2013 General Membership Meeting
Summary Proceedings

The Association of American Cancer Institutes Clinical Research Initiative (AACI CRI) convened its fifth annual membership meeting July 11-12 in Chicago. The meeting's popularity continued to grow with 170 attendees this year, 74 percent higher than the inaugural general meeting in 2009. The meeting hosted clinical research leaders from 60 cancer centers who discussed a variety of issues related to the conduct of cancer clinical trials at the nation's cancer centers.

The goal of the AACI CRI annual meeting is to improve clinical trials management at cancer centers. To achieve this, the meeting provided opportunities for clinical trials administrative and medical directors and staff to share best practices – through networking and interactive learning – that can lead to the discovery of novel cures and effective treatments for patients with cancer. This year's meeting program was expanded to increase attendance of the cancer centers' clinical trials medical directors and associate directors for clinical research who are responsible for providing leadership of the centers' clinical research efforts.

After a welcome from AACI Director of Programs, Janie Hofacker, RN, MS, and AACI CRI Steering Committee Chair Tony Reid, MD, PhD, the meeting commenced with the National Cancer Institute's (NCI) Margaret Mooney, MD, Branch Chief of Clinical Investigations, making a presentation on "Clinical Research at the Nation's Cancer Centers: An NCI Perspective". She discussed the transformation of the former NCI Clinical Trials Cooperative Group Program into the NCI National Clinical Trials Network. Dr. Mooney's presentation was followed by a panel discussion entitled, "Cancer Center Experience Using the New Cancer Support Grant (CCSG) Guidelines". The panel was comprised of Linda Weiss, PhD, Director of the Office of Cancer Centers at NCI, Terri Matson, CCRP, Director of Clinical Operations at Hollings Cancer Center, Chad Ellis,

PhD, Deputy Director of Research Affairs at Yale Comprehensive Cancer Center and Brian Springer, MHA, Executive Vice Present at Roswell Park Cancer Institute. Dr. Weiss talked about the new CCSG guidelines while the presenters shared their center's particular experiences with completing and submitting competitive and noncompetitive CCSG renewals using the new guidelines.

The CCSG panel discussion was followed by a presentation on adapting clinical trials management under the Affordable Care Act, which will become effective in 2014, and its clinical trials provisions, delivered by Steven Stranne, MD, JD, a Shareholder at Polsinellie Shughart PC.

A presentation from CRI's Trial Metrics Special Interest Group featured Erin Williams, BA, MBA, Associate Director of Clinical Research Operations Administration at Simmons Comprehensive Cancer Center, Karen Braddy, a business analyst from the University of Colorado Cancer Center, and University of Michigan's Theresa Royce, BBA, CCRP, Clinical Trials Office Manager, and Mathew Innes, BSE, MBA, Clinical Trials Office IT Manager. The presenters defined particular staffing metrics -"Predictive Effort Model", "Actual Effort Tracking Model" or a hybrid of both - that are used at their centers, and how each method for tracking staff workloads benefited management and staff.

Vicki Keedy, MD, SCI, Assistant Professor of Medicine at Vanderbilt-Ingram Cancer Center, and Steve Weitman, MD, PhD, Director of the Institute for Drug Development at the University of Texas Health Science Center at San Antonio, talked about the roles and responsibilities of clinical trials office medical directors. They discussed challenges and successes of their positions, structures of various medical directors' roles, funding support for staff positions, investigator-initiated trials opportunities for growth and advancements, preparation of a five-year strategic plan, and how they manage investigator compliance and promote investigator and staff training.

As an alternative to traditional, single-agent registration studies, Food and Drug Administration officials are exploring "master trial" protocols to allow simultaneous studies of multiple targeted oncology therapies.

Presenter, Jeff Allen, PhD, Executive Director of Friends of Cancer Research, discussed the design and implementation of a disease specific master protocol using a multi-arm randomized, controlled phase II/III master registration protocol to treat advanced stage squamous cell carcinoma. Michelle Rohrer, PhD, Vice President of US Regulatory Affairs for Genentech Roche, discussed the definition and benefits of the FDA's Breakthrough Therapy. She also presented data on the number of Breakthrough Therapy designations since October 1, 2012, and the number granted by the FDA.

A presentation entitled, "The Speeding up the Drug Discovery Process: Facilitating the Study Execution Process" consisted of several panelists describing the initiatives of several cancer-focused organizations aimed at accelerating the drug development process. Phil Porter, JD, Of Counsel at Northern Virginia, Hogan Lovells, and Sheila Prindiville, MD, MPH, Director of Coordinating Center for Clinical Trials at NCI, discussed the rationale, purpose and design of the START Clause Project. The project is supported by the CEO Roundtable on Cancer, NCI, and several cancer center directors who developed a common contracting template to speed up contract negotiations at the cancer centers. Jacalyn Kent, Director of Clinical Trial: Materials, Implementation and Transformation, at Eli Lilly and Company, discussed the mission and goals of TransCelerate and the progress of five initiatives that have been developed. Todd Rice, MD, MSCI, Assistant Professor of Medicine at Vanderbilt University School of Medicine, Marjorie Speers, PhD, President and CEO at the Association for the Accreditation of Human Research Protection Program, Inc., Jeffrey Cooper, MD, MMM, Vice President Global Consulting at WIRB-Copernicus Group and Jacquelyn L. Goldberg, JD, Head of the NCI Central Institutional Review Board, discussed streamlining the Institutional Review Board (IRB) review process. Their discussion focused on new approaches to shrinking the IRB review timeline while still meeting accreditation standards and regulatory requirements.

Abstract Presentations

AACI received 26 abstract submissions for the meeting. The CRI Steering Committee selected three of the

best abstracts for presentation and up to two authors of each winning abstract received complimentary meeting registration. In addition, 12 posters of abstract submissions were displayed at the meeting. All of the concepts submitted demonstrated creative and thoughtful methods of addressing clinical trial process issues. The abstracts focused on oncology research that illuminates clinical research management challenges and solutions. The winning abstracts were presented by the authors listed below. Congratulations to the winning authors and thank you to everyone who participated. (Please see the AACI CRI website at http://www.aaci-cancer.org/cri/crimeeting/abstracts.asp for a complete list of abstract authors.)

The winning abstracts were:

First Place: "Quality Improvement Initiative to Enhance Regulatory Compliance and Reduce Submission Errors Utilizing an Optimal Outcome Procedure System (OOPS)", Julie Haney; RN; MSL; CCRC and Virginia Doran; MLT; BS; MBA; CCRP, Roswell Park Cancer Institute

Second Place: "Accounts Receivable Management of Commercially Sponsored Clinical Trials", Joanne Brechlin, MBA, MPH; Meaghan Stirn, MBA; Moores UC San Diego Cancer Center, Clinical Trials Office

Third Place: "Using the FDA Electronic Submission Gateway for IND Applications at an Academic Cancer Center", Boris Brezen, PhD; Lee Doherty, Ed.M., Stanford Cancer Institute, Cancer Clinical Trials Office

This year's breakout sessions and subsequent "report backs" focused on nine topics:

- Trial Budgeting (led by Terri Matson, CCRP, Hollings Cancer Center and Nick Fisher, Siteman Cancer Center).

-IRB and Regulatory (led by Linda Beekman, RN, MBA, University of Michigan Comprehensive Cancer Center and Renee Webb, Robert H. Lurie Comprehensive Cancer Center).

-Structure and Roles at Clinical Trials Offices (led by Tony Reid, MD, PhD, UCSD Moores Cancer Center).

-Data Management (led by Melissa Nashawati, MPA, University of Texas Health Science Center at San Antonio and Lee Doherty, EdM, Stanford Cancer Institute).

-Monitoring and Auditing (led by Joy Ostroff, RN, BSN, OCN, UNC Lineberger Comprehensive Cancer Center and Sherrie Reynolds, RN, BSN, CCRP, Seidman Cancer Center at University Hospitals Case Medical Center).

-Medicare Coverage Analysis (led by Kelly Willenberg, MBA, BSN, CRC, CHRC, Kelly Willenberg, LLC).

-Changes to CCSG and Organizational Impact (led by Terri Stewart, University of New Mexico Cancer Center and Rhoda Arzoomanian, BSN, RN, MSM, UW Carbone Cancer Center).

-Industry Interactions (led by Elizabeth Anderson, MPH, BSN, Knight Cancer Institute Oregon Health and Science University and Kerry Bridges, MBA, RN, CCRC, Indiana University Simon Cancer Center).

-Education Programs (led by Miriam Bischoff, MBA, Stanford Cancer Institutes and Alyssa Gateman, MPH, CCRP, Dana-Farber/Harvard Cancer Center).

Many meeting attendees reported that the breakout session discussions were beneficial because they illuminated what other clinical trials leaders are doing to facilitate the clinical trials process. Attendees also reported that the sessions provided networking opportunities and fostered continued dialogue continues beyond the sessions. Please feel free to contact Amy Charley by email at amy@aaci-cancer.org or by phone at 412-802-6774 if you would like additional information on any presentation, abstract or poster that was presented at the 2013 meeting.

Post-meeting feedback from attendees was positive and affirmed the progress made by CRI over the past year as well as continued interest in the forum. AACI leadership will continue to fine tune the activities of the CRI SIGs to address current and emerging clinical research challenges and to identify best practices that enhance the drug discovery process, leading to treatments and a cure for cancer.