AACI

Association of
American Cancer Institutes

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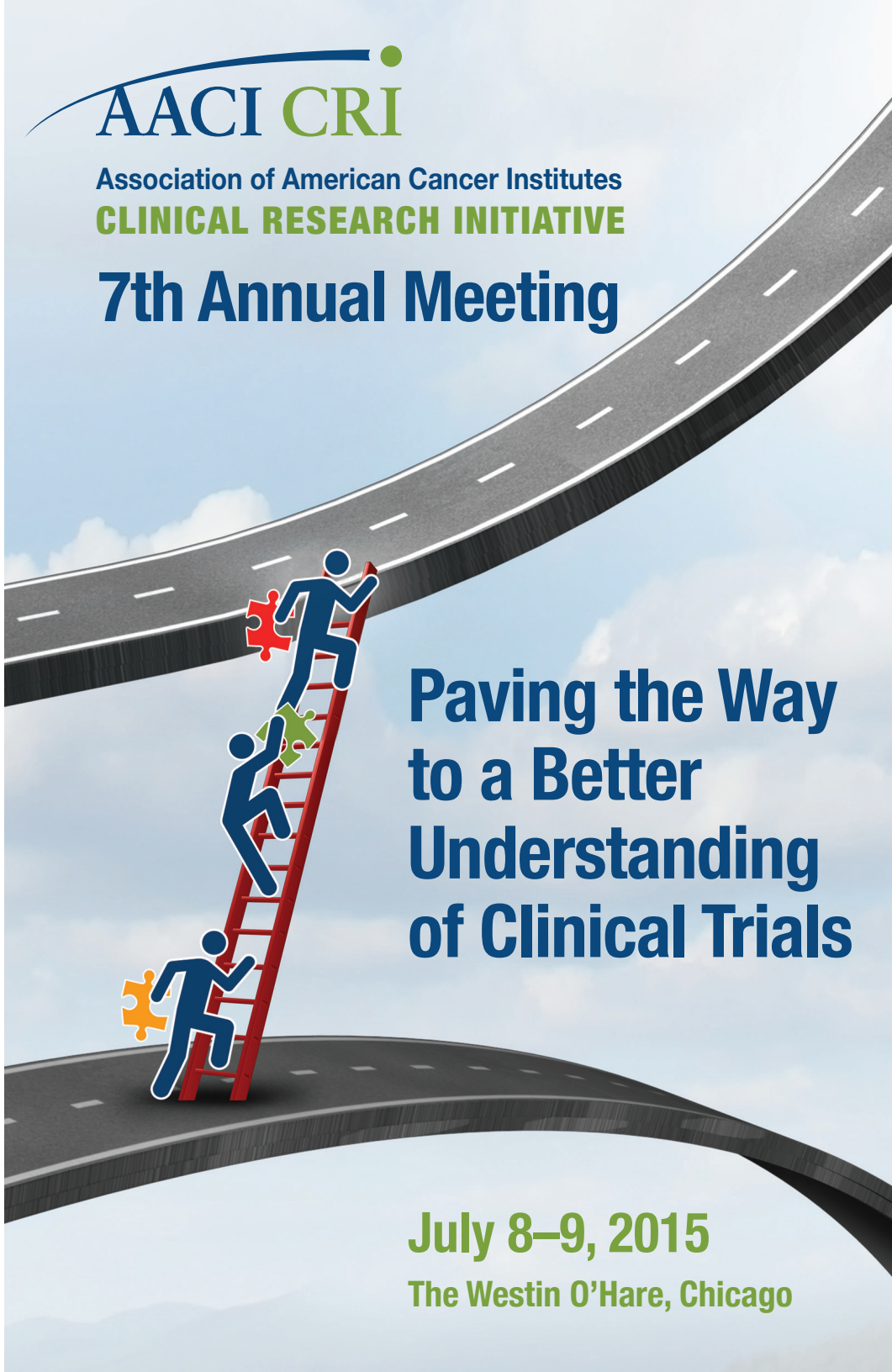
AACI CRI

Association of American Cancer Institutes
CLINICAL RESEARCH INITIATIVE

7th Annual Meeting



Paving the Way to a Better Understanding of Clinical Trials

July 8–9, 2015

The Westin O'Hare, Chicago

AACI CRI Welcome

As cancer research evolves, new approaches to treating patients are being developed via clinical trials. Clinical trials are becoming more complex with the integration of immunotherapies and targeted therapies. Multiple industry, government, and ad hoc groups focus on improving the clinical trials process and infrastructure. The goal of the AACI Clinical Research Initiative is to improve clinical trials management at cancer centers. To achieve this goal, the meeting provides opportunities for clinical trials office 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.

AACI CRI Meeting Objectives

Attendees should be able to:

1. Identify cancer center concerns about the clinical research process.

2. Identify strategies for disseminating information that support the development of oncology research process improvements and the formation of best practices.

3. Describe the impact of changes in the National Cancer Institute (NCI) clinical trials system and the NCI Cancer Center Support Grant guidelines.

4. Discuss trends and best practices in clinical trials safety and compliance.

5. Support peer-to-peer networking, collaboration and ongoing communications between clinical trials administrative and medical directors.

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

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

8. Promote partnerships with like-minded organizations, industry and business partners to facilitate the clinical research process and to increase the development of new cancer therapies.

9. Discuss the challenges of conducting clinical trials involving immunotherapies.

10. Understand the global impact of conducting clinical research in the US and abroad.

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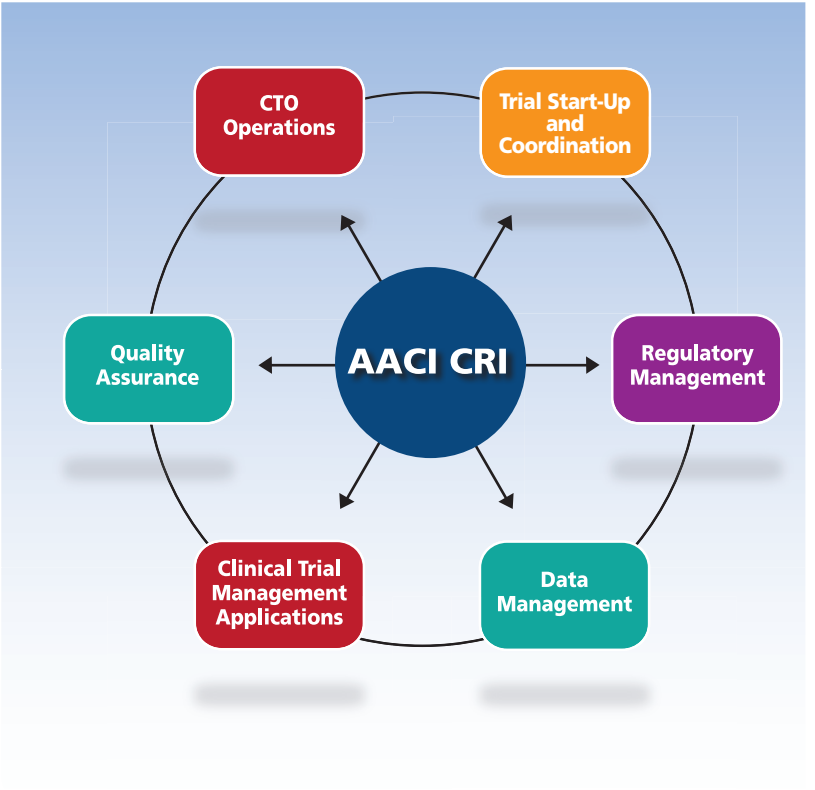
*The email login is **cri@aaci-cancer.org** and the password is **2015cri***

AACI CRI Working Groups

AACI CRI's Working Groups create and implement new tools for use across the AACI cancer center network. Currently, six 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.



MEETING PROGRAM

Association of American Cancer Institutes
7th Annual Clinical Research Initiative Meeting

The Westin O'Hare, Chicago

Wednesday, July 8

7:00 AM **Meeting Registration Begins – *East Foyer***

7:00 AM **Exhibits Open – *East Foyer***

7:00 AM **Continental Breakfast – *Grand Ballroom B***

8:00 AM **Welcome – *Grand Ballroom A***

Janie Hofacker, RN, BSN, MS
Association of American Cancer Institutes

Tony Reid, MD, PhD
UC San Diego Moores Cancer Center

8:15 AM **Immunotherapy and Cancer: Understanding the Challenges and Impact on the Clinical Trials Office – *Grand Ballroom A***

This session will focus on exciting advances made in treating cancer through the use of immunotherapy. Panelists will address the mechanisms for using immunotherapy in clinical trials, as well as the challenges that are faced when integrating immunotherapies into trials. Specific examples of trials incorporating these novel approaches will be presented.

Paul Martin, MD (Moderator)
Fred Hutchinson Cancer Research Center

Aude Chapuis, MD
Fred Hutchinson Cancer Research Center

Annick Desjardins, MD, FRCPC
Duke Cancer Institute
Duke University Medical Center

Jason Luke, MD, FACP
The University of Chicago Medicine Comprehensive Cancer Center

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9:30 AM Understanding How to Conduct "Basket" and "Umbrella" Trials – *Grand Ballroom A*

Panelists will present information about basket and umbrella trials. In basket studies, researchers test the effect of a single drug on a single mutation in a variety of cancer types, whereas in umbrella studies, the impact of different drugs on different mutations in a single type of cancer is tested. The Lung Cancer Master Protocol (Lung-MAP), ALCHEMIST (Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trials), and NCI Match Trial will be discussed during this session. Panelists will explain how basket and umbrella trials are effective in treating cancer and will discuss strategies to reduce the regulatory burden and patient accrual challenges in these types of trials. The role of the molecular tumor board will also be discussed.

Elizabeth Anderson, MPH, BSN (Moderator)
Knight Cancer Institute
Oregon Health and Science University

Dave Gerber, MD
Simmons Cancer Center
UT Southwestern Medical Center

Colleen Lewis, MSN, ANP-BC, AOCNP
Winship Cancer Institute
Emory University

Taofeek Owonikoko, MD, PhD, MSCR
Winship Cancer Institute
Emory University

Erin Williams, MBA
Simmons Cancer Center
UT Southwestern Medical Center

10:30 AM Break

10:45 AM How Do Cancer Centers Ensure Patient Safety When Conducting Clinical Trials? — *Grand Ballroom A*

Clinical trials are subject to a great deal of regulation and monitoring by independent committees and federal agencies to ensure studies are both safe and scientifically relevant. Institutional Review Boards (IRBs), Data Safety Monitoring Boards (DSMBs), and federal agencies all play a role in ensuring patient safety. Results of the Clinical Trials Transformation Initiative's (CTTI) Investigational New Drug Safety Advancement Project Survey will be presented and two cancer centers will share models for effectively following multiple guidelines to ensure patient safety while delivering novel therapies.

Vicki Keedy, MD, MSCI (Moderator)
Vanderbilt-Ingram Cancer Center

Annemarie Forrest, RN, MS, MPH
Clinical Trials Transformation Initiative (CTTI)

Collette Houston
Memorial Sloan Kettering Cancer Center

11:30 AM **2015 AACI CRI Abstract Presentations** ***— Grand Ballroom 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)

Cancer Center's Experience with Insurance Denials for Clinical Trial Participation after ACA Mandate

Christine Mackay, RN, MSA, CCRP
University of Kansas Cancer Center

Amanda Schwartz
American Society of Clinical Oncology (ASCO)

Leveraging AACI CRI Listserv Benchmarking and Technology to Reduce the Administrative Burden of Conducting Clinical Trials

Kate Huffman, RN, BSN, CCRA
University of Michigan Comprehensive Cancer Center

Protocol Information Management Systems (PIMS) Regulatory Binder: Streamlining Regulatory Binder Documentation Maintenance & Improving Compliance

Abdul Karim Abdullah
Memorial Sloan Kettering Cancer Center

Roy Cambria
Memorial Sloan Kettering Cancer Center

12:15 PM **Lunch** ***— Grand Ballroom B***

1:30 PM **Maintaining the Quality of the Clinical Research Enterprise** ***— Grand Ballroom A***

During this interactive session, panelists will share a variety of models for ensuring quality of care in the clinical research setting. Topics addressed will include onboarding and training of staff, regulatory issues, training investigators, employee satisfaction, and pharmacy issues.

Teresa Stewart, MS, CRCP (Moderator)
New Mexico Cancer Care Alliance
University of New Mexico Cancer Center

Vijaya Chadaram, RN, MSN, CCRP
Duke Cancer Institute
Duke University Medical Center

Brenda Hann, MBA
Stanford Cancer Institute

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2:15 PM **Promoting the Investigator/Clinical Research Coordinator Relationship to Ensure Clinical Trial Success — *Grand Ballroom A***

This session will focus on the importance of the relationship between the investigator and the clinical research coordinator. Panelists will discuss successful strategies for building a positive relationship between the investigator and coordinator, as well as the increased effectiveness and efficiency of trial operations when such a relationship exists.

James Thomas, MD, PhD (Moderator)
Medical College of Wisconsin Cancer Center

Jennifer Bunch
University of Kansas Cancer Center

Tara Lin, MD
University of Kansas Cancer Center

3:00 PM **Break**

3:15 PM **Concurrent Breakout Sessions**

1. Physician Clinical Research Training: Doing Good Clinical Trials and Conducting Quality and Compliant Research Work — *Lakeshore A*

Paul Martin, MD
Fred Hutchinson Cancer Research Center

2. Staff Retention and Training Programs: What Information Should be Included in the Training Manual? — *Lakeshore B*

Brenda Hann, MBA
Stanford Cancer Institute

Teresa Stewart, MS, CRCP
New Mexico Cancer Care Alliance
University of New Mexico Cancer Center

3. Managing Trials at Network and Affiliate Sites — *Grand Ballroom C*

Jennifer Davis, CCRP
Simmons Cancer Center
UT Southwestern Medical Center

Marlisa Isom, MS, CCRP
Fred Hutchinson Cancer Research Center

4:45 PM **Poster Session – *South Foyer***

6:00 PM **Welcome Reception – *South Foyer***

Thursday, July 9

7:00 AM **Continental Breakfast** – *Grand Ballroom B*

7:00 AM **Exhibits Open** – *East Foyer*

8:00 AM **Breakout Session Report Back** – *Grand Ballroom A*

8:30 AM **Attracting Support and Resources to Optimize Your Clinical Trials Office** – *Grand Ballroom A*

Panelists will discuss strategies for gaining institutional support in order to maximize clinical trials office operations. The panel will focus on the types of information that compel institutional leadership to provide additional support to the clinical trials office.

Randy Holcombe, MD (Moderator)
Mount Sinai Health System
Tisch Cancer Institute

Kirsten Erickson, PhD, MPH
University of Kansas Cancer Center

Roy Jensen, MD
University of Kansas Cancer Center

Brian Springer, MHA
Moffitt Cancer Center

Rebecca Turner, MS
Moffitt Cancer Center

9:30 AM **Trials and Tribulations: Effective and Ineffective Interventions** – *Grand Ballroom A*

In this session, presenters report the progress, or lack of progress, made in solving clinical trial operations problems presented in abstracts that were submitted for last year's CRI Annual Meeting.

Chad Adams, MPH (Moderator)
The University of Arizona Cancer Center

Lee Cranmer, MD, PhD
The University of Arizona Cancer Center

J. T. Diener, CCRP
Melvin and Bren Simon Cancer Center
Indiana University

Nancy Rollings, RN, MEd CCRC
Dartmouth-Hitchcock Norris Cotton Cancer Center

10:45 AM **Break**

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11:00 AM **Concurrent Breakout Sessions**

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Paul Martin, MD
Fred Hutchinson Cancer Research Center

2. Staff Retention and Training Programs: What Information should be Included in the Training Manual? — *Lakeshore B*

Brenda Hann, MBA
Stanford Cancer Institute

Teresa Stewart, MS, CRCP
New Mexico Cancer Care Alliance, University of New Mexico Cancer Center

3. Managing Trials at Network and Affiliate Sites — *Grand Ballroom C*

Jennifer Davis, CCRP
Simmons Cancer Center, UT Southwestern Medical Center

Marlisa Isom, MS, CCRP
Fred Hutchinson Cancer Research Center

12:30 PM **Lunch — *Grand Ballroom B***

1:30 PM **Breakout Session Report Back — *Grand Ballroom A***

2:00 PM **Understanding the NCI Cancer Center Support Grant (CCSG): Preparing for your Competitive Renewal and Site Visit – *Grand Ballroom A***

Presenters will discuss their experiences by highlighting their cancer center's clinical trials and data management activities as reported in NCI CCSG competitive and noncompetitive grant renewals. Presenters will share lessons learned for preparing NCI Data Tables 3 and 4 and preparing for the NCI site visit and tour of the clinical trials office. A Q&A session will follow the presentations.

Terri Matson (Moderator)
Hollings Cancer Center, University of South Carolina

Nick Fisher, MBA
Siteman Cancer Center

Sarah McNees, PhD
Dan L. Duncan Cancer Center, Baylor College of Medicine

Debra Wujcik, PhD, RN, FAAN
Vanderbilt-Ingram Cancer Center

3:00 PM **Closing Remarks**

3:15 PM **Adjourn**

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AACI CRI 2015 Steering Committee

Tony R. Reid, MD, PhD – Chair
UC San Diego Moores Cancer Center

Elizabeth Anderson, MPH, BSN
Knight Cancer Institute
Oregon Health and Science University

Paul Barr, MD
Wilmot Cancer Institute
University of Rochester Medical Center

Leigh Burgess, MHA, MEd, MA
Duke Cancer Institute
Duke University Medical Center

Chad A. Ellis, PhD
UNC Lineberger Comprehensive Cancer Center
University of North Carolina at Chapel Hill

Nicholas Fisher, MBA
Siteman Cancer Center

Janie Hofacker, RN, BSN, MS
Association of American Cancer Institutes

Randall F. Holcombe, MD
Mount Sinai Health System
Tisch Cancer Institute

Vicki L. Keedy, MD, MSCI
Vanderbilt-Ingram Cancer Center

Paul Martin, MD
UW School of Medicine
Fred Hutchinson Cancer Research Center

Sorena Nadaf, MS, MMI
UCSF Helen Diller Family Comprehensive Cancer Center
University of California, San Francisco

Barbara Duffy Stewart, MPH
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Teresa L. Stewart, MS, CRCP
University of New Mexico Cancer Center

James P. Thomas, MD, PhD
Medical College of Wisconsin Cancer Center

Steve Weitman, MD, PhD
Cancer Therapy and Research Center
University of Texas Health Science Center

Erin Williams, MBA
Simmons Cancer Center
UT Southwestern Medical Center

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