

2012 Alliance Group Meeting

The Alliance for Clinical Trials in Oncology looks forward to welcoming its membership to the upcoming 2012 Alliance Group Meeting June 28-30 at the InterContinental Chicago O'Hare Hotel in Chicago, IL. Registration is still open at www.alliance-website.org. Attendees of the annual meeting will find engaging scientific presentations and informative educational sessions.

Meeting At-A-Glance

Here are some highlights from more than 60 scheduled meeting sessions.

Clinical Research Professionals Informational Session

Thursday, June 28, 1 pm-5 pm

This session will begin with general updates from Alliance staff specifically for clinical research professionals. Gary L. Smith, MT, MGA, Branch Chief of the National Cancer Institute's Clinical Trials Monitoring Branch, will present an in-depth look at the NCI's Quality Assurance Program and a presentation on how to use the Medical Dictionary for Regulatory Activities (MedDRA) in Common Terminology Criteria for Adverse Events (CTCAE) and in the biopharmaceutical industry.

Audit Preparation Workshop

Thursday, June 28, 5:30 pm-8:30 pm

Alliance Audit Committee Co-Chairs will present an overview of audit resources and the Alliance audit program. Discussion topics will include the PI perspective on participating in audits, regulatory requirements for audits and drug accountability, how to prepare for an audit, how to appropriately tag medical records, evaluate the results from an audit report, and write a corrective action plan.

Plenary Session

Saturday, June 30, 10 am-1 pm

Monica M. Bertagnolli, MD, Group Chair of the Alliance for Clinical Trials in Oncology, will present awards to Alliance members and institutions, including the Clinical Scholar and Young Investigator Awards, The Richard L. Schilsky Cancer and Leukemia Group B Achievement Award, the Charles Moertel Lecture, and awards for accrual. Dr. Bertagnolli will also provide an overview of Alliance communications.

Clinical Research Professionals Educational Session

Friday, June 29, 8 am-12 pm

This session will focus on progressive education and refinement of data management skills for clinical research professionals. The importance of incorporating geriatric assessments in oncology clinical trials will be presented using the study N0949/CALGB 81002 as an example. The standard-of-care for stage II/III rectal cancer will be presented as it relates to the newly activated study N1048.

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Alliance Study Shows Significant Results for Patients with Multiple Myeloma



Philip L. McCarthy

Data from the first large U.S. study assessing the effectiveness of long-term “maintenance” therapy with lenalidomide for patients with multiple myeloma show that the drug significantly improves the time to progression and overall survival for patients with this deadly hematologic cancer. In a paper published May 10 in the *New England Journal of Medicine*, Alliance Investigator Philip L. McCarthy, MD, and co-authors report that maintenance therapy with lenalidomide (Revlimid[®]), following induction therapy and hematopoietic stem-cell transplant, increased the time to disease progression from a median of 27 months to 46 months ($p < 0.001$).

Dr. McCarthy, Professor of Oncology at the Roswell Park Cancer Institute, was the Principal Investigator of the study, CALGB 100104, a phase III randomized, double-blind, placebo-controlled clinical trial that opened in April 2005 and enrolled patients from 47 U.S. transplant centers.

Among 460 patients aged 29 to 71 (median age 59), 231 were randomly assigned to the lenalidomide arm, and 229 to the placebo group. All participants had received prior autologous hematopoietic stem-cell transplantation and had stable disease. The participants’ assignments and responses to date were unblinded in December 2009 when the primary endpoint of the study (time to disease progression) showed a statistically significant difference between the two study groups. After January 2010, 86 of 128 eligible

patients crossed over from the placebo arm to receive lenalidomide.

The treatment was fairly well-tolerated — particularly as compared to other treatments for multiple myeloma, such as thalidomide. There was more hematologic toxicity, particularly Grade 3 or 4 neutropenia, in the lenalidomide group. When the study data was analyzed again in October 2011, at a median follow-up of 34 months, 37 percent of participants receiving lenalidomide had disease progression or had died, compared to 58 percent of those in the placebo group. Researchers found that the therapy extended the time to disease progression by 19 months overall, even with the majority of placebo patients without progression crossing over to lenalidomide.

“These findings fill a gap that existed previously in terms of data on whether maintenance therapy with lenalidomide prolongs the time to disease progression after initial therapy. We now have evidence that it does, in this and the two other lenalidomide studies also presented in the *New England Journal of Medicine*,” said Dr. McCarthy. “This shows that patients with multiple myeloma now have options for prolonging the response to initial therapy. The next steps will be trying to improve on these responses by adding new agents that may prove even more effective in combination with lenalidomide following transplant.”

This study suggests that lenalidomide maintenance therapy until disease progression is feasible for prolonged administration. The increase in time to progression led to early study unblinding, and despite the crossover, benefits with respect to progression and overall survival were seen in

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Alliance Members on the Move



Harold J. Burnstein



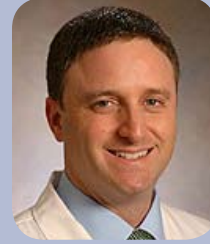
Bruce E. Johnson



Richard L. Schilsky



Deborah Schrag



Michael L. Maitland

Four Alliance members have been named 2012 Fellows of the American Society of Clinical Oncology (ASCO), a distinction that recognizes ASCO members for their extraordinary volunteer service, dedication, and commitment to the organization. Their efforts benefit ASCO, the specialty of oncology, and, most importantly, the patients they serve. The fellows include **Harold J. Burstein, MD, PhD**; **Bruce E. Johnson, MD**; **Richard L. Schilsky, MD**; and **Deborah Schrag, MD, MPH**. They were honored at the opening session at this year's ASCO meeting in Chicago, IL.

Michael L. Maitland, MD, PhD has been chosen as the recipient of the Leon I. Goldberg Young Investigator Award from the American Society for Clinical Pharmacology and Therapeutics. He is Assistant Professor of Medicine at the University of Chicago, and member of the Alliance Imaging and Pharmacogenomics and Population Pharmacology Committees.

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Alliance Study Shows Significant Results

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patients receiving lenalidomide maintenance therapy, especially those who had received lenalidomide-based induction therapy. It remains to be determined whether the incorporation of other new agents with lenalidomide will further increase the time to disease progression and overall survival.

“This trial demonstrates the benefits of cooperative group research,” said Monica M. Bertagnoli, MD, Chief of the Division of Surgical Oncology

at Brigham and Women’s Hospital, Professor of Surgery at Harvard Medical School, and Group Chair of the Alliance for Clinical Trials in Oncology. “Cooperative groups conduct trials that provide answers to important clinical questions.”

The paper is available at <http://www.nejm.org/doi/full/10.1056/NEJMoa1114083> (N Engl J Med 366;19).

New Research Network: Academic and Community Cancer Research United (ACCRU)



Axel Grothey

Academic and Community Cancer Research United (ACCRU) is a partnership of academic and community investigators that collaborate with industry partners to conduct clinical trials with the goal of improving cancer treatment and symptom control, according to Axel Grothey, MD, Group Chair, and Professor of Oncology in the Division of Medical Oncology at the Mayo Clinic. Established in 2004 as the Mayo Clinic Cancer Research Consortium (MCCRC) in partnership with the North Central Cancer Treatment Group, MCCRC changed its name to ACCRU in late 2011, coinciding with the formation of the Alliance for Clinical Trials in Oncology.

ACCRU is driven by a two-fold mission: to improve the duration and quality of life for cancer patients by performing high quality clinical trials in the community setting, and to improve the understanding of cancer biology and biological consequences of cancer treatment. ACCRU research is meant to be complimentary to the studies performed by the Alliance; however,

it does not function as a cooperative group. ACCRU maintains an administrative, membership and governance structure that is separate and independent of the Alliance. ACCRU studies are supported through industry or philanthropic sources. Some studies funded by the NCI Research Project Grant Program (or R01) have received supplemental support.

ACCRU provides a parallel track to test new agents and combinations in a variety of disease settings; rapid study activation; and studies in disease sites outside of the focus of the Alliance or when no cooperative group trial is available.

ACCRU focuses on a broad range of cancer research in areas of breast cancer, chronic lymphocytic leukemia, colorectal cancer, lung cancer, lymphoma, melanoma, ovarian cancer, pancreatic cancer, renal cell carcinoma, anorexia, anemia, peripheral neuropathy, skin toxicity, osteopenia, hot flashes and gastrointestinal toxicity. The ACCRU network comprises more than 60 institution members with over 450 treating locations across the U.S. and Canada.

All Alliance members are eligible to apply for ACCRU membership. For more information or an application, visit www.accru.org.

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What Works . . . Reaching the Community

Friday, June 29, 10 am-11:30 am

This session will examine the cultural differences, fears, and misunderstandings that may impede underserved populations from entering a clinical trial. Pre- and post-tests will be used to gauge the level of attendee's understanding. A panel of speakers will specifically examine African American, Asian, Hispanic/Latino, Native American and senior cultures.

12th Annual Jimmie Holland Lecture

Friday, June 29, 12 pm-1 pm

Electra Paskett, PhD, Chair of the Alliance Health Disparities Committee, will provide an overview of the health disparities research agenda and also present this year's lecture entitled "Interventions to Address Cancer Health Disparities: The Case of Cervical Cancer in Appalachia."

Community Oncology Committee

Friday, June 29, 12:30 pm-3:30 pm

Committee Co-Chairs Robert J. Behrens, MD, Jeffrey Kirshner, MD and Walter P. Peters, MD, will host two scientific presentations during this meeting: "Stage III Colon Cancer - Update on Chemotherapy and Beyond Chemotherapy Options" by Jeffrey A. Meyerhardt, MD, of Dana-Farber Cancer Institute, and "PROSPECT: A Phase II/III Trial of Neoadjuvant FOLFOX, with Selective Use of Combined Modality Chemoradiation versus Preoperative Combined Modality Chemoradiation for Locally Advanced Rectal Cancer Patients Undergoing Low Anterior Resection with Total Mesorectal Excision" by Alessandro Fichera, MD, of the University of Chicago and Deborah Schrag, MD, of the Dana-Farber Cancer Institute. In addition, Wortia McCaskill-Stevens, MD, Acting Chief of the National Cancer Institute's Community Oncology and Prevention Trials Research

Group, will provide updates on the Division of Cancer Prevention and discuss the merger of the Community Clinical Oncology Program and the NCI Community Cancer Centers Program.

Biomarkers of Aging, Functional Decline and Cancer Symposium

Friday, June 29, 1 pm-2:30 pm

This symposium will explore potential biomarkers that may indicate host changes such as senescence and functional decline. Circulating and tissue biomarkers will be included in this discussion. Participants will also learn more about the potential of linking host factor biomarkers with tumor biomarkers, and the overall applicability of combining these biomarkers with clinical comprehensive geriatric assessment.

Oncology Nursing Educational Session

Friday, June 29, 1 pm-3 pm

A case study of CALGB 170601: A randomized, placebo-controlled cross-over trial of duloxetine for the treatment of painful chemotherapy-induced peripheral neuropathy (CIPN) will be the focus of this educational session. Two experts will present "The Effect of Omega 3 on Atrophic Vaginitis in Postmenopausal Breast Cancer Survivors" and "Research on Secondary Lymphedema in the Cooperative Group Setting: CALGB, ACOSOG, and GOG."

Health Disparities Committee

Friday, June 29, 1 pm-3 pm

Committee Chair Electra D. Paskett, PhD, will host three scientific presentations during this meeting: "Race Disparities in Patient Participation in CALGB Cancer Pharmacogenomic Studies" by Lynn Dressler, PhD, of the University of North Carolina at Chapel

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Hill; “Comparison of Baseline Quality of Life Between Minority and Non-minority Patients Participating in Oncology Clinical Trials” by Judith Kaur, MD, of Mayo Clinic; and “Issues of Race and Genetic Ancestry in Disparities Studies” by Rick Kittles, PhD, of the University of Illinois.

Translational Research Symposium

Friday, June 29, 3 pm-6 pm

This symposium will highlight recent discoveries and scientific progress by Alliance investigators and collaborators who have used biospecimens collected through Alliance or legacy group trials. This presentation will include discussions on two recent imaging projects in lung cancer and lymphoma, the prognostic impact of molecular markers in stage III colon cancer, and genome-wide methylation profiling in acute myeloid leukemia.

American College of Surgeons Clinical Research Program General Session

Saturday, June 30, 8 am-10 am

Attend this session to learn more about the American College of Surgeons Clinical Research Program. A panel of speakers from the Cancer Care Standards Development Committee will discuss the development of a surgical standards manual; Genevieve Melton-Meaux, MD, of the University of Minnesota, will present an update on Adverse Event Reporting Standards for Surgical Procedures; Isabelle Bedrosian, MD, of MD Anderson, and Bryan Meyers, MD, MPH, of the Washington University School of Medicine in St. Louis, will provide updates on Alliance prevention trials and host a discussion on how surgeons can be more involved in these studies.

CALL FOR POSTERS

Alliance members are welcome to participate in the 2012 Alliance Poster Session on Friday, June 29, 6:30 pm-9:30 pm.

If you recently presented a poster at 2011-2012 scientific meeting related to cooperative group research, bring it to the Alliance meeting. Posters will be displayed during the cocktail reception.

If you plan to participate, contact Katherine Faherty (kefaherty@partners.org) by 5 pm ET on June 13.

FROM THE ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY FOUNDATION

The Alliance for Clinical Trials in Oncology Foundation wishes to thank all of the investigators for their high-quality applications submitted for the 2012 Alliance for Clinical Trials in Oncology Foundation Clinical Scholar and Investigator Awards. The Foundation received more than 35 applications and has convened an independent scientific review committee, co-chaired by Phillip Febbo, MD, (Alliance Translational Research Program Director) and John Leonard, MD, (Alliance Executive Committee Member and Lymphoma Committee Vice Chair), to review and select the award recipients. The committee represents expertise across all diseases and modalities studied within the Alliance. Applications will be judged on their scientific merit, feasibility of the research proposed and relevance to the scientific agenda of the Alliance. Award recipients will be announced during the Plenary Session of the 2012 Alliance Group Meeting on Saturday, June 30.

Alliance Members on the Move

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Monica Morrow

ASCO has awarded the the 2012 Gianni Bonadonna Breast Cancer Award and Lecture to **Monica Morrow, MD**. She is Chief of the Breast Surgery Service, Co-Chief of the Breast Program, and Anne Burnett Windfohr Chair of Clinical Oncology at Memorial Sloan-Kettering Cancer Center. She is also Professor of Surgery at Weill Cornell Medical College. Her clinical interests include the application of advances from clinical trials to daily surgical practice, the evaluation of new technology related to local therapy of breast cancer, and understanding how patients make breast cancer treatment decisions.



Kanti R. Rai

Kanti R. Rai, MB, BS, was presented with the 2012 David A. Karnofsky Memorial Award and Lecture at the 48th annual meeting of ASCO. The award acknowledges his outstanding achievements in cancer research and for his influence on the treatment of patients with cancer. Dr. Rai is Chief of the Chronic Lymphocytic Leukemia Research and Treatment Program at North Shore-long Island Jewish (LIJ) Health System, and the Joel Finkelstein Cancer Foundation Professor of Medicine at Hofstra North Shore-LIJ School of Medicine.



Hope S. Rugo

Hope S. Rugo, MD, is a new member of the ASCO Connection Editorial Board. She is a member of the Alliance Breast Committee, and a medical oncologist and hematologist specializing in breast cancer research and treatment at the University of California, San Francisco. She is also Professor of Medicine, Director of the Breast Oncology and Clinical Trials Education, and the principal investigator of multiple clinical trials focusing on combinations of novel targeted therapeutics with standard treatment to improve the treatment of both early- and late-stage breast cancer.

Meeting Dates

2012 Group Meeting

Open to all Alliance members

June 28-30, 2012

InterContinental Chicago O'Hare
5300 N. River Road
Rosemont, IL 60018

**Registration is now open; visit the Alliance web site for more information*

2012 Fall Committee Meetings

Open to Alliance committee members only

November 15-17, 2012

InterContinental Chicago O'Hare
5300 N. River Road
Rosemont, IL 60018

**Draft meeting schedule now available on the Alliance web site*

2013 Committee Meetings

Open to Alliance committee members only

March 14-17, 2013

InterContinental Chicago O'Hare
5300 N. River Road
Rosemont, IL 60018

**Breast Committee will meet on Sunday, March 17*

2013 Group Meeting

Open to all Alliance members

November 7-9, 2013

InterContinental Chicago O'Hare
5300 N. River Road
Rosemont, IL 60018

For meeting and travel queries, contact Katherine Faherty
phone: 617-525-3022
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For more information on the Alliance and updates to meeting information, visit www.alliance-website.org