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**GROUP CHAIR MESSAGE**



Jan Buckner, M.D.

In March, the North Central Cancer Treatment Group (NCCTG), the Cancer and Leukemia Group B (CALGB) and the American College of Surgeons Oncology Group (ACOSOG) formally announced plans to merge. The objective of this merger is to create one integrated cooperative group that will develop and conduct more efficient clinical research studies, thus bringing clinical trial results to patients more quickly. This new integrated group will be part of a more

robust and practice-changing clinical trial system in the future.

Transition teams, which include members from each of the three cooperative groups, are working hard to begin the integration of operations, scientific leadership and biobanking.

The first joint meeting of the new integrated group will take place in Chicago on November 17-19, 2011. We will provide more details on registration and meeting schedules once they are available.

We recognize that change can be disruptive, but we are optimistic that this integration will provide increased opportunities for patients and NCCTG members through expanded clinical research options.

During the transition time, please continue to partner with NCCTG research base staff to address any questions regarding NCCTG clinical trials.

We want to take this opportunity to thank all of our members who have provided outstanding support throughout the years. Your input in clinical trial design and conduct and your commitment to data and biospecimen collection have been the basis for our clinical research success. We look forward to continued collaboration as part of a new organization.

Jan Buckner, M.D.  
 NCCTG Group Chair

**New Alliance website**

For information on the Alliance, visit the newly created Alliance website at [www.alliance-website.org](http://www.alliance-website.org).





# National Cancer Institute develops new strategic plan for the Community Clinical Oncology Program and the Minority-based Community Clinical Oncology Program

## New plan recognizes the impact of incorporating genomic information into clinical research

Twenty-seven years ago, the National Cancer Institute (NCI) developed the Community Clinical Oncology Program (CCOP) to engage community oncology practices in cancer treatment and cancer control and prevention research. The Minority-based Community Clinical Oncology Program (MB-CCOP) was developed to offer a similar network for clinical research for institutions serving large minority and underserved communities.

While these programs have been successful in developing research infrastructures in local practices and accruing significant numbers of patients in cancer clinical trials, the changing science in cancer research warrants a change to the system. Current research strives to translate genomic information into medical practice and, therefore, the design of cancer clinical trials has become much more complex. Community practices must now collect and track biospecimens and analyze biomarkers. Regulatory requirements have also become a significant burden for community practices.

To address the changing research environment, NCI brought together investigators to address research priorities, programmatic structure to facilitate the research and the inclusion of underserved populations. Many NCCTG investigators from Mayo Clinic, the NCCTG research base and NCCTG memberships participated in this strategic planning process. (See list of NCCTG investigators involved in the strategic plan on page 3).

## Strategic plan objectives and recommendations

The following is a list of the new CCOP and MB-CCOP strategic plan goals and accompanying recommendations for achieving these objectives.

### Goal: Incorporate emerging science and novel trial designs into cancer prevention and control research

- Develop and enhance survivorship research, specifically focusing on the time after treatment completion
- Enhance research on acute treatment toxicities and cancer symptoms
- Foster research on risk assessment and risk modeling for cancer prevention and early detection
- Develop funding mechanisms for correlative studies in association with clinical trials in cancer prevention and control
- Foster relationships with basic science researchers in cancer prevention and treatment as well as basic science researchers in other areas pertinent to toxicities and symptoms
- Develop mechanisms to encourage training for young and mid-career cancer prevention and control investigators within the CCOP Research Bases and other academic centers

### Goal: Maximize community resources to conduct complex clinical trials (both cancer prevention and control and cancer treatment trials)

- Develop supplemental funding for biospecimen collection
- Develop a new funding model to support the true level of effort and incorporate more flexibility
- Encourage standardization and improve efficiency across the Network
- Develop a process to address those issues related to the changing health care environment that influence community practices and participation in clinical trials
- Provide support to, or partner with, professional organizations to develop mentorship programs for community physicians to participate in clinical trials
- Foster collaboration with the NCI Office of Communications and Education and other applicable resources to enhance efforts to



provide specific tools to communities on the value of clinical trials

- Address the potential overlap of activities with other NCI community programs

**Goal: Use epidemiological and biological data from under-represented populations in clinical trials to address disparate clinical outcomes**

- Apply current and emerging science to identify and address research questions in under-represented populations
- Develop a transdisciplinary working group to design pilot studies, which are nested with or independent of parent trials in order to evaluate the effect of interventions such as less stringent eligibility criteria for early and late stage cancers
- Promote cancer risk assessment of individuals in underserved communities

**Goal: Improve clinical trial access and participation among populations under-represented in cancer clinical research**

- Consider broadening the eligibility requirements for the MB-CCOPs to allow institutions that do not meet current criteria of 40 percent cancer patients from minority populations, but serve populations in need
- Facilitate language translation at the NCI and local institutional levels, and include language translation into the institution’s budget to support local needs
- Implement a plan for assigning CCOP credit for screening cancer patients and at-risk individuals for clinical trials, including screening within non-oncology practices, which serve underserved populations
- Develop recommendations/guidelines for publications to contribute to the literature regarding accrual of the minorities and underserved populations
- In conjunction with developing the flexible-funding model, review the accrual requirements for the MB-CCOPs and consider differential accrual requirements for different community organizations
- Develop an effective model to incorporate patient navigation into the MB-CCOP/CCOP infrastructure
- Increase diversity in the workforce within the clinical trials infrastructure by collaborating with other organizations that offer training support

**NCCTG investigators on the CCOP Strategic Planning Committee**

**Underserved Populations Committee**

- Jeffrey Berenberg, M.D. – Cancer Research of Hawaii
- Zoneddy Dayao, M.D. – University of New Mexico
- Sachdev Thomas, M.D. – Illinois Oncology
- Alan Lyss, M.D. – Heartland CCOP
- Jan Buckner, M.D. – Mayo Clinic/NCCTG Research Base
- Edith Perez, M.D. – Mayo Clinic/NCCTG Research Base

**Research Priorities Committee**

- Debra Barton, Ph.D., R.N. – Mayo Clinic/NCCTG Research Base
- Joseph Leach, M.D. – Metro-Minnesota
- Melanie Royce, M.D. – University of New Mexico
- Michael Method, M.D. – Northern Indiana
- James Bearden, M.D. – Upstate Carolina
- Jacqueline Vuky, M.D. – Virginia Mason CCOP
- Benjamin Marchello, M.D. – Montana CCOP

**Goal: Build on the success of the CCOP/MB-CCOP programs to further improve the ability of community institutions to accrue patients to clinical trials**

- Develop best practices accrual guidelines for the CCOP and MB-CCOP programs
- Systematically collect and maximize use of data in CCOP/MB-CCOP progress reports on patients screened for clinical trials including reasons for ineligibility, patient refusal and other barriers
- Develop a process to rapidly identify and address clinical trials with lagging accrual
- Encourage the development of correlative studies that address accrual in trials that may pose challenges due to patient concerns, staff workload, the complexity of the trial and the targeted patient population

To view the complete strategic plan, visit <http://prevention.cancer.gov/files/groups/community-oncology-program-strategic-plan.pdf>.

**NCCTG leaders respond to new strategic plan**

The new CCOP strategic plan will help NCCTG and Mayo Clinic researchers as they put together the competitive CCOP research base renewal grant this summer. The current grant funds activities through June 2012 and the new grant will cover the following five years.

*continued on page 4*



Debra Barton, Ph.D., R.N.

“There are many components of the strategic plan that the NCCTG CCOP research base has already been incorporating in our activities,” says Debra Barton, Ph.D., R.N., associate professor of oncology at Mayo Clinic in Rochester, Minn. “For example, we have conducted a natural history study to understand

chemotherapy induced peripheral neuropathy and added translational objectives to the ginseng study which evaluated cortisol and cytokines with respect to fatigue.”



Charles Loprinzi, M.D.

“We look forward to continuing to work closely with the NCI to bring an even broader research portfolio to our community research partners,” says Charles Loprinzi, M.D., the Regis Professor of Breast Cancer Research at Mayo Clinic in Rochester and the principal investigator for the NCCTG CCOP Research Base Grant. “This

will help to improve our ability to more optimally care for our patients.”



Gloria Petersen, M.D.

Gloria Petersen, M.D., Mayo Clinic Cancer Center associate director for Population Sciences and director of the Mayo Clinic SPORE in Pancreatic Cancer, views objectives in the new CCOP strategic plan as positive changes. “The new strategic plan will create important collaborations that should speed translational research, bridging

therapeutic trials and infrastructure with basic and population research,” says Dr. Petersen.

The new strategic plan also emphasizes the importance of cancer screening and prevention. “The new CCOP strategic plan links translational science and cancer prevention and control in the cooperative group setting,” says Jan Buckner, M.D., NCCTG group chair and an oncologist at Mayo Clinic in Rochester. “This will enable better understanding of high-risk populations for screening and prevention of cancer and treatment toxicity.”

## NCI leaders comment on the new strategic plan



Lori Minasian, M.D.



Wortia McCaskill-Stevens, M.D.

Lori Minasian, M.D., acting director of the Division of Cancer Prevention, and Wortia McCaskill-Stevens, M.D., acting director of the Community Clinical Oncology Program (CCOP), both at the National Cancer Institute (NCI), comment on the new CCOP and MB-CCOP strategic plan.

**Q From a scientific perspective, how is this new strategic program different from the current CCOP and MB-CCOP structure?**

**Dr. Minasian:** The CCOP program has supported the cooperative groups to do intervention clinical trials in cancer prevention and control, and the CCOPs were funded primarily for data management and support for patient accrual to the trials.

There are several changes that the new strategic plan initiates. First, the plan acknowledges that the community sites are underfunded for their level of effort and recommends funding that recognizes the multiple people that need to be engaged at the community level. The plan also addresses the fact that treatment trials themselves are profoundly changing; they are becoming more complex and requiring greater effort by the community programs. For example, multiple personnel are involved in biospecimen collection and tracking at the community level.

The plan also proposes to take what we have built through the MB-CCOP and expand the program by finding novel ways to incorporate underserved populations in clinical research.

In the area of cancer prevention and control, while we have made a fair amount of progress, we also need to step back



and gain understanding of the biology of cancer. We have done approximately 150 symptom management studies and most of them were agents that were explored based on empirical evidence. The new strategic plan will allow the CCOP research bases to do natural history and pharmacogenomic studies that will inform us about the biology of toxicities, cancer-related symptoms and survivorship issues. These studies will enable us to have a better understanding of the biology and will help us to better design cancer treatment and prevention trials.

**Dr. McCaskill-Stevens:** The most significant differences for the CCOP network (CCOP/MB-CCOP/research bases) are that the scientific priorities developed in our strategic plan are ones which are: (1) aligned with the current and future directions of NCI; this molecular driven approach to cancer care across the continuum is very promising, yet a challenge that the community sites need to test and successfully deliver to patients and at-risk individuals within their communities; and (2) these priorities were developed with an awareness of the current and rapidly changing health care environment – one which is drastically different from that which existed during the inception of the CCOP network.

The scope of cancer research from NCI's perspective has broadened over the recent years from the contribution of genomics to the inclusion of patients who have survived a cancer diagnosis but are challenged by chronic sequelae of treatment and cancer to the overall host. Our strategic plan includes an agenda for this broadened spectrum to address the critical research questions to improve cancer care.

**Q** **With NCI programs under review, what commitments has NCI made to fund the program going forward?**

**Dr. Minasian:** The CCOP program was extremely well reviewed by the Board of Scientific Advisors in November 2010. The board was thrilled that we acknowledged the value of specimen collections, of the need to identify appropriate funding models

for the community given the changing nature of the clinical trials. This was a ringing endorsement of not just the program but of the strategic approach to move the program in order to maintain its success into the next decade.

**Dr. McCaskill-Stevens:** Because of this strong endorsement, we are cautiously hopeful that our budget will support the implementation of our research goals.

**Q** **How will the reorganization of the cooperative group program impact the CCOP program in the future?**

**Dr. Minasian:** In the long run, it should be very good for the CCOPs because the goal of the consolidated program is to reduce operational issues at the community level by providing uniform systems for data collection, operations, logistics, auditing, etc. This should make it easier for community sites to conduct any group's studies in their practices and should allow them to have an even greater voice in selecting the studies that are most appropriate for them.

As far as NCI funding, the CCOPs are in a unique position going forward. It really doesn't matter what studies they accrue to – they are funded for the purpose of accruing patients. They should be able to participate in as many or as few groups as they wish in order to enroll patients in trials.

**Dr. McCaskill-Stevens:** Amidst the reorganization of the Cooperative Groups and the Institute of Medicine (IOM) recommendations, NCCTG members should feel that the strategic plan is closely aligned with the IOM recommendations. In addition, the Division of Cancer Prevention is fully engaged in the planning of this reorganization and making progress to implement and support the changes that will be required for the CCOP and MB-CCOP research bases.



## North Central Cancer Treatment Group (NCCTG) Cancer Health Disparities Committee Update

Working to increase access and improve outcomes for cancer patients

The mission of the North Central Cancer Treatment Group (NCCTG) Cancer Health Disparities Committee is to increase access and improve the outcomes and cancer experience for all patients. Many of the committee's activities focus on extending cancer care to minority and underserved populations. Established in 1994, the committee meets at each NCCTG semiannual meeting to discuss strategies for increasing patient accrual, information on current health care legislation, updates on specific clinical research involving minority patients and educational resources available to aid minority patients in their understanding of cancer care and participation in clinical trials.



Judith Kaur, M.D.

The committee's efforts have significantly increased minority patient enrollment. "Over the past 10 years, we have increased minority patient involvement in NCCTG clinical trials from 2 to 10 percent, when combining treatment and ancillary studies," says Judith Kaur, M.D., research base co-chair of

the NCCTG Cancer Health Disparities Committee, medical director for Native American Programs and an oncologist at Mayo Clinic in Rochester, Minn. "We have also worked to increase awareness about clinical trial participation in underserved populations through a variety of National Cancer Institute (NCI)-sponsored programs."

*"Over the past 10 years, we have increased minority patient involvement in NCCTG clinical trials from 2 to 10 percent, when combining treatment and ancillary studies."*

*Judith Kaur, M.D.*

### Minority-based CCOPs

The committee's activities extend in many directions. Five NCCTG memberships are designated as Minority-based Community Clinical Oncology Programs (MB-CCOPs) and have a significant number of minority patients within their community. These memberships include:

- Boston Medical Center MB-CCOP, Boston  
Timothy Cooley, M.D., principal investigator
- New Mexico MB-CCOP, Albuquerque, N.M.  
Zoneddy Dayao, M.D., principal investigator
- University of Hawaii MB-CCOP, Honolulu  
William Loui, M.D., principal investigator
- Virginia Commonwealth University MB-CCOP, Richmond, Va.  
Mary Helen Hackney, M.D., principal investigator
- Medical College of Georgia, Augusta, Ga.  
Anand Jillella, M.D., principal investigator

### Clinical research involving minority patients



Jeff Sloan, M.D.

Mayo Clinic and NCCTG researchers also initiate research involving minority patients. Jeff Sloan, Ph.D., research base co-chair for the NCCTG Quality of Life (QOL) Committee and a biostatistician at Mayo Clinic in Rochester, has incorporated survey measurements as part of clinical studies to identify when minority patients require intervention to improve their QOL and overall outcomes.

"In 2008, we conducted a patient-level meta-analytic investigation of the prognostic significance of baseline QOL for overall survival among 6,513 patients participating in 47 North Central Cancer Treatment Group (NCCTG) and Mayo Clinic Cancer Center oncology clinical trials," says Dr. Sloan. "Results indicated certain areas wherein minority patients reported greater QOL deficits relative to nonminority patients."



Michele Halyard, M.D.

Michele Halyard, M.D., a member of the NCCTG Cancer Health Disparities Committee and a radiation oncologist at Mayo Clinic in Arizona, has also conducted research with minority patients. "I have had the privilege of working on a Susan G. Komen Grant with other Mayo Clinic researchers and community members from

the Gila River Indian Community to examine the experience of women who were diagnosed with breast cancer within this Indian population," she says.



Gamini Soori, M.D.

"Conducting clinical research that includes minority patients is critical," says Gamini Soori, M.D., principal investigator for the Missouri Valley CCOP and community co-chair of the NCCTG Cancer Health Disparities Committee. "We know that there are genetic and biological differences that determine how patients respond

to treatments and drug toxicities. Therefore, it is important to include minority patients in clinical trials so that we can identify and address these differences in all population groups."

### Community Cancer Centers Program

Eight NCCTG memberships are part of the NCI Community Cancer Centers Program (NCCCP) initiative, which is a network of hospital cancer centers that serve as a community-based effort to support basic, clinical and population-based research, and address issues including prevention, screening, diagnosis, treatment, survivorship and end-of-life care. (See page 8 for listing of NCCTG memberships that participate in NCCCP.) The network also provides new opportunities to reduce cancer health disparities. The NCCCP started in 2007 as a pilot program with 16 community cancer centers and was expanded in 2010, using funds from the American Recovery and Reinvestment Act, to a total of 30 hospitals in 22 states.

*"Conducting clinical research that includes minority patients is critical. We know that there are genetic and biological differences that determine how patients respond to treatments and drug toxicities. Therefore, it is important to include minority patients in clinical trials so that we can identify and address these differences in all population groups."*

*Gamini Soori, M.D.*

"NCCTG members who participate in the NCCCP program conduct outreach programs to extend all aspects of cancer care to underserved populations," says Dr. Kaur. "Through these efforts, patients may undergo cancer screening and be diagnosed with cancer. Because of their membership in NCCTG, these centers may be able to offer patients treatment through an NCCTG clinical."

### Minority patient education

Spirit of EAGLES is another NCI-sponsored program based at Mayo Clinic and involves a network of American Indian and Alaska Natives communities, students, cancer advocacy groups and academic centers who collaborate on cancer prevention, education and research. One of the group's educational efforts was to create the Cancer 101 program that provides patients with information on cancer prevention, screening and treatment.

"Our NCCTG members are able to use the Cancer 101 program to work with minority patients," says Dr. Kaur. "This program was originally developed for Native American patients but has now been adapted for other minority groups. Spirit of EAGLES is now developing Cancer 102, which will include modules on biospecimen/biorepositories, cancer and genetics and cancer and chronic diseases." These materials will be especially useful for NCCTG members to educate their communities about personalized medicine and its potential to improve cancer care.

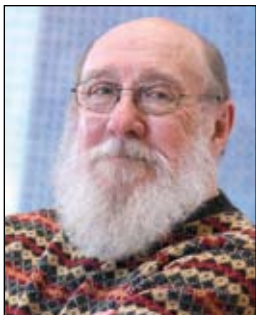


*“Patient advocates attend the Cancer Health Disparities Committee meetings to learn about initiatives for underserved communities and to share our perspective as patients in the discussions on education and recruitment of minority populations.”*

*Wayland Eppard*

A program within the Missouri Valley CCOP provides an excellent example of how memberships can work to educate minority patients. “Within our CCOP, we have created a health disparities group, consisting of leaders of several minority groups within our area,” says Dr. Soori. “Meeting several times a year over the past three years, our goal has been to educate minority leaders about cancer care and clinical trials available within our own community. We hope that this education will then be shared within each minority group so that when patients are diagnosed with cancer, they are already educated about our CCOP services and the potential of being treated through clinical trials.”

The NCCTG Cancer Health Disparities Committee also works closely with NCCTG Patient Advocates on community outreach efforts. These advocates play a special role in teaching patients about cancer screening, treatment and clinical trial participation. Both Cynthia Chauhan and Wayland Eppard, co-chairs of the NCCTG Patient Advocate Committee, have been involved with the Health Disparities Committee since it began.



Wayland Eppard

“Patient advocates attend the Cancer Health Disparities Committee meetings to learn about initiatives for underserved communities and to share our perspective as patients in the discussions on education and recruitment of minority populations,” says

**NCCTG members who are part of the NCCCP initiative**

Billings Clinic  
Billings, Mont.

Geisinger Medical Center  
Danville, Pa.

Lehigh Valley Hospital  
Allentown, Pa.

Mercy Medical Center  
Des Moines, Iowa

Penrose-St. Francis Health Services  
Colorado Springs, Colo.

The Queen’s Medical Center  
Honolulu

Saint Mary’s Health Care  
Grand Rapids, Mich.

Spartanburg Regional Hospital  
Spartanburg, S.C.

Eppard. “In addition, we share information about minority patient education and recruitment at our annual patient advocate symposium each year.”

**Future plans**

The NCCTG Cancer Health Disparities Committee is planning on compiling a summary of “best practices” for health disparities programs, which would include a list of programs that have been successful within NCCTG memberships along with proposed new initiatives to meet the needs of minority patients. “We want to share our experiences with oncology practices outside of NCCTG, in an effort to apply successful strategies to more underserved populations,” says Dr. Soori.

NCCTG Cancer Health Disparities Committee meetings are open to all members. For more information on the committee’s activities, contact the co-chairs of the NCCTG Health Disparities Committee:

- Judith Kaur, M.D., at [kaur.judith@mayo.edu](mailto:kaur.judith@mayo.edu)
- Gianni Soori, M.D., at [gsoori@unchemwest.com](mailto:gsoori@unchemwest.com)



## Clinical trial N0949 to compare standard therapies for metastatic colorectal cancer in elderly patients



Axel Grothey, M.D.

Previous studies have demonstrated that fit, elderly metastatic colorectal cancer patients benefit from combination treatment with fluoropyrimidine and oxaliplatin (FOLFOX and XELOX) chemotherapy. Yet, the majority of cancer research historically has been conducted on younger patient groups, with elderly patients being significantly underrepresented in clinical trials. Clinical trial N0949 will fill an important need by providing efficacy and toxicity data of regimens used in current day practice for the growing under-represented population of elderly patients with metastatic colorectal cancer. The trial opened in January 2011, with projected accrual of 380 patients in the United States.

Oxaliplatin has been shown to be tolerable in elderly patients with metastatic colorectal cancer, but it is associated with higher toxicity than fluoropyrimidine treatment alone, in particular neurotoxicity, which can impair patients' quality of life and reduce their ability to go about activities of daily living. In addition, it is unclear if oxaliplatin is really needed to optimize efficacy in the context of modern medical therapy, which now routinely incorporates the monoclonal antibody bevacizumab in first-line therapy.

Therefore, this study is a two-arm randomized phase III trial with a primary endpoint of progression-free survival of elderly metastatic colorectal cancer patients, testing for the superiority

of modified FOLFOX7 or XELOX plus bevacizumab versus fluoropyrimidine-based therapy (i.e., 5-FU/LV or capecitabine) plus bevacizumab. Secondary endpoints include the assessment and comparison between treatment arms of overall survival, response rates and adverse events of these elderly patients with metastatic colorectal cancer.

This clinical trial will also investigate and validate geriatric/frailty and quality-of-life assessment tools in the elderly metastatic colorectal cancer patients enrolled in this study. In addition, blood and tissue biospecimens will be collected for correlative studies to examine biomarkers that may predict tumor response and/or toxicity in these patients.

"This study will evaluate current standard treatment options for elderly patients with metastatic colorectal cancer in the U.S.," says Axel Grothey, M.D., an oncologist at Mayo Clinic in Rochester, Minn., and principal investigator for the trial. "Our results will be combined with findings from a similar trial that is being conducted by the Japanese Clinical Oncology Group. This prospectively pooled analysis will evaluate and compare the overall survival of more than 760 elderly metastatic colorectal cancer patients who are randomized to receive fluoropyrimidine-based therapy plus bevacizumab, with or without oxaliplatin."

Accrual to this study will be conducted jointly through the North Central Cancer Treatment Group, the Cancer and Leukemia Group B (CALGB) and the US Intergroup. Nadine Jackson McCleary, M.D., M.P.H., an oncologist at Dana-Farber Cancer Institute in Boston, is the CALGB co-chair for this study.



*"Our results will be combined with findings from a similar trial that is being conducted by the Japanese Clinical Oncology Group. This prospectively pooled analysis will evaluate and compare the overall survival of more than 760 elderly metastatic colorectal cancer patients who are randomized to receive fluoropyrimidine-based therapy plus bevacizumab, with or without oxaliplatin."*

*Axel Grothey, M.D.*



## NCCTG abstracts from July to December 2010

### Breast

Lawrence Shulman, M.D.; Donald Berry, M.D.; Heather Becker, M.D.; Clifford Hudis, M.D.; Silvana Martino, D.O.; Eric Winer, M.D.; James Atkins, M.D.: **4 versus 6 cycles of doxorubicin and cyclophosphamide or paclitaxel as adjuvant therapy for breast cancer in women with 0-3 positive axillary nodes: CALGB 40101 A 2x2 factorial phase III trial: first results comparing 4 versus 6 cycles of therapy.** SABCS, 2010. (Protocol Number: C40101) *Slide presentation*

Ann McCullough, M.D.; Patrizia Dell'Orto, M.D.; Monica Reinholz, Ph.D.; Richard Gelber, M.D.; Amylou Dueck, Ph.D.; Leila Russo, M.D.; Robert Jenkins, M.D., Ph.D.; Stefania Andrighetto, M.D.; Beiyun Chen, M.D., Ph.D.; Wilma Lingle, Ph.D.; Christian Jackisch, M.D.; Edith Perez, M.D.; Martine Piccart-Gebhart, M.D.; Giuseppe Viale, M.D.: **Concordance of HER2 central assessment by two international central laboratories: a ring study within the framework of the adjuvant HER2-positive ALTO trial BIG2-06/N063D/EGF106708.** SABCS, 2010. (Protocol Number: N063D) *Poster*

Joseph Sparano, M.D.; Molin Wang, Ph.D.; Silvana Martino, D.O.; Vicky Jones, M.D.; Edith Perez, M.D.; Thomas Saphner, M.D.; Antonio Wolff, M.D.; George Sledge Jr., M.D.; William Wood, M.D.; John Fetting, M.D.; Nancy Davidson, M.D.: **Obesity at diagnosis is associated with inferior outcomes in hormone receptor breast cancer.** SABCS, 2010. (Protocol Number: E1199) *Slide presentation*

Monica Reinholz, Ph.D.; Amylou Dueck, Ph.D.; Anne Wiktor, B.S.; Wilma Lingle, Ph.D.; Robert Jenkins, M.D., Ph.D.; Nancy Davidson, M.D.; Silvana Martino, D.O.; Peter Kaufman, M.D.; Leila Kuttah, M.D.; George Sledge Jr., M.D.; Lyndsay Harris, M.D.; Julie Gralow, M.D.; Xochiquetzal Geiger, M.D.; Edith Perez, M.D.: **c-MYC (MYC) Protein expression and associations with trastuzumab benefit in early-stage, HER2-positive breast cancer in context of the NCCTG adjuvant trial, N9831.** SABCS, 2010. (Protocol Number: N9831) *Poster*

Debra Barton, Ph.D.; Kelli Burger, M.S.; Paul Novotny, M.S.; Jeff Sloan, Ph.D.: **Self reported cognitive function in breast cancer survivors: a 12 month longitudinal descriptive study.** SABCS, 2010. (Protocol Number: N00C9) *Poster*

Michele Halyard, M.D.; Amylou Dueck, Ph.D.; Thomas Pisansky, M.D.; Sarah McLaughlin, M.D.; Lori Pierce, M.D.; Lawrence Marks, M.D.; Lawrence Solin, M.D.; Barbara Pockaj, M.D.; Edith Perez, M.D.: **Impact of adjuvant trastuzumab on local regional recurrence; Data from the NCCTG N9831 study.** SABCS, 2010. (Protocol Number: N9831) *Poster*

Edith Perez, M.D.; Amylou Dueck, Ph.D.; Michael Press, M.D., Ph.D.; Beiyun Chen, M.D., Ph.D.; Robert Jenkins, M.D., Ph.D.; Soonmyung Paik, M.D.; Chungyeul Kim, M.D.; Anne Wiktor, B.S.; Reid Meyer, M.D.; Rhett Ketterling, M.D.; Ivonne Villalobos, M.H.A.; Melanie Finnigan; Marc Buyse, Sc.D.; Joanne Zujewski, M.D.; Mona Shing, M.D.; Howard Stern, M.D., Ph.D.; Wilma Lingle, Ph.D.; Monica Reinholz, Ph.D.; Dennis Slamon, M.D., Ph.D.: **Round-Robin Review of HER2 Testing in the Context of Adjuvant Therapy for Breast Cancer.** SABCS, 2010. (Protocol Number: N9831) *Poster discussion*

Paul Goss, M.D.; James Ingle, M.D.; Judy-Anne Chapman, M.D.; Matthew Ellis, M.D., Ph.D.; George Sledge Jr., M.D.; Thomas Budd, M.D.; Manuela Rabaglio, M.D.; Karen Gelmon, M.D.; Lois Shepherd, M.D.; Kathleen Pritchard, M.D.: **Final analysis of NCIC CTG MA27: a randomized phase III trial of exemestane versus anastrozole in postmenopausal women with hormone receptor-positive primary breast cancer.** SABCS, 2010. (Protocol Number: MA.27) *Slide presentation*



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## GI

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Michelle Neben Wittich, M.D.; Pamela Atherton, M.S.; James Martenson Jr., M.D.; Timothy Kozelsky, M.D.; Donald Wender, M.D.; Robert Behrens, M.D.; Charles Loprinzi, M.D.; Michael Haddock, M.D.: **Assessment of Long-Term Rectal Function in Patients Who Received Pelvic Radiation Therapy, Pooled Data from Two Prospective NCCTG Trials (969256 and N00CA)**. ASTRO, 2010. (Protocol Number: N09C1) *Poster*

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## Hematology

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Stephen Ansell, M.D., Ph.D.; Hui Tang, Ph.D.; Grzegorz Nowakowski, M.D.; Daniel Nikcevich, M.D., Ph.D.; Garth Nelson, M.S.; Charles Erlichman, M.D.; Thomas Witzig, M.D.: **Phase II clinical trial of denileukin diftitox in combination with rituximab in previously untreated follicular B-cell non-Hodgkin's lymphoma**. ASH 116:2862, 2010. (Protocol Number: N0682) *Poster*

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## Neuro-Oncology

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Brett Friday, M.D.; Jan Buckner, M.D.; Keith Anderson, M.S.; Caterina Giannini, M.D., Ph.D.; John Kugler, M.D.; Miroslaw Mazurczak, M.D.; Patrick Flynn, M.D.; Howard Gross, M.D.; Eduardo Pajon, M.D.; Kurt Jaeckle, M.D.; Evanthia Galanis, M.D.: **A phase II trial of the HDAC inhibitor vorinostat in combination with the proteasome inhibitor bortezomib in recurrent GBM**. Presented at SNO, Montreal, Quebec, Canada, November 18-21, 2010. (Protocol Number: N0779) *Poster*

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## Quality of Life

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Jeff Sloan, Ph.D.: **Recent advances in the genetic underpinnings of QOL from the GENEQOL Consortium**. International Society for Quality of Life Research ~ London, England, (#1812), October 27-30, 2010. (Protocol Number: N9741 and N0147) *Oral presentation*

Jeff Sloan, Ph.D.: **Expansion of the Wilson & Cleary Theoretical Model to incorporate genetic influences on quality of life**. International Society for Quality of Life Research ~ London, England, (#1777), October 27-30, 2010. (Protocol Number: N9741 and N0147) *Oral presentation*

Jeff Sloan, Ph.D.; Paul Novotny, M.S.; Daniel Sargent, Ph.D.; Paul Decker, M.S.: **Calibration of Quality-Adjusted Life Years (QALYS) For Oncology Clinical Trials (OCT)**. International Society for Quality of Life Research ~ London, England, (#1783), October 27-30, 2010. (Protocol Number: N9741 and N0147) *Poster*

Michele Halyard, M.D.; Angelina Tan, B.S.; Matthew Callister, M.D.; Jonathan Ashman, M.D., Ph.D.; Sujay Vora, M.D.; William Wong, M.D.; Steven Schild, M.D.; Pamela Atherton, M.S.; Jeff Sloan, Ph.D.: **Assessing the clinical significance of real-time quality of life (QOL) data in cancer patients treated with radiation therapy**. International Society for Quality of Life Research ~ London, England, (#MCS285), October 27-30, 2010. (Protocol Number: 89-20-52) *Poster*

Jeff Sloan, Ph.D.; Paul Novotny, M.S.; Daniel Sargent, Ph.D.; Paul Decker, M.S.; Rui Qin, Ph.D.: **Clinically Significant Effect Sizes for Survival and Response Endpoints Using the 1/2 Standard Deviation Rule**. International Society for Quality of Life Research ~ London, England, (#1772), October 27-30, 2010. (Based on multiple NCCTG protocols) *Oral presentation*

*continued on page 12*



## NCCTG and MCCRC Clinical Trials Update

### Trials activated first quarter 2011

#### NCCTG trials

- N0949:** Randomized phase III trial of mFOLFOX7 or XELOX plus bevacizumab versus 5-fluorouracil/leucovorin or capecitabine plus bevacizumab as first-line treatment in elderly patients with metastatic colorectal cancer (Axel Grothey, M.D., principal investigator)
- N1047:** Colorectal peritoneal carcinomatosis treated with systemic chemotherapy alone: pooled analysis of NCCTG trials (Jan Franko, M.D., principal investigator)

#### MCCRC trial

- I2I-MC-JMMC:** A phase I/randomized phase II study to evaluate LY2603618 in combination with gemcitabine in patients with pancreatic cancer (Robert McWilliams, M.D., principal investigator)

### Trials expected to be activated second quarter 2011

#### NCCTG trials

- N08C9:** Phase III, randomized study of sulfasalazine versus placebo in the prevention of acute diarrhea in patients receiving pelvic radiation therapy (Robert Miller, M.D., principal investigator)
- N1085:** A phase I/II study of everolimus (RAD001) plus R-CHOP for new untreated diffuse large B-cell lymphoma (Patrick Johnston, M.D., principal investigator)
- N1087:** Phase I/II study of the combination of bendamustine, rituximab and MK-2206 in the treatment of relapsed chronic lymphocytic leukemia and small lymphocytic lymphoma (Tait Shanafelt, M.D., principal investigator)
- N1088:** A phase I/II study of bendamustine, rituximab and lenalidomide in patients with refractory/relapsed indolent non-Hodgkin's lymphoma (Grzegorz Nowakowski, M.D., principal investigator)
- N10C1:** Vaginal dehydroepiandrosterone (DHEA) for vaginal dryness: a phase III randomized, double blind, placebo-controlled study (Debra Barton, Ph.D., R.N., principal investigator)

#### MCCRC trial

- B022589:** A randomized 3 arm multicenter phase III study to evaluate the efficacy and the safety of T-DM1 combined with pertuzumab or T-DM1 combined with pertuzumab-placebo versus the combination of herceptin plus taxane as first line treatment in HER2-positive progressive or recurrent locally advanced or metastatic breast cancer (Alvaro Moreno-Aspitia, M.D., principal investigator)



## Shane Morita, M.D., is the recipient of the second North Central Cancer Treatment Group (NCCTG) Junior Faculty Academic Community Partnership Award Award will fund research on the ethnic differences of melanoma

Shane Morita, M.D., an oncologic surgeon at The Queen's Medical Center and the University of Hawaii, is the recipient of the second North Central Cancer Treatment Group (NCCTG) Junior Faculty Academic Community Partnership Award. Dr. Morita will use the three-year award to conduct research on ethnic differences of melanoma.

Dr. Morita's experiences as an oncologic surgeon in Hawaii led to the idea for his research on melanoma. "Working in Hawaii over the past two years, I have treated a significant number of non-Caucasian patients with melanoma, a disease which is predominantly seen in Caucasian patients," says Dr. Morita. "When I reviewed the data from the Hawaii Tumor Registry for the time period 2000-2005, I found that although Caucasians comprised the vast majority of melanoma cases, non-Caucasians had a disproportionately higher mortality."

"This project will be the first of its kind to investigate ethnic disparity of melanoma and explore the frequency of both germline as well as somatic mutations in a diverse, multiethnic population with the principal goal of improving overall patient care," says Dr. Morita.

Svetomir Markovic, M.D., Ph.D., an oncologist at Mayo Clinic in Rochester, Minn., will serve as Dr. Morita's mentor during the award period. "This research offers a unique opportunity to test different aspects of the disease in two populations and examine the molecular events that actually drive cancer development," says Dr. Markovic. "The research results may uncover biological factors that not only relate to melanoma but all types of cancer. By identifying genetic and molecular similarities among the different ethnic groups, we may discover what is more relevant to the actual biology of the tumor and, therefore, be able to



Svetomir Markovic, M.D., Ph.D., (left) and Shane Morita, M.D., attending the fall 2010 NCCTG meeting.

determine what critical areas can be targeted with therapy."

Dr. Morita hopes that this research will provide novel information to further understand the biology of melanoma and serve as a platform for the development of future clinical trials to treat patients with melanoma.

The NCCTG Junior Faculty Academic Community Partnership Award, which is funded through a grant from Millennium Pharmaceuticals, Inc., was established in 2009 to recruit, train, mentor and support selected junior-level physicians at NCCTG member sites who will, in turn, become cancer research leaders within their local community practices.

Bret Friday, M.D., Ph.D., an oncologist at Duluth Clinic in Duluth, Minn., received the first NCCTG Junior Faculty Academic Community Partnership Award and is currently conducting research in neuro-oncology under the mentorship of Evanthia Galanis, M.D., an oncologist at Mayo Clinic in Rochester.



## Cynthia Chauhan receives Distinguished Service in Cancer Education Patient Volunteer-Advocate Award



Cynthia Chauhan

In November 2010, the Mayo Clinic Cancer Center awarded Cynthia Chauhan, co-chair of the North Central Cancer Treatment Group (NCCTG) Patient Advocate Committee, the Distinguished Service in Cancer Education Patient Volunteer-Advocate Award.

The award recognizes patient volunteers associated with

Mayo Clinic for outstanding contributions in cancer education for patients, staff and the community.

In addition to her advocacy role within Mayo Clinic and NCCTG, Chauhan serves as a patient advocate for many national groups, including the National Cancer Institute Translational Research Branch. She is known and respected for her exceptional dedication to patient education and advocacy surrounding clinical research.

“Cynthia Chauhan is an amazing educator and advocate,” says Jan Buckner, M.D., group chair of NCCTG. “She has spent countless volunteer hours working directly with patients, health care providers, clinical and laboratory investigators, and federal staff to advocate on behalf of cancer patients, survivors, and their families.”

During her time as a patient advocate for NCCTG, Chauhan has worked with Patient Advocate Committee co-chair Wayland Eppard to develop and convene nine symposia focused on cultivating a strong clinical trial and research knowledge base for NCCTG site community advocates. In addition, she has worked with the staff and advocates at community sites to establish and promote their advocacy programs.

### Leadership update



Sumithra Mandrekar, Ph.D.

#### Research Base

Sumithra Mandrekar, Ph.D., a biostatistician at Mayo Clinic in Rochester, Minn., is now the group statistician for NCCTG. Dr. Mandrekar had been serving as the acting group statistician, replacing Dan Sargent, Ph.D., in July 2010.

#### NCCTG Membership

Craig Nichols, M.D., has replaced Jacqueline Vuky, M.D., as principal investigator for Virginia Mason membership.

Grant Seeger, M.D., has replaced Tudor Dentchev, M.D., as the principal investigator for the Grand Forks membership.

Michele Halyard, M.D., will replace Tom Fitch, M.D., as the principal investigator for Mayo Clinic Arizona.



## Fall 2010 NCCTG meeting highlights

### Fall Symposium

Presentation of 16th annual Charles G. Moertel, M.D., lecture plaque. Pictured are: (left to right) Jan Buckner, M.D., NCCTG group chair; David Moertel; Lawrence Einhorn, M.D., Charles G. Moertel lecturer and Distinguished Professor of Medicine and Lance Armstrong Foundation Distinguished Professor of Medicine at Indiana University; Virginia Moertel; and Axel Grothey, M.D., NCCTG group vice chair. Dr. Einhorn's lecture was entitled "Testis Cancer: A Model for Curable Cancer."



Fall 2010 symposium speakers were (left to right) Grace Dy, M.D., Assistant Professor of Oncology at Roswell Park Cancer Institute, Buffalo, N.Y.; George Kim, M.D., Assistant Professor of Oncology at Mayo Clinic in Jacksonville, Fla.; and Evanthia Galanis, M.D., Professor of Oncology at Mayo Clinic in Rochester, Minn., and co-chair, NCCTG Neuro-oncology Committee.



NCCTG leaders are (left to right) Daniel Nikcevich, M.D., NCCTG Executive Committee vice chair; Jan Buckner, M.D.; Axel Grothey, M.D.; and Philip Stella, M.D., NCCTG Executive Committee chair.





## General Session



Daniel Sargent, Ph.D., speaks at the fall meeting General Session after being honored for his service as NCCTG group statistician.



Sumithra Mandrekar, Ph.D., NCCTG group statistician, provides an update on data management systems at General Session.



Debra Freiberg, supervisor for the NCCTG Operations Office, speaks to members at General Session.

### NCCTG wishes to thank the following sponsors for their support of the spring 2011 Group Meeting:

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### Future Meeting Dates

First Joint NCCTG, CALGB and  
ACOSOG Alliance Meeting  
November 17-19, 2011  
Chicago



### NCCTG Administration

- Jan Buckner, M.D.,** *Group Chair*
- Axel Grothey, M.D.,** *Group Vice Chair*
- Charles Loprinzi, M.D.,** *Cancer Control Program Director*
- Julian Molina, M.D., Ph.D.,** *Cancer Treatment Program Director*
- Sumithra Mandrekar, Ph.D.,** *Group Statistician*
- Randolph Marks, M.D.,** *Data Monitoring Committee Chair*
- James Martenson, M.D.,** *Radiation Oncology Committee Co-chair*
- Barbara Pockaj, M.D.,** *Surgery Committee Co-chair*
- Lori Erickson, M.D.,** *Pathology Committee Chair and Biospecimen Resource Co-director*
- Monica Reinholz, Ph.D.,** *Biospecimen Resource Co-director*
- Kelly Paulson,** *Operations Coordinator*
- Lori Wangsness,** *Systems Coordinator*
- Ken Saling,** *Group Administrator*

#### NCCTG Insights

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