# Alliance for Clinical Trials In ONcology Summer 2011 Volume 1, No. 1

# **Alliance Elects Group Leaders**

At its first Board of Directors meeting held in Chicago, IL, on July 15, 2011, the Alliance for Clinical Trials in Oncology launched the newly formed cooperative group by ratifying its constitution, and electing and appointing more than 15 new leaders. These leaders will serve a three-year term during the transition, and consist of former members of three recently merged National Cancer Institute-funded cooperative groups: Cancer and Leukemia Group B/CALGB, North Central Cancer Treatment Group/NCCTG and American College of Surgeons Oncology Group/ACOSOG.

Dr. Monica M. Bertagnolli, former CALGB Group Chair since April 2010, was elected Group Chair to lead the Alliance, spearheading the merger of the three legacy groups. She currently serves as the Chief of Surgical Oncology at Dana-Farber Brigham and Women's Cancer Center and Professor of Surgery at Harvard Medical School, and is a noted clinical and translational researcher.

"I am proud to say that a generous spirit of cooperation and shared purpose has allowed us to come together in record time without hampering the ongoing work of our individual scientific and accrual teams," said Dr. Bertagnolli. "It takes a community to do the work that we do, and I am very grateful for the confidence this community has entrusted in me to move our new group forward."

The board also elected several board representatives to serve on the Executive Committee, listed on page 4. The Executive Committee is responsible for recommending to the Board of Directors, overall policy and direction, as well as Alliance priorities and activities. The Executive Committee is chaired by the Group Chair and includes the Vice Chair, Program Principal Investigators, and eight representatives elected from the voting members of the Board of Directors, including four Principal Investigators from academic institutions and four Principal Investigators from community member institutions.

In addition, the Alliance board approved the following senior leadership appointments.

- Alliance Vice Chair: Edith A. Perez, MD (Mayo Clinic)
- Principal Investigator and Director, Central Protocol Operations Program: Gini Fleming, MD (University of Chicago)
- Principal Investigator and Group Statistician: Daniel J. Sargent, PhD (Mayo Clinic)

- Principal Investigator and Director, Translational Research Program: Phillip G. Febbo, MD (University of California, San Francisco)
- Principal Investigator and Director, Cancer Control, Prevention and Health Outcomes Program: Jan C. Buckner, MD (Mayo Clinic)
- Principal Investigator and Director, American College of Surgeons Clinical Research Program: Heidi Nelson, MD (Mayo Clinic)

### **Alliance Vision**

Under Dr. Bertagnolli's leadership, the vision of the Group is to reduce the impact of cancer by uniting a broad community of scientists and clinicians from many disciplines that are committed to discovering, validating and disseminating effective strategies for the prevention and treatment of cancer.

To accomplish this, the Alliance will be guided by a mission to conduct high-quality, multi-disciplinary cancer control, prevention and treatment trials that engage a comprehensive research network. It will continue to further an understanding of the biological basis of the cancer process and its treatment from discovery to validation to clinical practice. It will also provide a scientific and operational infrastructure for innovative clinical and translational research in academic and community settings.

The scientific committees will meet on September 16-17, 2011 in Chicago, to define the new group's scientific agenda. All members are invited to attend the first Alliance meeting, which will be held November 17-19, 2011 in Chicago. The Alliance will operate using an accrual-based institutional membership model. The Alliance transition is anticipated to be a three-year process, culminating in 2014 with the election of a new Alliance Group Chair to serve a full term of office.

**About the Merger** The merger of the CALGB, NCCTG and ACOSOG reflects the call in April 2010 from the Institute of Medicine to strengthen and streamline operations among NCI clinical trials cooperative group programs. In June 2010, CALGB, NCCTG and ACOSOG integrated their statistical, data management and information technology functions. In November 2010, NCI announced plans to transform the clinical trials system by reducing the number of adult cooperative groups from nine to four. Having already merged some functions, the three groups began evaluating the possibility of full integration to further streamline operations, expand their scientific research opportunities and apply for funding as a new integrated cooperative group.

# Alliance Structure

The Alliance structure is comprised of the Board of Directors, Executive Committee, Office of the Group Chair and five programs.

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			Committee Publications		Solid Tumor Correlative Sci		moun	alth Outcomes		Mentorship	
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## **Alliance Transition Board of Directors**

Maher Abbas, MD Steven Alberts, MD James Atkins, MD Nancy Bartlett, MD Robert Behrens, MD Clara Bloomfield, MD Judy Boughey, MD Daniel Budman, MD Harold Burstein, MD, PhD Jeffrey Crawford, MD Shaker Dakhil, MD Martin Edelman, MD Patrick Flynn, MD Stephen Graziano, MD Howard Gross, MD Stephen Grubbs, MD Clifford Hudis, MD Kelly Hunt, MD David Hurd. MD Anthony Jaslowski, MD Maged Khalil, MD Hedy Kindler, MD Jeffrey Kirshner, MD John Kugler, MD Rodney Landreneau, MD Marilyn Leitch, MD John Leonard, MD Ellis Levine, MD Minetta Liu, MD Alan Lyss, MD Benjamin Marchello, MD Miroslaw Mazurczak, MD Bryan Meyers, MD Rex Mowat, MD Daniel Nikcevich, MD John Olson, MD Barbara Parker, MD Michael Perry, MD Bruce Peterson, MD Mitchell Posner, MD Kendrith Rowland, MD Thomas Shea, MD Gamini Soori, MD Preston Steen, MD Phillip Stella, MD Gary Unzeitig, MD Donald Wender, MD Richard White, MD Edward Wos. MD Robin Zon, MD

Kaiser Permanente Los Angeles Mayo Clinic Southeast Cancer Control Consortium CCOP Washington University School of Medicine Iowa Oncology Research Association CCOP The Ohio State University Comprehensive Cancer Center Mavo Clinic North Shore University Hospital - LIJ CCOP Dana-Farber Cancer Institute Duke University Medical Center Wichita CCOP University of MD Greenebaum Cancer Center Metro-Minnesota CCOP SUNY Upstate Medical University Dayton CCOP Christiana Healthcare Services CCOP Memorial Sloan-Kettering Cancer Center MD Anderson Cancer Center Wake Forest University School of Medicine St. Vincent's CCOP, Green Bay Geisinger Medical Center CCOP University of Chicago Hematology Oncology Associates of Central New York CCOP llinois Oncology Research Association CCOP University of Pittsburgh UT Southwestern Medical Center Weill Cornell Medical College **Roswell Park Cancer Institute** Georgetown University Medical Center, Lombardi Cancer Center Heartland Cancer Research CCOP Montana Cancer Consortium CCOP Sanford - Sioux Falls Washington University School of Medicine Toledo Community Oncology Program CCOP Duluth Clinic CCOP Duke University Medical Center Moores University of California San Diego Cancer Center University of Missouri/Ellis Fischel Cancer Center University of Minnesota University of Chicago Carle Cancer Center CCOP University of North Carolina at Chapel Hill Missouri Valley Cancer Consortium CCOP Sanford Medical Center - Fargo Michigan Cancer Research Consortium CCOP Doctors Hospital of Laredo Siouxland Hemotology-Oncology Associates, LLP Carolinas Medical Center/Levine Cancer Institute Medcenter One Health Systems - Bismarck Northern Indiana Cancer Research Consortium CCOP

## **Alliance Executive Committee**

Monica Bertagnolli, MD – *Chair* Edith A. Perez, MD – *Vice Chair* Daniel J. Sargent, PhD – *PI & Group Statistician* Gini Fleming, MD – *PI & Director* Phillip G. Febbo. MD – *PI & Director* Jan C. Buckner, MD – *PI & Director* Heidi Nelson, MD – *PI & Director* Clara Bloomfield, MD Patrick Flynn, MD Stephen Grubbs, MD Clifford Hudis, MD Kelly Hunt, MD John Leonard, MD Philip Stella, MD Gary Unzeitig, MD Dana-Farber Brigham and Women's Cancer Center Mayo Clinic Statistics and Data Management Program Central Protocol Operations Program Translational Research Program Cancer Control, Prevention and Health Outcomes Program American College of Surgeons Clinical Research Program The Ohio State University Metro-Minnesota CCOP Christiana Healthcare Services CCOP Memorial Sloan-Kettering Cancer Center MD Anderson Cancer Center Weill Cornell Medical College Michigan Cancer Research Consortium CCOP Doctors Hospital of Laredo

# Alliance Committee Chairs

## Office of the Group Chair

Breast

Gastrointestinal Genitourinary Leukemia Lymphoma Myeloma Neuro-Oncology Respiratory Clinical Research Associates Experimental Therapeutics Oncology Nursing

Radiation Oncology Transplant

## Cancer Control, Prevention and Health Outcomes Research Program

Cancer in the Elderly

Community Oncology

Comparative Effectiveness Research Health Disparities Health Outcomes

Prevention Symptom Intervention

#### **Translational Research Program**

ImagingLarry Schwartz, MDLeukemia Correlative SciencesGuido Marcucci, MDPathologyEric Hsi, MDPharmacogenomics and Population PharmacologyMark Ratain, MD\*All other committee chairs are in the process of being appointed.

Eric Winer, MD Alan Venook, MD Eric Small, MD Richard Stone, MD Bruce Cheson, MD Paul Richardson, MD Evanthia Galanis, MD Everett Vokes, MD Kandie Dempsey, MS, RN Charles Erlichmann, MD Lisa Kottschade, MSN, RN Ellen Lavoie Smith, PhD Jeffrey Bogart, MD Steven Devine, MD

Clifford Hudis, MD

Hyman Muss, MD Harvey Cohen, MD Jeffrey Kirshner, MD Daniel Nikcevich, MD Walter Peters, MD Deborah Schrag, MD, MPH Electra Paskett, PhD Jeffrey Sloan, MD Ethan Basch, MD James Marshall, MD Charles Loprinzi, MD



## 'Time Flies When You're Having Fun!'

A Closer Look at the Alliance Statistics and Data Center

By Daniel J. Sargent, PhD Alliance Group Statistician

They say, 'Time flies when you are having fun,' and I can only agree. This June marked one year since I was named Group Statistician of the CALGB, and now of the Alliance. In this short time, I have been incredibly impressed by both legacy CALGB Statistical Center faculty and staff as well as the legacy ACOSOG and NCCTG staff, who all remain totally dedicated to the many ongoing initiatives within our new Alliance.

The largest new initiative for the statistical center remains the implementation of Medidata RAVE®. This advance, which will upgrade the Alliance to a true state-of-the-art system, is requiring a revision of almost all aspects of data collection and management. ACOSOG Z4099 Phase III study of sublobar resection versus stereotactic body radiation therapy in high risk patients with stage I non-small cell lung cancer (NSCLC) is already open in RAVE, and the first CALGB study (CALGB 50901 A phase II trial of ofatumumab in previously untreated follicular non-Hodgkin's lymphoma (NHL)), opened July 15. As of early 2012, we plan that all new Alliance studies will open in the RAVE system.

The other major focus of effort within the statistical center is the ongoing project to integrate the systems and processes of three legacy groups (CALGB, ACOSOG and NC-CTG). A great deal of coordination is involved in such an undertaking, and we have had multiple face-to-face meetings between the Duke and Mayo staffs (including Duke staff coming to Minnesota in January – a true sign of dedication!) We are working through the nitty-gritty details of harmonizing policies and procedures, with the single purpose of creating the most efficient and effective polices for the new organization.

On the IT side, we have already come to several important decisions that are in the process of being implemented. It is targeted that by winter 2012, all new trials launched by the Alliance will use a single registration/randomization application, the protocol administrative information for all studies will be stored centrally in a single system, all study data will go into a single instance of RAVE, and the rosters for the three groups will be contained within a single database.

In addition, on April 5, 2011, we launched a major project to consolidate the physical hardware (computer servers) for all Alliance activities to a single center at the Mayo Clinic. This will have substantial functional and financial benefits to the Alliance. This is a major project that will take approximately 15 months to complete (ending June 30, 2012). The Alliance has created an open dialogue with the affected IT personnel at Duke and is committed to retaining these staff members through the completion of this project.

Within the biostatistics staff, we have completed our initial staffing model for the Alliance. As most disease committee leaders know, I have been meeting individually with committee chairs, co-chairs, and statistical faculty to understand the existing collaborations. The Alliance is blessed with a 'multitude of riches' in this regard, with expert statistical staff at multiple locations (Duke, Mayo Clinic, Ohio State and MD Anderson). I am committed to maintaining this irreplaceable expertise, while at the same time ensuring operations are consistently organized and managed and that existing productive relationships are maintained. The statistics faculty and staff at all four statistical center institutions are excited about the possibility of creating new collaborations and sharing their knowledge with new colleagues.

The next years will bring continued exciting changes, and we welcome input from all Alliance members as we work together to build the new statistics and data center. Thank you for everything you do to make our Group the success that it is, and for your continued patience and cooperation as we work through these transitions.

#### Alliance for Clinical Trials In ONcology

#### **ACTION NEWS**

ACTION NEWS is published by the Alliance for Clinical Trials in Oncology bi-monthly and distributed to the Group's active membership through the Alliance website (www.alliance-website.org) and by broadcast e-mail. ACTION NEWS reserves the right to make corrections, changes and deletions in submitted copy in conformity with the newsletter's editorial policies.

Forward all correspondence to Jamilah Owens, Alliance Communications Specialist, at jowens@uchicago.edu.

## 2011-2012 Alliance Meeting Dates

2011 Fall Committee Meetings\* September 16-17, 2011 Hyatt Regency O'Hare Rosemont, IL

2012 Spring Committee Meetings\* March 15-17, 2012 InterContinental Chicago O'Hare Rosemont, IL

2012 Fall Committee Meetings\* November 15-17, 2012 InterContinental Chicago O'Hare Rosemont, IL 2011 Fall Group Meeting November 17-19, 2011 InterContinental Chicago O'Hare Rosemont, IL

2012 Summer Group Meeting June 28-30, 2012 InterContinental Chicago O'Hare Rosemont, IL

For questions regarding Alliance meetings and travel information, please contact Katherine Faherty, Alliance Administrative and Meetings Coordinator, at 617-525-3022 or kefaherty@partners.org.

\*Closed meetings open to members of committees or invited guests.

#### Alliance for Clinical Trials in Oncology

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