

First Alliance Group Meeting - November 2011

The Alliance for Clinical Trials in Oncology will present its first annual Group meeting on November 17-19, 2011, in Chicago, IL. The plenary session will feature as keynote speaker, William R. Sellers, MD, Vice President and Global Head of NIBR Oncology Research at the Novartis Institute of Biomedical Research, Inc. Dr. Sellers will lecture on "The Genetic Basis for Cancer Therapeutics."

Other key education sessions will include the CRA Committee, CRA Continuing Education Session, Oncology Nursing Education Session, Cancer Control Education Session, Translational Research Program Open Session, the American College of Surgeons Clinical Research Program General Session, a poster session and dinner reception.

Online meeting registration is now open. A link has been posted on the Alliance web site (www.alliance-website.org). Meeting attendees should register for individual sessions as well as the overall meeting. Registration is required to attend the Group meeting. Meeting attendees will receive an e-mail confirmation once online registration has been successfully completed. Funded travelers will receive a separate e-mail detailing Alliance procedures from Katherine Faherty, Alliance Meetings and Administrative Coordinator.

A block of rooms has been reserved at the InterContinental Chicago O'Hare. Meeting attendees funded through the Alliance for Clinical Trials in Oncology should make room reservations through the online registration site. All other attendees will receive a web link to reserve a room at the Group rate in an e-mail confirmation. Please do not contact the hotel directly to make reservations. All guest rooms are available on a first come, first served basis. Once online registration opens, make sure to register early.

The Alliance Group Meeting schedule is currently available for download on the Alliance web site (www.alliance-website.org).

Legacy Group Trials Receive BIQSFP Funding

Two legacy Group (Cancer and Leukemia Group B/CALGB and American College of Surgeons Oncology Group/ACOSOG) trials have received funding through the National Cancer Institute's Biomarker, Imaging and Quality of Life Studies Funding Program (BIQSFP). The studies include CALGB 80803: A randomized phase II trial of PET scan-directed combined modality therapy in esophageal cancer, chaired by Karyn Goodman, MD, and ACOSOG Z11103: ALternate approaches for clinical stage II and III Estrogen Receptor positive breast cancer NeoAdjuvant TrEatment (ALTERNATE) study, chaired by Cynthia Ma, MD, PhD. Funding for CALGB 80803 will be used to support central radiology and pathology review. Funding for ACOSOG Z11103 will be used to support obtaining research biopsies and conducting immunohistochemical assays on those tissue specimens.

The BIQSFP is a funding mechanism and prioritization process, established by NCI's Clinical Trials Working Group (CTWG), for essential correlative studies and quality of life studies that are incorporated into the fundamental design of a clinical trial and are not currently supported by the U10 funding mechanism. It ensures that the most important, scientifically meritorious biomarker, imaging and quality of life studies or Cost-Effectiveness Analysis (CEA) can be initiated in a timely manner in association with appropriate clinical trials. These funded targeted biological studies, imaging and quality of life studies embedded in clinical trials have the potential to modify standard of practice.

New Alliance Appointments*

Office of the Group Chair

Constitution and Bylaws Committee

Chair – Roscoe Morton, MD, Medical Oncology & Hematology Associates

Ethics Committee

Chair – Jeffrey Peppercorn, MD, Duke University Medical Center

Institutional Performance Evaluation Committee

Chair – Ellis Levine, MD, Roswell Park Cancer Institute

Membership Committee

Chair – Daniel Nikceovich, MD, Saint Mary's Medical Center/Duluth Clinic Health System

Pharmacy Committee

Chair – Darryl Grendahl, RPh, Mayo Clinic Cancer Center

**Other appointments are currently underway.*

10 Ways to Assure Compliant Enrollment of Eligible Patients

#10 – Provide the most current institutional review board (IRB) approved consent form to the patient, being extremely mindful of any updates that are tagged as Rapid Release Amendments allowing expedited approval, *but* still requiring a local suspension to enrollment until the consent form is amended and IRB approved. (*Refer to Cancer Therapy Evaluation Program (CTEP) issued memorandum from March 20, 2008 and the Office for Human Research Protections (OHRP) memorandum dated September 29, 2008.*)

#9 – Review the protocol for clear distinction between required study companion protocols, embedded companions and optional companion studies.

#8 – Do not perform any “study-related only” tests or procedures prior to the patient signing an informed consent document. This includes the submission of any research samples taken during standard-of-care procedures.

#7 – Assure that the patient has signed your locally required Health Insurance Portability and Accountability Act (HIPAA) form to allow for protected health information (PHI) to be submitted to the study sponsored group for data analysis.

#6 – Complete any study required eligibility checklists, or create your own for each study to assure all requirements are met. Beginning with the “Exclusion criteria” section of the protocol can help save time when checking eligibility status.

#5 – Obtain source documentation for each eligibility requirement, including outside reports such as last pelvic exam, or long ago pathology reports. Remember that if the on-study form includes participant evaluation questions, for example possible ONJ issues, source documentation is needed to complete the form.

#4 – Obtain clear documentation of performance status at on-study needs, and do not leave only the descriptions of ADL's (activities of daily living), for assumption.

#3 – Provide clear documentation if the eligibility section of the protocol requires the patient to be counseled for birth control measures; this needs to be available for audit review.

#2 – Seek a “second look” review by another research staff person to double check all required elements, and assure all pre-study required tests are completed and on-study tissue and sample submissions are ready to ship.

#1 – Use the study provided Registration Worksheet to review all required dates and approvals for completion of on-line registration.