unit head, Mayo Clinic Cancer Center Protocol Development Unit. “Investigators received the report in many different ways. Some reports were sent to Web portal sites, requiring the principal investigator to search for the report. Next, they needed to read the report and determine if the adverse event report applied to their study. Frequently, the reports did not provide information that was critical to ongoing NCCTG trials. In addition, NCCTG research staff spent time recording, tracking and forwarding these reports to member sites participating in the specified clinical trial.”

So, the research team began to examine the regulatory requirements for these adverse event reports as well as the value added, if any, of tracking this information. The team investigated the issue, making sure that all regulatory, legal, quality and safety issues were addressed.

After a thorough analysis, it was determined that tracking these adverse events was not required by any regulatory agency nor did this tracking add any value to the research effort.

Just like the principal investigators, NCCTG member sites were bearing the burden of recording and tracking this information. Philip Stella, M.D., an oncologist and the principal investigator for NCCTG's Ann Arbor membership, spoke for community physicians in a letter sent to all National Cancer Institute-funded cooperative group chairs in spring 2009. He addressed the serious burden that tracking this adverse event reporting brings on community practices, whose priority is offering their patients access to the latest cancer treatments.



Philip Stella, M.D.

Dr. Stella's actions increased the awareness about the issue and reinforced NCCTG's efforts to resolve the problem. On June 1, 2009, NCCTG implemented a new policy, which states that NCCTG will distribute adverse event reports received from industry sponsors only when the sponsor has specified changes to the research protocol and/or consent form, or other corrective actions that need to be taken in response to the report.

“We are working with each of our sponsors to insure the smooth transition to this new policy,” explains McJoynt. “Many pharmaceutical companies were aware of this issue and are taking steps to modify their processes to meet our new requirements. Our primary concern is still to maintain quality and safety in all of our clinical research efforts.”

This new policy was shared with the NCCTG membership at the May meeting. “We received applause when we announced that we would not be forwarding these individual reports to members,” says McJoynt. “Member sites can focus their efforts to care for patients, rather than managing uninformative data.”



NCCTG's new adverse event reporting policy

As of June 1, 2009, NCCTG has the following adverse event reporting guidelines for trial sponsors:

NCCTG will distribute only those individual external adverse event reports received from industry sponsors (e.g., IND Safety Reports, Dear Investigator letters, etc.) that meet all of the following criteria, as established in 21 CFR 312.32 (c)(A):

1. Unexpected
2. Related or possibly related to participation in the research
3. Serious events that suggest that the research places subjects or others at a greater risk of physical or psychological harm than was previously known or recognized.

External adverse events received from industry sponsors will be distributed from the NCCTG research base only when the event report includes: (1) a clear explanation of why the adverse event or series of adverse events has been determined to be an unanticipated problem; and (2) a description of any proposed protocol changes or other corrective actions to be taken in response to the unanticipated problem.

(Note: External adverse event reports received from Clinical Therapy Evaluation Program will continue to be forwarded to NCCTG sites until further notice. These reports should continue to be forwarded to your local IRB per local IRB policy and procedures.)

The U. S. Food and Drug Administration and U. S. Department of Health and Human Services Office for Human Research Protections (OHRP) state that it is neither useful nor necessary that reports of individual adverse events occurring in subjects enrolled in multicenter studies be distributed routinely to investigators or IRBs at all institutions conducting the research.

This regulatory guidance can be found at the following links:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm079753.pdf>

<http://www.hhs.gov/ohrp/policy/AdvEvntGuid.htm>

For questions regarding this policy, please contact:

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NCCTG streamlining efforts in the news

The National Cancer Institute Bulletin July 14, 2009 issue featured an article on the Mayo Clinic Cancer Center's efforts to streamline the protocol development process for clinical trial development.

This effort extended to NCCTG trials. Read the story at <http://www.cancer.gov/ncicancerbulletin/071409/page3#f>



2009 NCCTG Abstracts for American Society of Clinical Oncology (ASCO)

Breast Cancer

**N0338 — Surgical practice patterns following NCCTG N0338 Phase II trial of Docetaxel and Carboplatin administered every two weeks as induction therapy for stage II and stage III breast cancer
Presenter: Heidi Apsey, C.N.P., N.P., R.N.

**N0436 & N0437 — Cytokeratin-19 (CK19) and mammaglobin (MGB1) gene expression in circulating tumor cells from metastatic breast cancer patients enrolled in clinical trials N0436 & N0437
Presenter: Monica Reinholz, Ph.D.

**N9831 — Benefit of adjuvant trastuzumab in breast cancer patients with focal human epidermal receptor 2 (HER2) amplified clones: data from N9831 intergroup adjuvant trial.
Presenter: William Sukov, M.D.

***N0337 — Phase II study of capecitabine in combination with vinorelbine and trastuzumab for the first or second treatment of HER2 positive metastatic breast cancer
Presenter: Winston Tan, M.D.

***N9831 — Baseline and recurrence levels of soluble HER2 in early stage HER2neu positive breast cancer from the NCCTG adjuvant intergroup trial N9831.
Presenter: Alvaro Moreno Aspitia, M.D.

Cancer Control

*N07C1 — Pregabalin for hot flashes in women: NCCTG trial N07C1
Presenter: Charles Loprinzi, M.D.

**N04C7 — Evaluation of the effect of intravenous calcium and magnesium on chronic and acute neurotoxicity associated with oxaliplatin: results from a placebo-controlled Phase III trial
Presenter: Axel Grothey, M.D.

**N06CA — A randomized controlled trial evaluating a topical treatment for chemotherapy-induced neuropathy
Presenter: Debra Barton, R.N., Ph.D.

**N05C3 — The use of vitamin E for prevention of chemotherapy induced peripheral neuropathy: a Phase III double-blind, placebo controlled study
Presenter: Lisa Kottschade, R.N., C.N.P.

***N06CA — Relationship of sensory symptoms and motor function in patients with chemotherapy induced peripheral neuropathy utilizing EORTC QLQ CIPN20
Presenter: Sherry Wolf, R.N.

Gastrointestinal Malignancies

**INT 0116 — Chemoradiation of resected gastric cancer: a 10 year follow-up of the Phase III trial INT 0116.
Presenter: John Macdonald, M.D.



*N0441 — Impact of older age on the efficacy of newer adjuvant therapies in more than 12,500 patients with stage II/III colon cancer: findings from the ACCENT database

Presenter: Nadine Jackson McCleary, M.D., Ph.D.

*N0441 — Use of two-year disease-free survival as a primary endpoint in stage III adjuvant colon cancer trials with fluoropyrimidines with or without oxaliplatin or irinotecan: new data from 12,676 patients from MOSAIC, X-ACT, PETACC-3, NSABP C-06, C-07 and C89803

Presenter: Daniel Sargent, Ph.D.

**93-46-51 — Postoperative surveillance recommendations for early stage colon cancer based on results from the clinical outcomes of surgical therapy trial

Presenter: Vassiliki Tsikitis, M.D.

***INT 0114 — Use of the ratio of metastatic to examined lymph nodes to predict local recurrence in rectal cancer: analysis of data from intergroup trial 0114

ASCO GI Symposium

Presenter: Michael Meyers, M.D.

***N0148 — Adjuvant chemotherapy for resected stage II and III colon cancer: comparison of widely used two prognostic calculators

Presenter: Aditya Bardia, M.B.B.S.

***N0742 — Meta-analyses of randomized trials assessing the interest of postoperative adjuvant chemotherapy and prognostic factors in gastric cancer

Presenter: Marc Buyse, Ph.D.

***N0742 — Meta-analyses of randomized trials assessing the influence of chemotherapy and prognostic factor in advanced/recurrence gastric cancer

Presenter: Carmelo Posso, M.D.

***N0742 — Disease-free survival as a surrogate endpoint for overall survival in adjuvant trial of curatively resected stomach cancer using individual-patient-data meta-analysis

Presenter: Tomasz Burzykowski, Ph.D.

***N994C — Model-based prediction of defective DNA mismatch repair using clinicopathological variables in stage II and III colon cancers

Presenter: Amy French

***N994C — Prognostic impact of body-mass index upon cancer recurrence and survival in stage III colon cancer patients treated in adjuvant therapy trials

Presenter: Frank Sinicrope, M.D.

****N0148 — Analysis of prognostic Web-based models for stage II and III colon cancer: a population-based validation of Numeracy and ADJUVANT! Online

Presenter: Sharlene Gill, M.D.

Lung Cancer

***N0028 — Survival of patients treated with high-dose radiotherapy and concurrent chemotherapy for unresectable non-small cell lung cancer

Presenter: Steven Schild, M.D.

***N04224 — Comparison of progression-free survival and tumor response as endpoints for predicting overall survival in untreated extensive-stage small cell lung cancer: findings based on NCCTG trials

Presenter: Nathan Foster, M.S.



Neuro-oncology

**N027D — NCCTG Phase I trial of temsirolimus (CCI-779) and temozolomide (TMZ) in combination with radiation therapy in newly diagnosed glioblastoma multiforme patients
Presenter: Jann Sarkaria, M.D.

***R9402 — Cognition and quality of life after chemotherapy plus radiotherapy versus radiation therapy for pure and mixed anaplastic oligodendrogliomas
Presenter: Meihua Wang, M.D.

Novel Therapies

*N0489 — Final results of NCCTG N0489: epratuzumab and rituximab in combination with cyclophosphamide, doxorubicin, vincristine and prednisone chemotherapy (ER-CHOP) in patients with previously untreated diffuse large B-cell lymphoma
Presenter: Ivana Micallef, M.D.

***N057E — A Phase II trial of carboplatin and nabpaclitaxel (AB1-007) in patients with unresectable stage IV melanoma, final data from N057E
Presenter: Svetomir Markovic, M.D., Ph.D.

Quality of Life

**Multiple NCCTG studies — Assessing simple measures of patient-reported fatigue for oncology clinical trials: a pooled analysis of 3,915 patients
Presenter: Heshan Liu

***Multiple NCCTG studies — A patient-level pooled analysis of the prognostic significance of baseline fatigue for overall survival among 3,915 patients participating in 43 NCCTG and Mayo Clinic Cancer Center oncology clinical trials.
Presenter: Jeff Sloan, Ph.D.

***Multiple NCCTG studies — Baseline quality of life is an independent prognostic factor for overall survival in lung cancer patients
Presenter: Xinghua (Cathy) Zhao

Statistical Methods

***Multiple NCCTG Studies — Challenges to accrual predictions to Phase III cancer clinical trials: a survey of study chairs and lead statisticians of 248 National Cancer Institute sponsored trials
Presenter: Anneka Schroen, M.D.

***Excessive false positive errors in single arm Phase II trials: a simulation-based analysis
Presenter: Hui Tang, Ph.D.

Key:

*Oral Presentation

**Poster Discussion

***Poster

****Publication



Collaboration — Investigators for three NCCTG clinical trials, all using bevacizumab, sorafenib and the same correlative studies, hope to combine their results for stronger prognostic analysis

The North Central Cancer Treatment Group (NCCTG) is known for its emphasis on collaboration — amongst researchers and the community physician. As researchers strive to identify potential new therapies in a time of limited resources, the role of collaboration becomes even more important. Recently, three NCCTG Phase II trials opened, all utilizing the same targeted agents — bevacizumab and sorafenib — with parallel timetables for correlative research. Each trial addresses a different type of cancer — hepatocellular carcinoma (N0745), recurrent glioblastoma multiforme (N0776) and metastatic colorectal cancer (N054C).

Earlier laboratory studies showed the potential benefits of bevacizumab and sorafenib. Each of the three cancers being studied in the NCCTG trials relies on the development of new blood vessels to stimulate tumor growth. Bevacizumab targets the vascular endothelial growth factor in order to shut off new blood vessel growth or angiogenesis. Sorafenib targets receptors inside the cancer cells and endothelial cells that stimulate tumor and blood vessel growth and promote tumor cell proliferation.

“By combining the two agents, we hope to shut off the development of new blood vessels in order to cripple the cancer cells and stop tumor growth,” says Steven Alberts, M.D., an oncologist at Mayo Clinic in Rochester and principal investigator for the hepatocellular trial.

In addition to testing the same treatments, each trial incorporates tissue, cellular and molecular biomarker studies at the same time points. “The three trials combined will enroll almost 200

patients,” explains Dr. Alberts. “By examining the correlative laboratory findings from each trial, we will have a greater opportunity to analyze biomarkers that may predict which patients will benefit from this treatment. As always, our members’ efforts to submit tissue and blood specimens help make this type of large scale analysis possible.”

Investigators received funds through a Stimulus Grant for the hepatocellular carcinoma trial to support accrual efforts for this rarer type of tumor. Accrual for the other trials is progressing, with approximately half of the expected patients already enrolled.

The glioblastoma trial is also incorporating advanced imaging techniques in conjunction with the trial’s laboratory correlative studies. “Patients will undergo dynamic contrast-enhanced magnetic resonance imaging to help us further evaluate the effectiveness of the therapy,” says Evanthia Galanis, M.D., an oncologist at Mayo Clinic in Rochester, and principal investigator for the glioblastoma trial. “We are seeing vascular changes in the tumor as early as three days after treatment with bevacizumab and sorafenib begins. This imaging could also help us identify a normalization window for the tumor vasculature which will allow us to design future combination studies.”

If the targeted agent combination proves to be effective, researchers hope to apply it to other types of cancer. “Bevacizumab is an integral component of medical therapy for advanced colorectal cancer,” says Axel Grothey, M.D., an oncologist at Mayo Clinic in Rochester, and principal investigator for N054C. “If the combination of bevacizumab with sorafenib shows efficacy in patients who have failed several treatment options before, we will explore this regimen in earlier lines of therapy and in other tumor types.”

This collaborative effort in clinical trial design and implementation across three different disease areas will serve as a model for future trials. “By combining our analysis, we significantly increase the likelihood of obtaining correlative results that can guide our next steps on how to best utilize these treatments,” says Dr. Galanis.



Three trials combine collaborative research efforts to obtain more definitive results.



NCCTG memberships win American Society of Clinical Oncology (ASCO) awards

ASCO Clinical Trials Participation Award

Two NCCTG memberships were among the eight community oncology programs to be honored with the Clinical Trials Participation Award at the 2009 ASCO meeting in June. This award was established to recognize and promote high quality clinical research sites.



*Roscoe F. Morton, M.D.
Robert Behrens, M.D.
Iowa Oncology Research
Association CCOP*



*Gamini Soori, M.D.
Nebraska Cancer
Specialists*

ASCO Community Oncology Research Grant

Nebraska Cancer Specialists was also one of three practices to receive the ASCO Community Oncology Research Grant. This award provides funds to support activities related to the improvement of a community practice's clinical research program.

Spring 2009 NCCTG Meeting Highlights — General Session



Roscoe Morton, M.D., (left) is recognized for his service as principal investigator for the Iowa Oncology Research Association CCOP by Jan Buckner, M.D., NCCTG group chair. Dr. Morton has stepped down and Robert Behrens, M.D., will serve as the principal investigator for this group.



Paul Schaefer, M.D. (left) is recognized for his service as principal investigator for the Toledo membership by Dr. Buckner. Dr. Schaefer has stepped down and Rex Mowat, M.D., will serve as the new principal investigator for this group.

Spring Symposium — Integration of Biomarkers in Treatment Decisions and Trial Design



Daniel Sargent, Ph.D., NCCTG group statistician at Mayo Clinic in Rochester, Minn., speaks on “Statistical Background of Biomarker-Driven Clinical Trials.”



Robert Jenkins, M.D., Ph.D., an oncologist and molecular geneticist at Mayo Clinic in Rochester, speaks on “An overview of Biomarkers in Oncology.”



Axel Grothey, M.D., NCCTG vice chair and an oncologist at Mayo Clinic in Rochester, provides an update on NCCTG gastrointestinal trials.



Julian Molina, M.D., Ph.D., an oncologist at Mayo Clinic in Rochester, provides an update on NCCTG lung cancer research.



Matthew Goetz, M.D., an oncologist at Mayo Clinic in Rochester, provides an update on NCCTG breast cancer research.



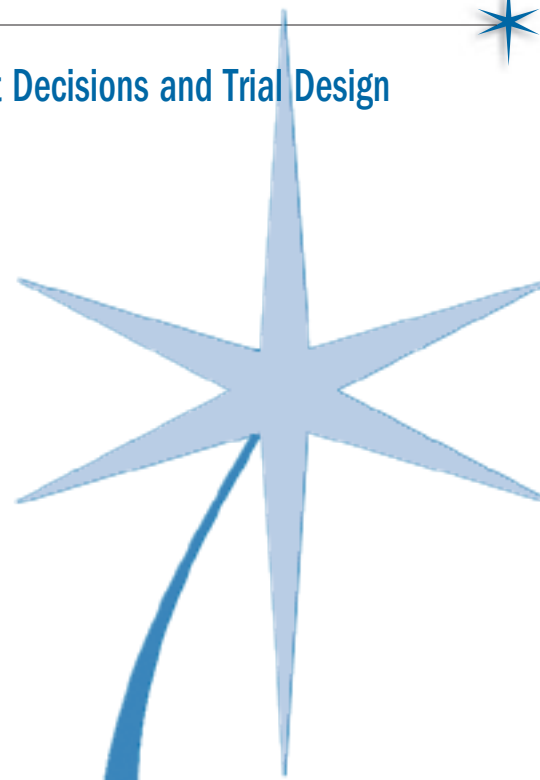
Jann Sarkaria, M.D., a radiation oncologist at Mayo Clinic in Rochester, gives an update on NCCTG neuro-oncology research.



Albert Bernath, M.D., from Geisinger Medical Center in Danville, Pa., asks a question.



John Reynolds, M.D., from Medcenter One Health System in Bismarck, N.D., asks a question.





NCCTG trials to open third and fourth quarter 2009

N0747 — A Randomized Phase II Trial of Sunitinib Plus Capecitabine Versus Capecitabine Alone (with the potential for crossover) for Elderly and/or Poor Performance Status Patients with Metastatic Adenocarcinoma of the Esophagus or Gastroesophageal Junction

Principal investigator: Aminah Jatoi, M.D.

N0849 — Randomized Phase II Trial of Extended Neoadjuvant Therapy for Locally Advanced Adenocarcinoma of the Esophagus, Gastroesophageal Junction, or Gastric Cardia

Principal investigator: Steven Alberts, M.D.

N0871 — A Phase II Study of Carboplatin (CBDCA), Paclitaxel (TAXOL), and Everolimus (RAD001) in Previously Untreated Patients with Measurable Disease with Cancer of Unknown Primary (CUP)

Principal investigator: Matthew Goetz, M.D.

N0577 — Phase III Intergroup Study of Radiotherapy versus Temozolomide Alone versus Radiotherapy with Concomitant and Adjuvant Temozolomide for Patients with 1p/19q Codeleted Anaplastic Glioma

Principal investigator: Kurt Jaeckle, M.D.

N0872 — Phase I/II Study of Dasatinib/Bevacizumab in Recurrent Glioblastoma

Principal investigator: Evanthia Galanis, M.D.

NCCTG wishes to thank the following sponsors for their support of the fall 2009 Group Meeting:

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Editor: Sharon Rosen, Communications

Future Meeting Dates

Sept. 22–25, 2009

May 11–14, 2010 • Oct. 11–14, 2010

May 10–13, 2011 • Oct. 4–7, 2011

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