2014 AACI CRI Meeting Summary Proceedings

The Association of American Cancer Institutes (AACI) Clinical Research Initiative (CRI) convened its sixth annual membership meeting July 9-11 in Chicago. The meeting's popularity continues to grow and the meeting program was expanded an additional half day this year to allow separate meeting session tracks for clinical trials medical directors and administrative directors. The meeting hosted 189 clinical research leaders from 59 cancer centers who discussed a variety of issues related to the conduct of cancer clinical trials at the nation's cancer centers.

This year's meeting focused on precision oncology and its impact on clinical research at the nation's cancer centers. Attendees learned how cancer centers manage the challenges of activating new clinical trial designs that require centers to become "research ready" sites. 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 for patients with cancer.

After a welcome from AACI Director of Programs, Janie Hofacker, RN, MS, and AACI CRI Steering Committee Chair, Tony Reid, MD, PhD, Director of Early Phases Clinical Research at UC San Diego Moores Cancer Center, the meeting commenced with a keynote presentation from Razelle Kurzrock, MD, FACP, Senior Deputy Center Director at UC San Diego Moores Cancer Center. Dr. Kurzrock discussed the genesis of precision oncology and its impact on cancer care and clinical trial design in her presentation, "Precision Oncology: Next-Generation Sequencing and its Impact on Clinical Trials". She described the phase 1 clinical trial program at Moores Cancer Center's which uses a master protocol titled PREDICT (Profile-Related Evidence Determining Individualized Cancer Therapy) which utilizes molecular technologies to match patients with targeted cancer treatment that optimizes chances for response. Dr. Kurzrock, a working group chair for AACI's Molecular Diagnostics Initiative (MDI), informed meeting attendees about the progress of MDI which is focused on addressing numerous obstacles impeding the implementation of comprehensive molecular diagnostics at cancer centers.

The keynote presentation was followed by a panel comprised of clinical trial leaders and pharmaceutical representatives titled, “Precision Oncology: Exploring the New Wave of Clinical Trials”. Moderator, Steve Weitman, MD, PhD, Director of the Institute for Drug Development at Cancer Therapy and Research Center at the University of Texas Health Science Center, lead the panel into a lively discussion about targeted clinical trials that accommodates fewer patients and the difficulties the pharmaceutical industry sponsors and investigators face when designing and activating efficient and cost-effective trials. August Salvado, MD, Vice President of Early Development, Strategy and Innovation at Novartis Oncology, gave an overview of Novartis’ Signature Trial Program. The Signature Program addresses many challenges associated with targeted clinical trials by changing the traditional clinical paradigm by bringing the protocol to the patient through the identification of certain genetic mutations. It is a patient-triggered, target-specific and tissue-agnostic clinical trial program that aims to prepare centers to become research- ready sites that are able to provide targeted therapies to cancer patients. Matthew Wiener, PharmD, from Pharmatech, Inc. provided an overview of Pharmatech’s Just-In-Time enrollment model. The Just-In-Time enrollment model is a patient-centric research network that pre-identifies patients based on standard of care procedures without the sponsor incurring the cost of opening multiple non-accruing sites. Sites are opened when the first patient has been pre-identified. Once a patient is pre-identified, site IRB approval is obtained (within 72 hours) and the patient is dosed within 10 days (on average). Elizabeth Anderson, MPH, BSN, Director of the Clinical Trials Office at Knight Cancer Institute Oregon Health and Science University and Ashlee Drawz, CCRC, Research Supervisor at Northwestern University, discussed their centers’ experiences and best practices for addressing the challenges when working with the Signature Program and becoming research-ready sites.

AACI President-Elect George Weiner, MD, Director of the Holden Comprehensive Cancer Center moderated a discussion on the financial, logistical and ethical ramifications of precision oncology with panelists Lee Newcomer, MD, MHA, Senior Vice President at United Healthcare and Wendy Selig, President and CEO of Melanoma Research Alliance. The panelist discussed the communication needed to satisfy payers’ questions about the value of precision oncology along with how to communicate the benefits and risks to patients who provide specimen and data for molecular testing.

Clinical trials office medical directors who attended the meeting participated in a small group discussion moderated by Dr. Tony Reid that focused on physician effort allocation models and ASCO’s cancer quality initiatives that intersect with clinical research initiatives. Dr. Randall Holcombe, MD, Director of Clinical Cancer Affairs at Mount Sinai Medical Center and Deputy Director at the Tisch Cancer Institute,

began the session by focusing on several physician compensation approaches and how incentive plans can be applied to clinical research. Dr. Richard Schilsky, MD, FASCO, Chief Medical Officer at ASCO explained CancerLinQ, a health information technology platform that aims to create a national system capable of collecting the EMR data from every single medical oncology encounter in the country. Currently, CancerLinQ addresses risk stratification, matches patients for clinical trials, moves precision medicine into the community and re-engineers clinical research.

"Death by Start-Up: Clinical Trials Activation Challenges" was an interesting meeting session that focused on cancer center clinical trial challenges. Meeting presenters addressed ways centers are working to shorten clinical trials activation timelines. Vicki L. Keedy, MD, MSCI, Assistant Medical Director, Clinical Trials Shared Resource at the Vanderbilt-Ingram Cancer Center, explained how the increase in trial complexity has created the need to utilize additional institution ancillary services such as dermatology and eye examinations. However, the ancillary services are unable to examine subjects within the protocol time requirements which results in a delay of trial activation. To address this issue, Vanderbilt-Ingram Cancer Center developed a Clinical Research Implementation Committee (CRIC) comprised of members representing the institution's ancillary services, trial finance and clinical areas. CRIC reviews trials and addresses concerns in advance of trials being submitted to the institutions' regulatory review committees. As a result, trial activation is no longer impacted. Steve Weitman, MD, PhD, Director of the Institute for Drug Development at the Cancer Therapy and Research Center at the University of Texas Health Science Center, discussed how complex protocols require more biopsies and blood sample collections and include the involvement of more trial sites. On several occasions, sponsors did not inform the University of Texas Health Science Center of limited trial accrual potential which resulted in trials either being delayed or closed before patient accrual was complete. Suggested solutions included a team approach between the sponsor and trial site. This ensures that both agree on the reimbursement of reasonable trial start-up costs, that at least one slot is available to each site and that an early study termination fee is included in the trial contract. Erin Williams, MBA, Associate Director, CRO Administration, Simmons Cancer Center UT Southwestern Medical Center, provided a presentation showing how trial fees charged by an institution's ancillary departments has risen over the last five years and has resulted in stalled budget negotiations. To address this issue, institutions are seeking cancer center assistance with financing federally funded grant trials, are working with leadership at all levels to address financial concerns, asking institutional departments to provide adjusted fee schedules, and are looking at other sources of revenue and funding to continue to provide financial assistance to support the clinical trial office (CTO).

Paul Barr, Assistant Professor of Medicine and Oncology, Wilmot Cancer Institute at the University of Rochester Medical Center, moderated the "Return on Investments in Clinical Research" session. The session provided an opportunity for presenters to share practices for earning a positive return on investments in high-quality complex clinical research trials. Collette M. Houston, Executive Director, Clinical Research, Memorial Sloan Kettering (MSK), presented efficiency and workflow improvements at MSK. The improvements have resulted in a reduction in protocol activation time, standardization of clinical research budgeting processes, optimizing patient wait time, tracking of staff time and effort, and an enhancement to the overall quality of protocol and consent form documents. Kirsten Erickson, MPH, PhD, Senior Director, Clinical Trials Office, University of Kansas Cancer Center, provided a presentation on financing clinical trial offices. She explained the intense financial pressure CTOs are under and the importance of defining target subsidy rates. Michael K Benedict, PharmD, Associate Center Director for Administration, Georgia Regents University Cancer Center, discussed how industry research trials increase the challenges for the CTO because of business mergers, the burdens of site monitoring, and differing data collection practices. To mitigate the impact on the CTO bottom line, Dr. Benedict recommended that meeting attendees understand research rules and regulations, educate industry partners, and listen to coordinators about CTO challenges and solutions.

Another important session, "Managing the Challenges of Performing Multi-Center Investigator Initiated Trials" discussed the challenges of activating and funding Investigator Initiated Trials (IIT) at centers which now require funding from multiple sources including institutions, the government, non-profit organizations, foundations and pharmaceutical companies. As these funding sources have decreased in recent years, centers must identify new IIT revenue streams. This session explored models presenters are using to fund, activate, and coordinate IITs while assuring patient safety, regulatory compliance and quality data collection. Dan Sullivan, MD, Associate Cancer Center Director, Clinical Sciences, Moffitt Cancer Center, moderated the session and introduced the challenges of activating IITs and the funding mechanism for NCI N01 Contract for Phase 2 IIT Studies. Patricia LoRusso, DO, Director, Eisenberg Center for Translational Therapeutics at the Karmanos Cancer Institute, discussed her experiences with working with NCI UM1 Grant Mechanism for funding and implementing Phase 1 Trials. Matthew Milowsky, MD, Associate Professor of Medicine, UNC Lineberger Comprehensive Cancer Center presented his experiences with designing and implementing pharmaceutical company supported ITTs while Joy Ostroff, RN, BSN, OCN, Administrative Director for the UNC Lineberger Comprehensive Cancer

Center, provided an overview of the roles and responsibilities of the lead site when working with multi-center trials.

A CTO leader session, **"**Using the New Cancer Center Support Grant (CCSG) Guidelines for Clinical Research and the Clinical Trials Office", was moderated by Rhoda Arzoomanian, BSN, RN, MSM, Associate Director, Clinical Investigation Associate Director for the Yale Cancer Center, Yale University School of Medicine. Terri Matson, Administrative Director, Clinical Trials Office at the Hollings Cancer Center, Medical University of South Carolina and Gina Varner, MPH, Senior Clinical Research Data Manager at the UC San Diego Moores Cancer Center, shared their experiences with completing and submitting competitive and noncompetitive NCI CCSG renewals using the new CCSG guidelines as well as lessons learned from the feedback received from their NCI CCSG site visit teams. A helpful Q&A session followed the presentations.

On the third day of the meeting, Dr. Paul Martin, MD, UW School of Medicine, Medical Director Fred Hutchinson Cancer Research Center, moderated the session, "Speeding Up the Drug Discovery Process: Facilitating Study Execution." Jacalyn M. Kent, Senior Director, Clinical Development Information & Optimization, TransCelerate Investigator, Platform Leader Eli Lilly and Company, discussed the national efforts underway to accelerate the activation of pharmaceutical trials such as the initiatives developed by TransCelerate BioPharma Inc., aimed at making the clinical trial process more efficient. Nick Fisher, Director of Clinical Research at the Siteman Cancer Center of the Barnes-Jewish Hospital at Washington University School of Medicine, updated meeting attendees on the progress of the AACI Corporate Roundtable project where cancer center clinical trial and pharmaceutical company leaders are discussing ways to be more transparent when working together to advance the activation of industry sponsored trials. Kimberly Irvine, Executive Vice President and Chief Operating Officer, Biomedical Research Alliance of New York (BRANY), discussed how BRANY works with cancer centers to simplify clinical research approvals and to provide site management to the centers for all types trials.

The "NCI Clinical Trials Network Update" session was moderated by Claire Verschraegen, MD, MS, Director, Hematology/Oncology Division and Department of Medicine at the Vermont Cancer Center, and provided meeting attendees with an update on the transformation of the former NCI Clinical Trials Cooperative Group Program into the NCI National Clinical Trials Network. Margaret Mooney, MD, Chief, Clinical Investigations Branch of the Cancer Therapy Evaluation Program and Division of Cancer

Treatment and Diagnosis at the National Cancer Institute, explained the transformed system and funding mechanism, while Miriam Bischoff, MS, MBA, Executive Administrative Director, Clinical Research of the Stanford Cancer Institute, presented a cancer center perspective and the best practices Stanford Cancer Institute has put into place to operationalize working with the new trials network.

Abstract Presentations

AACI received 24 abstract submissions for the meeting. The CRI meeting abstracts focused on oncology research that illuminates clinical research management challenges and solutions. The CRI Steering Committee selected three of the best abstracts for presentation and two authors of each winning abstract received complimentary meeting registration. In addition, 18 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 winning abstracts were presented by the authors listed below. To review all AACI CRI meeting abstracts please go to http://www.aaci-cancer.org/cri/crimeeting/abstracts.asp

The winning abstracts were:

First Place

Title: "Improving Clinical Trial Activation Efficiency Through Technology, Systems Integrations and Analytics"

Authors: Joe Lengfellner; Ann Rodavitch; Collette Houston; Joe Larkin; Paul Sabbatini, MD; Sarah Wise

Cancer Center: Memorial Sloan Kettering Cancer Center

Second Place

Title: "Tumor Imaging Metrics Manager: The Complete Workflow Solution for Quantitative Imaging Assessment of Tumor Response for Oncology Clinical Trials"

Authors: Richard A. Bronen; Trinity Urban; Kimberly Hall; William B. Hanlon; Annick D. Van den Abbeele; Gordon J. Harris

Cancer Center: Dana-Farber/Harvard Cancer Center and Yale Cancer Center

Third Place

Title: Less Is More: Specializing Regulatory Responsibilities to Decrease Time to IRB Approval

Authors: Chloe Fournier and Nick Fisher

Cancer Center: Siteman Cancer Center

Breakout Sessions

AACI provided nine breakout sessions that focused on national clinical trial challenges and solutions. The breakout sessions provided opportunities for meeting attendees to share best practices which can ultimately lead to the discovery of novel cures and effective treatments for patients with cancer.

1.) "The Financial Implications of Trials with Large Screen Failures." co-lead by Nick Fisher, MBA, Siteman Cancer Center and Meaghan Stirn, MBA, UC San Diego Moores Cancer Center
2.) "Designing a Trial Portfolio to Address Screen Failures." co-lead by Dr. Randall F. Holcombe and Dr. Tony Reid,
3.) "Creating and Managing an IT Infrastructure for Precision Oncology Trials." led by Sorena Nadaf, MS, MMI, UCSF Helen Diller Family Comprehensive Cancer Center
4.) "Review of Clinical Trial Data Management Tools and Standards to Facilitate Accurate and Timely Data Capture." co-lead by Lee Doherty, EdM, Stanford Cancer Institute and Melissa Nashawati, MPA, Cancer Therapy and Research Center at the University of Texas Health Science Center
5.) "Using a Risk-Based Approach to Establishing Institutional Risk for Implementation of Trial Monitoring and/or Trial Auditing: How to Get Started and What are the Differences?" co- lead by Alyssa K. Gateman, MPH, CCRP, Yale Center for Clinical Investigation and Sarah McNees, PhD, CCRP, The Dan L. Duncan Cancer Center at Baylor College of Medicine
6.) "Learning More about Tools Available for Facilitating Site Pre-Qualification When Conducting Multi-Center Trials" co-lead by Joy Ostroff, RN, BSN, OCN and Kirstin Potter, MS, CCRP, Indiana University Simon Cancer Center
7.) "Managing the Challenges of Clinical Trial Implementation: Keeping Everyone on the Same Page." co-lead by Kerry Bridges, MBA, RN, CCRC, Simon Cancer Center and Terri Matson, CCRP
8.) "Addressing the Challenges of Centralizing Clinical Oncology Disease Programs." co-lead by Miriam Bischoff, Stanford Cancer Institute and Erin Williams, MBA
9.) "Unlocking the Mysteries of the CCSG to Highlight Your Center's Clinical Research Activities.: co-lead by Rhoda Arzoomanian, BSN, RN, MSM and Terri Stewart, MS, CCRP, University of New Mexico Cancer Center

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 working groups to address current and emerging clinical research challenges. Please feel free to contact AACI Program Coordinator, 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 2014 meeting.