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AACI CRI Welcome

The goal of the AACI CRI annual meeting is to improve clinical trials management at cancer centers. To achieve this, the meeting provides 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 cures and treatments for patients with cancer.

This year's meeting will focus on "Precision Oncology" and its impact on clinical research at the nation's cancer centers. Attendees will learn how cancer centers are managing the challenges of activating new trial designs that call for trial sites to be "research ready" when they identify cancer patients with unique tumor profiles requiring targeted investigational agents.

The meeting program has been extended an additional half day to allow separate meeting session tracks for both clinical trials medical directors and administrative directors.

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AACI CRI Meeting Objectives

1. Identify cancer center concerns about precision oncology as it relates to clinical research and clinical trial design.

2. Highlight strategies for disseminating information about oncology research process improvement and best practices to expedite trial activation.

3. Explore innovative trial designs and development of a trial portfolio for all cancer tumors.

4. Discuss changes in the National Cancer Institute (NCI) National Clinical Trials Network and the NCI Cancer Center Support Grant guidelines.

5. Analyze trends and best practices in clinical trial safety and compliance.

6. Support peer-to-peer networking and collaboration among clinical trial administrators and medical directors.

7. Recommend policies to promote staff retention, job satisfaction, diversity and stability for the cancer center clinical research workforce.

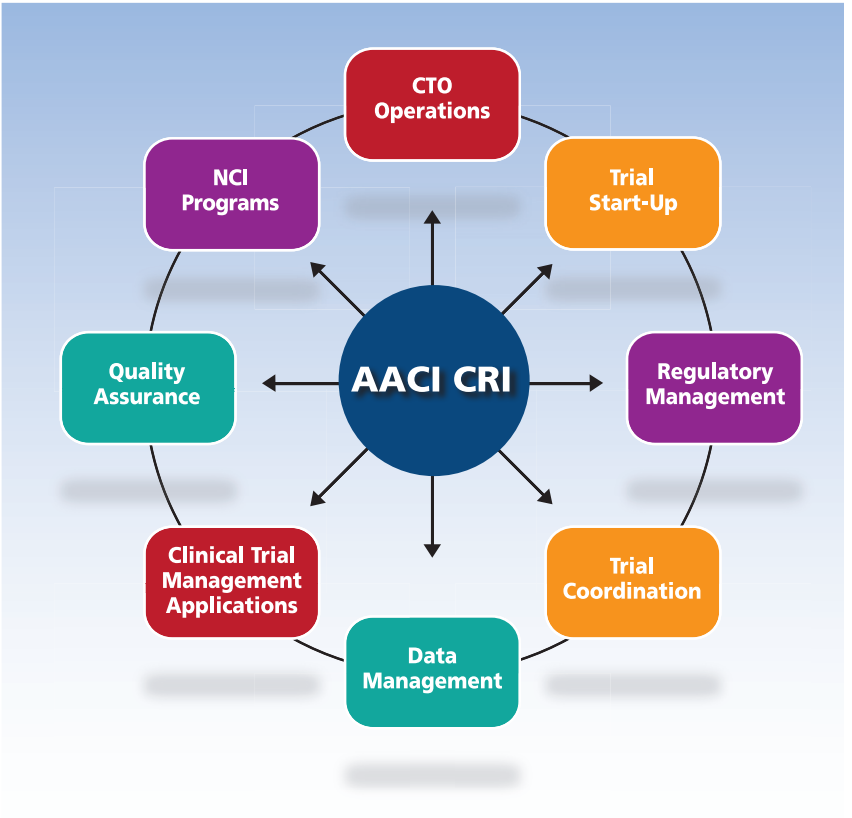
8. Develop investigator and clinical research staff training programs to facilitate clinical research compliance.

9. Promote partnerships with like-minded organizations to enhance the clinical research process and analyze the development of new cancer therapies.

Without the continued launching and successful completion of effective clinical trials, progress in the fight against cancer will stall. We invite you to share your expertise and your center's solutions to the range of serious challenges that affect the conduct of clinical trials at AACI cancer centers.

AACI CRI Working Groups

CRI's Working Groups create and implement new tools for use across the AACI cancer center network. To date, eight working groups have been established to share best practices, promote the efficient operation of cancer center clinical research facilities, and leverage the ability of the AACI cancer center network to advocate for change in the national clinical trials enterprise.



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MEETING PROGRAM

Association of American Cancer Institutes
6th Annual Clinical Research Initiative Meeting

The Westin O'Hare, Chicago, Wednesday July 9 - Friday July 11

Wednesday, July 9

12:30 PM **Registration Begins — *East Foyer***

1:30 PM **Welcome and Introduction — *Grand A***

Janie Hofacker, RN, MS
Director of Programs
Association of American Cancer Institutes

Tony Reid, MD, PhD
Director, Early Phase Clinical Research
UC San Diego Moores Cancer Center

1:35 PM **Precision Oncology: Next-Generation Sequencing and its Impact on Clinical Trials — *Grand A***

The genomic revolution presents a host of challenges for cancer centers and clinical trial leaders. This session will focus on the genesis of precision oncology and its impact on cancer care and clinical trial design, where the molecular characteristics of a tumor play a critical role in guiding the selection of therapy. Participants will learn about the progress of the AACI's Molecular Diagnostics Initiative which addresses obstacles impeding the implementation of comprehensive molecular diagnostics at cancer centers, including the acquisition of appropriate tissues, development of mutation panels, selection of technology platforms and regulatory reimbursement policies.

Razelle Kurzrock, MD, FACP
Senior Deputy Center Director, Clinical Science
Director, Center for Personalized Cancer Therapy and Clinical Trials Office
UC San Diego Moores Cancer Center

2:35 PM **Precision Oncology: Exploring the New Wave of Clinical Trials — *Grand A***

Precision oncology involves a systematic assessment of a patient's cancer genomic information and can improve care by tailoring treatments for patients. It poses clinical trial design challenges because the standard clinical trial framework must be adapted to include genomic information. "Targeted" trials accommodate fewer patients, making

it difficult for pharmaceutical industry sponsors and investigators to design and activate efficient and cost-effective trials that meet a study's objectives. This session describes a new trial concept that aims to prepare centers to become "research ready" sites and position centers to provide targeted therapies to cancer patients.

Steve Weitman, MD, PhD (Moderator)
Director of the Institute for Drug Development
Cancer Therapy and Research Center at the
University of Texas Health Science Center

Elizabeth Anderson, MPH, BSN
Director, Clinical Trials Office
Knight Cancer Institute
Oregon Health and Science University

Ashlee Drawz
Research Supervisor
Northwestern Medicine Developmental Therapeutics Institute
Robert H. Lurie Comprehensive Cancer Center
Northwestern University

August Salvado, MD
Vice President of Early Development, Strategy and Innovation
Novartis Oncology

Matthew B. Wiener, PharmD
Founder and Chief Scientific Officer
Pharmatech Inc.

3:35 PM Charge for Breakouts — *Grand A*

Tony Reid, MD, PhD

3:40 PM Break

4:00 PM Concurrent Breakout Sessions: Personalized Medicine

1.) The Financial Implications of Trials with Large Screen Failures (Focus on Clinical Trials Office Directors) — *Grand A*

Nick Fisher, MBA (Breakout co-leader)
Director of Clinical Research
Siteman Cancer Center
Barnes-Jewish Hospital at Washington University School of Medicine

Meaghan Stirn, MBA (Breakout co-leader)
Interim Assistant Director
Clinical Investigations Program
UC San Diego Moores Cancer Center

2.) Designing a Trial Portfolio to Address Screen Failures (Focus on Clinical Trials Office Medical Directors) — *Lakeshore A*

Randall F. Holcombe, MD (Breakout co-leader)
Director, Clinical Cancer Affairs, Mount Sinai Medical Center
Deputy Director, Tisch Cancer Institute

Tony Reid, MD, PhD (Breakout co-leader)

3. Creating and Managing an IT Infrastructure for Precision Oncology Trials — *Lakeshore B*

Sorena Nadaf, MS, MMI (Breakout leader)
Associate Director, Chief Information and Informatics Officer
UCSF Helen Diller Family Comprehensive Cancer Center

5:00 PM Adjourn

6:00 PM Welcome Reception and Cancer Center Poster Session — *Grand B*

Cancer center members who have submitted abstracts to the CRI Steering Committee for review will present posters at this year's meeting and will provide an overview of the solutions implemented to address challenges at their cancer centers. Everyone is invited to attend.

Thursday, July 10

7:00 AM Registration Opens — *East Foyer*

7:00 AM Breakfast — *Grand B*

8:00 AM Welcome — *Grand A*

Janie Hofacker, RN, MS
Tony Reid, MD, PhD

8:05 AM Report Backs for Day 1 Breakout Sessions — *Grand A*

The Financial Implications of Trials with Large Screen Failures (Focus on Clinical Trials Office Directors)

Nick Fisher, MBA (Breakout co-leader)
Meaghan Stirn, MBA (Breakout co-leader)

Designing a Trial Portfolio to Address Screen Failures (Focus on Clinical Trials Office Medical Directors)

Randall F. Holcombe, MD (Breakout co-leader)
Tony Reid, MD, PhD (Breakout co-leader)

Creating and Managing an IT Infrastructure for Precision Oncology Trials

Sorena Nadaf, MS, MMI (Breakout leader)

8:40 AM Return on Investments in Clinical Research — *Grand A*

Presenters will share cancer center best practices for earning a positive return on investments in high-quality clinical research trials.

Paul Barr, MD (Moderator)
Assistant Professor of Medicine and Oncology
Wilmot Cancer Institute
University of Rochester Medical Center

Michael K. Benedict, PharmD
Associate Center Director for Administration
Georgia Regents University Cancer Center

Kirsten Erickson, PhD, MPH
Senior Director, Clinical Research Office
University of Kansas Cancer Center

Collette M. Houston
Executive Director, Clinical Research Operations
Memorial Sloan-Kettering Cancer Center

9:25 AM Managing the Challenges of Performing Multi-Center Investigator Initiated Trials — *Grand A*

Investigator Initiated Trials (IITs) at cancer centers require funding from multiple sources including institutions, 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 will explore the models cancer centers are using to fund, activate, and coordinate IITs while assuring patient safety, regulatory compliance and quality data collection.

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Dan Sullivan, MD (Moderator)
Associate Cancer Center Director, Clinical Sciences
Moffitt Cancer Center

Patricia M. LoRusso, DO
Director of the Eisenberg Center for Translational Therapeutics
Karmanos Cancer Institute
Wayne State University

Matthew I. Milowsky, MD
Associate Professor of Medicine and Section Chief
Genitourinary Oncology Service
UNC Lineberger Comprehensive Cancer Center

Joy Ostroff, RN, BSN, OCN
Administrative Director
Clinical Research, UNC Cancer Network
UNC Lineberger Comprehensive Cancer Center

10:25 AM Break — *East Foyer*
Sponsored by Essex Management

10:40 AM Death by Start-Up: Clinical Trial Activation Challenges — *Grand A*

As cancer centers seek to shorten their clinical trial activation timelines, new institutional policies are being created that threaten trial activation start-up. Clinical trials require considerable institutional commitment and resources, including Institutional Review Board and radiology reviews, Medicare coverage determinations and various approvals that are costly, but necessary, for trial activation. As a result, hospital service providers and institutional review committees are seeking reimbursement alternatives. This session will explore how centers are addressing barriers to swift trial activation.

James P. Thomas, MD, PhD (Moderator)
Section Head, Solid Tumor Oncology, Director of Clinical Investigations
Medical College of Wisconsin Cancer Center

Vicki L. Keedy, MD, MSCI
Assistant Professor of Medicine
Clinical Director, Sarcoma Program
Assistant Medical Director, Clinical Trials Shared Resource
Vanderbilt-Ingram Cancer Center

Steve Weitman, MD, PhD

Erin Williams, MBA
Associate Director - CRO Administration
Simmons Comprehensive Cancer Center
University of Texas Southwestern Medical Center at Dallas

11:25 PM Abstract Presentations — *Grand A*

Abstracts from CRI members focus on oncology research that illuminates clinical research management challenges and solutions. The CRI Steering Committee selected three abstracts for presentation at this year's meeting. Each presentation will be ten minutes followed by a five-minute Q & A session.

Tony Reid, MD. PhD (Moderator)

Improving Clinical Trial Activation Efficiency through Technology, Systems Integrations and Analytics

Joe Lengfellner
Manager, Clinical Research Technology
Office of Clinical Research
Memorial Sloan-Kettering Cancer Center

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

Richard A. Bronen, MD
Professor, Diagnostic Radiology and Neurosurgery
Yale University School of Medicine

Gordon Harris, PhD
Professor of Radiology, Harvard Medical School
Director, 3D Imaging Service, Massachusetts General Hospital
Director, Tumor Imaging Metrics Core
Dana-Farber/Harvard Cancer Center

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

Nick Fisher, MBA

Chloe C. Fournier, CCRP
Clinical Research Specialist, Regulatory Team
Siteman Cancer Center
Barnes-Jewish Hospital at Washington University School of Medicine

12:10 PM Lunch — *Grand B*
Sponsored by WIRB-Copernicus Group

1:10 PM Precision Oncology: Understanding the Value from a Payer, Provider and Patient Perspective — *Grand A*

The financial, logistical and ethical ramifications of precision oncology require effective models for communicating its benefits to providers, payers and patients. This panel will explore 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 specimens for molecular testing.

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George J. Weiner, MD (Moderator)
Director
Holden Comprehensive Cancer Center
University of Iowa

Lee Newcomer, MD, MHA
Senior Vice President, Oncology, Genetics and Women's Health
United HealthCare

Wendy K.D. Selig
President and CEO
Melanoma Research Alliance

2:10 PM Concurrent Sessions

Clinical Trials Office Leaders Track: Using the New Cancer Center Support Grant (CCSG) Guidelines for Clinical Research and the Clinical Trials Office *— Grand A*

Presenters will share 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 Q&A session will follow the presentations.

Rhoda Arzoomanian, BSN, RN, MSM (Moderator)
Associate Director, Yale Center for Clinical Investigation
Associate Director for the Yale Cancer Center
Yale University School of Medicine

David Gosky, MA, MBA
Director, Administration and Finance
Markey Cancer Center
University of Kentucky

Terri Matson
Administrative Director, Clinical Trials Office
Hollings Cancer Center
Medical University of South Carolina

Gina Varner, MPH
Senior Clinical Research Data Manager
UC San Diego Moores Cancer Center

Medical Directors Track: Physician Effort Allocation Models and How Cancer Quality Initiatives Intersect with Clinical Research Initiatives *— Lakeshore B*

Personalized cancer care can influence patients' treatment options and clinical trial selection, in part by creating "rare cancers" that can limit accrual for some clinical trials. In addition, with changes in physician reimbursement and reductions in government funding for research,

it is becoming more difficult to cover physician compensation and other physician expenses at academic cancer centers.

This session will focus on several approaches to physician compensation at cancer centers and will explore productivity benchmarks that affect clinical care quality and clinical trial participation. The session will also provide information from the American Society of Clinical Oncology aimed at helping physicians to design and conduct future trials.

Tony Reid, MD, PhD (Moderator)

Randall F. Holcombe, MD

Richard Schilsky, MD, FACP, FASCO
Chief Medical Officer
American Society of Clinical Oncology

3:10 PM Charge for Breakouts — Grand A

Tony Reid, MD, PhD

3:15 PM Break — *East Foyer*

3:30 PM Concurrent Breakout Sessions: Multi-Center Focus

1.) Review of Clinical Trial Data Management Tools and Standards to Facilitate Accurate and Timely Data Capture — *Grand A*

Lee Doherty, EdM (Breakout co-leader)
Regulatory Manager
Stanford Cancer Institute

Melissa Nashawati, MPA (Breakout co-leader)
Director of Quality Assurance for Research Administration
Cancer Therapy and Research Center at the
University of Texas Health Science Center

2.) 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? — *Lakeshore A*

Alyssa K. Gateman, MPH, CCRP (Breakout co-leader)
Assistant Director, Office of Quality Assurance and Training
Yale Center for Clinical Investigation

Sarah McNees, PhD, CCRP (Breakout co-leader)
Associate Director, Clinical Trials Support Unit
The Dan L. Duncan Cancer Center at Baylor College of Medicine

3.) Learning More about Tools for Facilitating Site Pre-Qualification When Conducting Multi-Center Trials — *Lakeshore B*

Joy Ostroff, RN, BSN, OCN (Breakout co-leader)

Kristin Potter, MS, CCRP (Breakout co-leader)
Affiliate Site Research Manager
Indiana University Melvin and Bren Simon Cancer Center

4:30 PM **Adjourn**

Friday, July 11

7:00 AM **Breakfast — *Grand B***

8:00 AM **Report Backs for Day 2 Breakout Sessions — *Grand A***

Review of Clinical Trials Data Management Tools and Standards to Facilitate Accurate and Timely Data Capture
Lee Doherty, EdM (Breakout co-leader)
Melissa Nashawati, MPA (Breakout co-leader)

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?
Alyssa K. Gateman, MPH, CCRP (Breakout co-leader)
Sarah McNees (Breakout co-leader)

Learning More about Tools for Facilitating Site Pre-Qualification When Conducting Multi-Center Trials
Joy Ostroff, RN, BSN, OCN (Breakout co-leader)
Kristin Potter, MS, CCRP (Breakout co-leader)

8:30 AM **Speeding Up the Drug Discovery Process: Facilitating Study Execution — *Grand A***

Presenters will discuss national efforts to accelerate pharmaceutical trials. TransCelerate BioPharma Inc., an umbrella group of 19 leading pharmaceutical companies aimed at making the clinical trial start up process more efficient, will give an update on its initiatives. An update on the progress of the AACI Corporate Roundtable project will be presented. Kimberly Irvine, Executive Vice President and Chief Operating Officer, Biomedical Research Alliance of New York (BRANY), will discuss how BRANY works with cancer centers to simplify clinical research approvals and site management of all trials.

Paul Martin, MD (Moderator)
UW School of Medicine, Medical Director
Fred Hutchinson Cancer Research Center

Nick Fisher, MBA

Sonja Halverson
Contracts and Fiscal Manager, Industry Sponsored Agreements
Fred Hutchinson Cancer Research Center

Kimberly Irvine, CIP, CIM
Executive Vice President and Chief Operating Officer
Biomedical Research Alliance of New York

Jacalyn M. Kent
Senior Director, Clinical Development Information & Optimization
TransCelerate Investigator Platform Leader
Eli Lilly and Company

Kristi Stiffler, MPH
Director, Clinical Research Support
Fred Hutchinson Cancer Research Center

9:30 AM NCI Clinical Trials Network Update — *Grand A*

Presenters will discuss the transformation of the former NCI Clinical Trials Cooperative Group Program into the NCI National Clinical Trials Network.

Claire Verschraegen, MD, MS (Moderator)
Professor of Medicine
Director, Hematology/Oncology Division
Department of Medicine
Vermont Cancer Center

Miriam Bischoff, MS, MBA
Executive Administrative Director, Clinical Research
Stanford Cancer Institute

Margaret Mooney, MD, MBA
Chief, Clinical Investigations Branch
Cancer Therapy Evaluation Program
Division of Cancer Treatment and Diagnosis
National Cancer Institute

10:15 AM Concurrent Breakout Sessions

1.) Managing the Challenges of Clinical Trial Implementation: Keeping Everyone on the Same Page — *Grand A*

Kerry Bridges, MBA, RN, CCRC (Breakout co-leader)
Administrator, Clinical Research Office
Indiana University Melvin and Bren Simon Cancer Center

Terri Matson, CCRP (Breakout co-leader)

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2.) **Addressing the Challenges of Centralizing Clinical Oncology Disease Programs — *Lakeshore A***

Miriam Bischoff, MS, MBA (Breakout co-leader)
Executive Administrative Director, Clinical Research
Stanford Cancer Institute

Erin Williams, MBA (Breakout co-leader)

3.) **Unlocking the Mysteries of the CCSG to Highlight Your Center's Clinical Research Activities — *Lakeshore B***

Rhoda Arzoomanian, BSN, RN, MSM (Breakout co-leader)

Terri Stewart, MS, CCRP (Breakout co-leader)
Director of the Clinical Trials Office
Executive Director of the New Mexico Cancer Care Alliance
University of New Mexico Cancer Center

11:15 PM Report Backs for Day 3 Breakout Sessions — *Grand A*

Managing the Challenges of Clinical Trial Implementation: Keeping Everyone on the Same Page
Kerry Bridges, MBA, RN, CCRC (Breakout co-leader)
Terri Matson, CCRP (Breakout co-leader)

Addressing the Challenges of Centralizing Clinical Oncology Disease Programs
Miriam Bischoff, MS, MBA (Breakout co-leader)
Erin Williams, MBA (Breakout co-leader)

Unlocking the Mysteries of the CCSG to Highlight Your Center's Clinical Research Activities
Rhoda Arzoomanian, BSN, RN, MSM (Breakout co-leader)
Terri Stewart, MS, CCRP (Breakout co-leader)

12:00 PM Adjourn

AACI Corporate Roundtable Members

AACI is grateful for the support of the 2014 corporate roundtable members:

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