AACI

Association of
American Cancer Institutes

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AACI CRI

Association of American Cancer Institutes
CLINICAL RESEARCH INITIATIVE

8th Annual Meeting

Achieving Operational Excellence

July 20–21, 2016 • Loews Chicago O'Hare Hotel

AACI CRI 2016 Steering Committee

Paul Martin, MD - Chair
Fred Hutchinson Cancer Research Center

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

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

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

Nicholas Fisher, MBA
Siteman Cancer Center

Rosemarie Gagliardi, MPH, cEdD
Mount Sinai Health System
Tisch Cancer Institute

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

Jessica Moehle, CCRP
Huntsman Cancer Institute
University of Utah

Sorena Nadaf, MS, MMI
City of Hope Comprehensive Cancer Center

Barbara Duffy Stewart, MPH
Association of American Cancer Institutes

Erin Williams, MBA
Simmons Comprehensive Cancer Center
UT Southwestern Medical Center

Stephen Williamson, MD
University of Kansas Cancer Center

Wireless Internet and Presentation Information

Wireless Network: **AACI CRI WiFi** Access Pin: **2016cri**

To access CRI Annual Meeting documents please visit
http://portal.aaci-cancer.org
The email login is **cri@aaci-cancer.org** and the password is **2016cri**

NOTES

AACI CRI Welcome

Efficient management is a mainstay of any successful cancer clinical trials program. Stimulating the timely staging of critical clinical trials for optimal patient benefit requires the development of standard trial management guidelines and robust methods of evaluation.

The goal of the AACI Clinical Research Initiative (CRI) is to improve clinical trials management at cancer centers. To help achieve this goal, the CRI annual meeting provides opportunities for clinical trials office administrative and medical directors and staff to share best practices—through peer-to-peer networking, collaboration and ongoing communication—that can lead to the development of more effective treatments for patients with cancer.

AACI's CRI provides a forum for clinical research leaders to share information and to advocate for improving the national clinical trials enterprise. CRI objectives include developing better methods to disseminate information across cancer centers, identifying clinical research challenges, and sharing proven means of addressing challenges and measuring progress. The CRI program aligns with AACI's strategic goal to stimulate interactions among cancer centers in order to maximize the use of resources and to facilitate research. The individuals involved in CRI fill a variety of leadership roles and possess a comprehensive understanding of their center's entire clinical trials system.

AACI CRI Meeting Objectives

Attendees should be able to:

1. Address cancer center challenges about clinical research operations processes.

2. Identify lessons learned from the NCI-MATCH trial.

3. Describe the impact of changes in the NCI Cancer Center Support Grant guidelines.

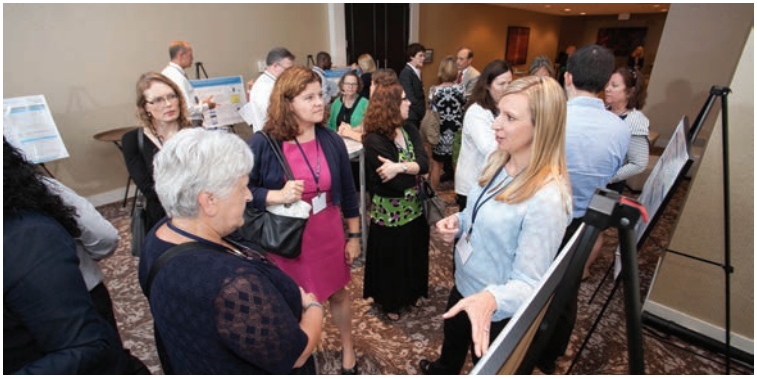
4. Discuss how clinical trial offices are adapting to new basket and umbrella trials.

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

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

7. Discuss different types of structural models used at various clinical trials offices.

8. Operationalize the challenges of preparing for audits.



MEETING PROGRAM

Association of American Cancer Institutes
8th Annual Clinical Research Initiative Meeting

Loews Chicago O'Hare Hotel — Chicago, Illinois

Wednesday, July 20

7:00 AM **Meeting Registration Begins** — ***Grand Foyer***

7:00 AM **Exhibits Open** — ***Grand Foyer***

7:00 AM **Continental Breakfast** — ***Guggenheim Ballroom***

8:00 AM **Welcome** — ***Louvre Ballroom***

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

Paul Martin, MD
Fred Hutchinson Cancer Research Center

George J. Weiner, MD
Holden Comprehensive Cancer Center
University of Iowa

8:15 AM **When the Physician Becomes the Patient** — ***Louvre Ballroom***

In November 2012, after experiencing symptoms including fatigue and chest pain, Dr. Eaton had a sinking feeling that he had leukemia. After diagnostic tests confirmed his suspicions, he suddenly found himself in a new role of patient and clinical trial subject. Given less than a five percent chance of survival, Dr. Eaton went through multiple rounds of chemotherapy before receiving CAR T-Cell therapy at the University of Pennsylvania. After receiving this form of immunotherapy, his cancer was reduced to undetectable levels. He subsequently underwent a stem cell transplant and has returned to a healthy life.

Keith Eaton, MD, PhD
Fred Hutchinson Cancer Research Center

9:00 AM **Trial Feasibility Committees: Do You Need One?** — ***Louvre Ballroom***

Panelists will discuss the pros and cons of using formal trial feasibility review committees to determine trial resource allocation and costs prior to trial activation. They will also discuss the composition of the committee, which trials are reviewed, protocol criteria evaluated, who makes the final decision to approve or reject trials and the impact on trial activation timelines.

Moderator: Stephen Williamson, MD
University of Kansas Cancer Center

Jessica Moehle, CCRP
Huntsman Cancer Institute
University of Utah

Melissa Nashawati, MPA
Cancer Therapy and Research Center at the
University of Texas Health Science Center

9:45 AM ASCO Workload Assessment Tool — *Louvre Ballroom*

Clinical research program managers are regularly faced with assessing how much of a workload research staff can effectively manage. The ability to apply objective metrics towards workload may provide insight to better meet research program challenges and aid in balancing staff workload. This session will describe a web-based, acuity-driven, workload tool that was developed to assess the feasibility and workload of research nurses and research coordinators and is now available to use.

Moderator: Teresa Stewart, MS, CRCP
University of New Mexico Comprehensive Cancer Center

Marge Good, RN, MPH, OCN
National Cancer Institute

Patricia Hurley, MSC
American Society of Clinical Oncology (ASCO)

10:15 AM Break

10:30 AM Lessons Learned from the NCI-MATCH Trial — *Louvre Ballroom*

NCI-MATCH has presented new opportunities and challenges for clinical trials offices. This session will present an overview of the NCI-MATCH Trial and panelists will share successes and challenges of implementing NCI-MATCH at their institutions, focusing on why they chose to open or not open the trial, and differences in opening the trial at community sites versus academic centers.

Moderator: Erin Williams, MBA
Simmons Comprehensive Cancer Center
UT Southwestern Medical Center

Ingrid Block, APRN, CNS
Peggy and Charles Stephenson Cancer Center
University of Oklahoma Health Sciences Center

Stanley R. Hamilton, MD
University of Texas
MD Anderson Cancer Center

Helen Peck, RN, MA, OCN, CCRP
Sylvester Comprehensive Cancer Center
University of Miami Health System

11:30 AM Being Flexible Can Influence Clinical Trials Office Success — *Louvre Ballroom*

As scientific advances in treating cancer rapidly develop, cancer center clinical trials offices find that being flexible is a key to keeping abreast with changing clinical practice. Panelists will focus on how to create and maintain a flexible CTO office structure that facilitates trial accrual and rapid and compliant data collection with regards to the NCI-MATCH Trial. Presenters will also describe how their centers are accelerating trial start-up and avoiding bottlenecks in managing trials, and the benefits of using trial master agreements.

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

Bojana Askovich, PhD
University of Washington

Todd Bauer, MD
Sarah Cannon Research Institute

Ashlee Drawz, CCRC
Robert H. Lurie Comprehensive Cancer Center
Northwestern University

12:30 PM Lunch — *Guggenheim Ballroom*

1:30 PM 2016 CRI Abstract Presentations — *Louvre Ballroom*

Abstracts received from AACI cancer center members focus on oncology research that illuminates clinical research operational challenges and solutions. The CRI Steering Committee selected three abstracts for presentation at this year's meeting.

Moderator: Paul Martin, MD
Fred Hutchinson Cancer Research Center

The Clinical Trial Management Tool: An Innovative Approach to Regulatory Operations
Abby Statler, MPH, MA, CCRP
Cleveland Clinic Taussig Cancer Institute
The Cleveland Clinic Foundation

CRANIUM (Clinical Research Assessment Metrics) A Workload Assessment Model for a NCI Comprehensive Cancer Center
Sally Fairbairn, CCRP
Huntsman Cancer Institute
University of Utah

Using Data to Determine Study Budgets for Clinical Trials Office Staff
Kate Harper, MBA, CCRP
University of Michigan Comprehensive Cancer Center

2:15 PM Types of Structural Models — *Louvre Ballroom*

This session will discuss various clinical trials office structural models for activating and coordinating oncology interventional trials. Panelists will address nursing versus non-nursing coordinator models and differences between centralized and decentralized systems.

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

Rhoda Arzoomanian, MSM, RN, BSN
Yale Cancer Center
Yale University School of Medicine

Miriam Bischoff, MS, MBA
Stanford Cancer Institute

Teresa Stewart, MS, CRCP
University of New Mexico Comprehensive Cancer Center

3:00 PM Break

3:15 PM Concurrent Breakout Sessions

Electronic Regulatory Binders — *Louvre Ballroom 1*

Marcia Latif, MPH, CCRP
Memorial Sloan Kettering Cancer Center

Tricia Bentz, MHA, CCRP
Hollings Cancer Center
Medical University of South Carolina

Types of Monitoring — *Guggenheim Ballroom 1*

Monica Orians, CCRP
University of Michigan Comprehensive Cancer Center

Boosting Patient Accrual — *Guggenheim Ballroom 2*

Deidre Cleary, RN, BSN, CCRC
University of Pittsburgh Cancer Institute
UPMC CancerCenter

Neal Meropol, MD
Case Comprehensive Cancer Center, Case Western Reserve University
Seidman Cancer Center at University Hospitals Case Medical Center

CCSG: Revised Guidelines, Expectations and Strategic Planning — *Guggenheim Ballroom 3*

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

Rosemarie Gagliardi, MPH, cEdD
Mount Sinai Health System
Tisch Cancer Institute

Discussant: Henry Ciolino, PhD
National Cancer Institute

Update on AACI Physician Clinical Leadership Initiative for CTO Medical Directors (Wednesday Only) — *Metropolitan*

Paul Martin, MD
Fred Hutchinson Cancer Research Center

Randall Holcombe, MD, MBA
Mount Sinai Health System
Tisch Cancer Institute

5:00 PM **Poster Session and Welcome Reception — *Grand Foyer***
Reception Sponsored by Nimblify

Thursday, July 21

7:00 AM **Continental Breakfast — *Grand Foyer***

7:00 AM **Vendor Presentation: Complion — *Guggenheim Ballroom 1***

7:00 AM **Exhibits Open — *Grand Foyer***

8:00 AM **Welcome — *Louvre Ballroom***

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

8:15 AM **Staff Retention and Training — *Louvre Ballroom***

This session will focus on methods used to promote staff retention and address staff training needs. In addition, the presenters will discuss the importance of standardizing training and continuing education for all staff including principal investigators.

Moderator: Paul Martin, MD
Fred Hutchinson Cancer Research Center

Patricia Bebee, MS, RN, CCRP
University of Michigan Comprehensive Cancer Center

Brenda Hann, MBA
Stanford Cancer Institute

Mindy Roberts, MA, CIP
Knight Cancer Institute
Oregon Health and Science University

Erin Williams, MBA
Simmons Comprehensive Cancer Center
UT Southwestern Medical Center

9:35 AM Concurrent Breakout Sessions

Electronic Regulatory Binders — *Louvre Ballroom 1*

Marcia Latif, MPH, CCRP
Memorial Sloan Kettering Cancer Center

Tricia Bentz, MHA, CCRP
Hollings Cancer Center
Medical University of South Carolina

Types of Monitoring — *Guggenheim Ballroom 1*

Monica Orians, CCRP
University of Michigan Comprehensive Cancer Center

Boosting Patient Accrual — *Guggenheim Ballroom 2*

Deidre Cleary, RN, BSN, CCRC
University of Pittsburgh Cancer Institute
UPMC CancerCenter

Neal Meropol, MD
Case Comprehensive Cancer Center, Case Western Reserve University
Seidman Cancer Center at University Hospitals Case Medical Center

CCSG: Revised Guidelines, Expectations and Strategic Planning — *Guggenheim Ballroom 3*

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

Rosemarie Gagliardi, MPH, cEdD
Mount Sinai Health System
Tisch Cancer Institute

Discussant: Henry Ciolino, PhD
National Cancer Institute

11:00 AM Trials and Tribulations: Effective and Ineffective Interventions — *Louvre Ballroom*

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. Each presentation will be 15 minutes and a Q & A session will follow after all of the presentations.

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

Therica Miller, MBA, CCRP
Samuel Oschin Comprehensive Cancer Institute
Cedars-Sinai Medical Center

Lauren Wall, MS
The University of Chicago Medicine Comprehensive Cancer Center

Randall Holcombe, MD, MBA
Mount Sinai Health System
Tisch Cancer Institute

Alyssa Ryan, MBA
Mount Sinai Health System
Tisch Cancer Institute

12:00 PM **Lunch** – ***Guggenheim Ballroom***

1:00 PM **Breakout Sessions Report Back** — ***Louvre Ballroom***

1:30 PM **Who's Ready for Audits?** — ***Louvre Ballroom***

Clinical trial audits are necessary for clinical trial compliance and subject safety. Panelists will share experiences with monitoring challenges, preparing and coordinating a FDA audit, managing a quality assurance program and guaranteeing compliance when conducting trials funded by the NCI National Clinical Trials Network.

Elaine Armstrong, MS
Southwest Oncology Group (SWOG)

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

2:15 PM **Clinical Trials Office Budget Development** — ***Louvre Ballroom***

Presenters will discuss financial reporting metrics for their cancer center clinical trials offices and their use of budget modeling. In addition, they will present innovative processes being used to justify trial startup costs, identify and capture underfunded trial costs, and the benefits of conducting a review for closed trials to assess budget performance.

Moderator: Terri Matson
Hollings Cancer Center
Medical University of South Carolina

Anita Bowler, CCRP
Huntsman Cancer Institute
University of Utah

Courtney Wood, MPA
Knight Cancer Institute
Oregon Health and Science University

3:00 PM **Closing Remarks** — ***Louvre Ballroom***

3:15 PM **Adjourn**

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AACI CRI Exhibitors

ASCO Research Community Forum

The ASCO Research Community Forum serves as a go-to resource for the oncology research community. The Forum's key objectives are to: 1) convene community-based researchers, including those affiliated with academic centers, to share best practices, identify challenges, and brainstorm about effective strategies to conducting research; and 2) develop and disseminate solution-oriented resources and tools to the broader research community that address challenges and facilitate clinical trial participation and accrual. The Forum is led by a Council that includes physician investigators and research staff (e.g., research administrators, research nurses, and clinical research coordinators) from research sites in a range of settings, primarily community-based research programs and academic research networks with affiliated community-based research sites.

Complion

Complion, the eRegulatory provider for AACI Cancer Centers, was founded by certified clinical research professionals to empower sites and eliminate redundancy. Complion's 21 CFR Part 11 compliant document management system has workflows for Delegation of Authority, Qualifications, Multi-Center Studies, eSignatures, Quality Assurance, Remote Monitoring, eSubmissions to the FDA Gateway, Advanced Reporting and many others. Complion's clients are saving at least 40% more time over the paper regulatory process and are eliminating the need for paper and physical archival space.

Florence Healthcare

Florence eBinder Suite is purpose built software for managing clinical trial regulatory and patient source document Binders. The eBinder Suite saves important physical space and provides the needed 11 CRF 21 workflows for trial teams to save time and improve compliance. Electronic signatures allow teams across multiple geographic locations to work effectively and the eBinder Suite even lets monitors remotely evaluate binder status. Top level reporting allows trial administration to identify bottlenecks and empower trial teams to get time back from paperwork to focus on putting the patient at the center of the trial.

Foundation Medicine

Foundation Medicine (NASDAQ:FMI) is a molecular information company dedicated to a transformation in cancer care in which treatment is informed by a deep understanding of the genomic changes that contribute to each patient's unique cancer.
The company offers a full suite of comprehensive genomic profiling assays, FoundationOne®, FoundationOne Heme® and FoundationACT™, to identify the molecular alterations in a patient's cancer and match them with relevant targeted therapies, immunotherapies and clinical trials. Foundation Medicine's molecular information platform aims to improve day-to-day care for patients by serving the needs of clinicians, academic researchers and drug developers to help advance the science of molecular medicine in cancer. For more information, please visit http://www.FoundationMedicine.com or follow Foundation Medicine on Twitter (@FoundationATCG).

PFS Clinical

PFS Clinical is dedicated to helping research institutions improve the management of their clinical trials from study start-up to final payment. Clients include academic medical centers, hospitals, dedicated research sites, multi-specialty practices and trial/site management organizations. Staffed by experts with relevant experience in clinical research administration, PFS Clinical's suite of services include coverage analysis, financial management, budget and contract negotiation, claims review, corporate marketing, patient recruitment, and business development. For more information, visit www.pfsclinical.com.

Save the Date

9th Annual CRI Meeting

Loews Chicago O'Hare Hotel

JULY 12–13, 2017

AACI CRI

Clinical Research Initiative

Please complete your meeting evaluation

www.aaci-cancer.org/CRIevaluation