AACI CRI

BUILDING BEST PRACTICES

ASSOCIATION OF AMERICAN CANCER INSTITUTES

CLINICAL RESEARCH INITIATIVE

5th Annual Meeting

July 11–12, 2013

InterContinental, Chicago O'Hare

AACI

Association of
American Cancer Institutes

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AACI CRI 2013 Steering Committee

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UCSD Moores Cancer Center

James P. Thomas, MD, PhD – Immediate Past Chair
Medical College of Wisconsin Cancer Center

Rhoda Arzoomanian, RN, BSN, MSM
University of Wisconsin Carbone Cancer Center

Leigh Burgess, MHA, MEd, MA
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AACI CRI Welcome

Multiple industry, government, and ad hoc groups meet to improve the clinical trials process and infrastructure in the United States. AACI CRI provides a venue for academic cancer centers to network and partner with industry and regulatory agencies to work together in advancing cancer clinical research and to overcome obstacles to drug discovery.

AACI 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 ways to disseminate information across cancer centers, identifying clinical research challenges, and sharing proven means of addressing issues and measuring progress. The CRI program aligns with AACI's strategic goal to stimulate interactions among cancer centers to maximize the use of resources and facilitate research. The individuals involved in CRI fill a variety of leadership roles and possess a comprehensive understanding of their centers' entire clinical trials system.

The goal of the AACI CRI annual meeting is to improve clinical trials management at cancer centers. To achieve this goal, 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 novel cures and effective treatments for patients with cancer. This year's meeting program has been expanded to increase attendance of the cancer centers' clinical trials office medical directors and associate directors for clinical research who are responsible for providing leadership of the centers' clinical research efforts.

AACI CRI Meeting Goals

1. Identify cancer center concerns involving the clinical research process.
2. Identify strategies for disseminating information that supports the development of oncology research process improvement and best practice policies.
3. Describe the impact of changes in the National Cancer Institute (NCI) Clinical Trials System and the NCI Cancer Center Support Grant guidelines on the cancer centers.
4. Discuss trends and best practices in clinical trials safety and compliance.
5. Support peer-to-peer networking and collaboration and ongoing communication strategies with clinical trials administrative and medical directors.
6. Recommend policies for the research team to 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 compliance.
8. Promote partnerships with like-minded organizations to facilitate the clinical research process and increase 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.

AACI CRI Special Interest Groups

Key to CRI's success is the work of Special Interest Groups (SIGs) that create and implement new tools to share across the AACI cancer center network. To date, seven SIGs have been established in order 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. Through the SIGs, CRI disseminates best practice models that lead to increased access to new cancer therapies.

AACI Corporate Roundtable Members

AACI is grateful for the support of the 2013 corporate roundtable members:

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MEETING PROGRAM

Association of American Cancer Institutes
5th Annual Clinical Research Initiative Meeting

InterContinental Chicago O'Hare

Thursday, July 11

7:00 am: Registration Open — Artist Foyer

7:00 am: Breakfast — Cassatt A/B

General Sessions — Cassatt C/D

8:00 am: Welcome and Introduction

Tony Reid, MD, PhD
Director of Early Phase Clinical Research Program
UCSD Moores Cancer Center

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

8:15 am: Clinical Research at the Nation's Cancer Centers: NCI Perspective

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

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

Cancer Center Experience Using the New Cancer Center Support Grant (CCSG) Guidelines

Dr. Linda Weiss will discuss the new CCSG guidelines and their implications for cancer centers' clinical trials offices. Presenters will share their experiences with completing and submitting competitive and non-competitive CCSG renewals using the new guidelines. A Q&A session will follow the presentations.

Tony Reid, MD, PhD *(Moderator)*

Linda K. Weiss, PhD
Director, Office of Cancer Centers
National Cancer Institute

Terri Matson, CCRP
Director of Clinical Operations
Hollings Cancer Center

Chad Ellis, PhD
Deputy Director, Research Affairs
Yale Comprehensive Cancer Center

Brian Springer, MHA
Executive Vice President
Roswell Park Cancer Institute

10:15 am: Break — Artist Foyer *Sponsored by USDS*

10:30 am: Nothing is as Constant as Change: Adapting Clinical Trials Management Under the Affordable Care Act

Dr. Steven Stranne will discuss the Affordable Care Act and its clinical trials provisions, which become effective in 2014.

Steven Stranne, MD, JD
Shareholder
Polsinelli Shughart PC

11:15 am: Trial Metrics Special Interest Group Presentation

To define staffing metrics in clinical trial offices, cancer centers have been testing the "Predictive Effort Model," the "Actual Effort or Time Tracking Model," or a hybrid of the two measurement methods. Three centers will report their findings in this session.

Douglas Stahl, PhD, MBA *(Moderator)*
Vice President, Clinical Research Operations
City of Hope National Medical Center and Beckman Research Institute

Erin Williams, BA, MBA
Associate Director, Clinical Research Operations Administration
University of Texas Southwestern Medical Center
Simmons Comprehensive Cancer Center

Karen Braddy
Business Analyst
University of Colorado Cancer Center

Theresa Royce, BBA, CCRP
Manager, Clinical Trials Office
University of Michigan Comprehensive Cancer Center

Matthew Innes, BSE, MBA
IT Manager, Clinical Trials Office
University of Michigan Comprehensive Cancer Center

12:00 pm: Lunch — Cassatt A/B

1:00 pm: The Role of the Clinical Trials Office Medical Director

Medical directors at cancer center clinical trials offices provide clinical and operational leadership for their institutions' clinical trials programs. Presenters for this session will focus on challenges and successes of their positions, structures of various medical directors' roles, funding support for staff positions and investigator initiated trials, opportunities for growth and advancement, preparation of a five-year strategic plan, and how they manage investigator compliance and promote investigator and staff training.

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
Director, Institute for Drug Development
AT&T Distinguished Chair of Drug Development
University of Texas Health Science Center at San Antonio

Paul M. Barr, MD
Assistant Professor of Medicine and Oncology
University of Rochester Medical Center

1:45 pm: Breakthrough Therapies and Master Trial Protocols

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. Presenters will discuss the current status of these protocols.

Jeff Allen, PhD
Executive Director
Friends of Cancer Research

Michelle Rohrer, PhD
Vice President, US Regulatory Affairs
Genentech Roche

2:30 pm: Break — Artist Foyer

2:45 pm: Speeding up the Drug Discovery Process: Facilitating the Study Execution Process

A number of initiatives have been launched by cancer-focused organizations to accelerate the drug development process. For example, the Standard Terms of Agreement for Research Trials (START) Clauses were created by the CEO Roundtable on Cancer, a nonprofit organization composed of corporate leaders and the NCI. Similarly, TransCelerate BioPharma, Inc. an umbrella group of ten leading pharmaceutical companies, has formed a non-profit organization aimed at making the clinical trial process more efficient. Presenters will detail these organizations' efforts.

Randall F. Holcombe, MD *(Moderator)*
Director, Clinical Cancer Affairs, Mount Sinai Medical Center
Deputy Director, Tisch Cancer Institute

Phil Porter, JD
Of Counsel, Northern Virginia
Hogan Lovells

Sheila Prindiville, MD, MPH
Director, Coordinating Center for Clinical Trials
National Cancer Institute

Jeff Kasher, PhD
Vice President, Clinical Trials: Materials, Implementation and Transformation
Eli Lilly and Company

3:30 pm: Assuring Research Subject Protection in a Streamlined IRB Review Process

Streamlining the IRB review process while promoting high-quality research and providing human subject protections for trials using multiple trial sites is a challenge for AACI cancer centers. Presenters will discuss new approaches to shrinking the IRB review timeline while meeting accreditation standards and regulatory requirements.

Vicki Keedy, MD, MSCI *(Moderator)*

Todd Rice, MD, MSCI
Assistant Professor of Medicine
Vanderbilt University School of Medicine

Marjorie A. Speers, PhD
President and CEO
Association for the Accreditation of Human Research Protection Program, Inc.

Jeffrey Cooper, MD, MMM
Vice President Global Consulting
WIRB-Copernicus Group

Jacquelyn L. Goldberg, JD
Head - NCI Central Institutional Review Board
National Cancer Institute

4:30 pm: Cancer Center Abstract Presentations

Abstracts from CRI members focus on oncology research that illuminates clinical research management challenges and solutions. The CRI Steering Committee has selected three abstracts for presentation at this year's meeting. Each presentation will be 10 minutes followed by a 5 minute Q & A session.

Quality Improvement Initiative to Enhance Regulatory Compliance and Reduce Submission Errors Utilizing an Optimal Outcome Procedure System (OOPS)

Virginia L. Doran, MLT, MBA, CCRP
Administrator, Regulatory Affairs
Clinical Research Services
Roswell Park Cancer Institute

Julie Haney, RN, MSL, CCRC
CRS Sr. Administrator II
Study Submission & Regulatory Affairs
Roswell Park Cancer Institute

Accounts Receivable Management of Commercially Sponsored Clinical Trials

Joanne Brechlin, MBA, MPH
Project Manager
Clinical Trials Office
UCSD Moores Cancer Center

Meaghan Stirn, MBA
Interim Assistant Director, Clinical Investigations Program
UCSD Moores Cancer Center

Using the FDA Electronic Submission Gateway for IND Applications at an Academic Cancer Center

Lee Doherty, EdM
Regulatory Manager
Stanford Cancer Institute

5:15 – 5:45 pm: Vendor Presentations — *Concurrent Sessions*

New this year — CRI attendees can hear directly from vendors providing support for CRI. Everyone is encouraged to attend.

Clinicaltrials.gov Reporting: Why Isn't Anyone Acting?

Presented by Virtify — **Cassatt B**

– Everyone knows the new law is coming.
– What happens when the FDA issues a warning letter?
– What we hear when we talk to administrators.

Tom Witmer
Vice President, US Sales
Virtify, Inc.

Data-Driven Approaches and Tools for Workload Management and Site Performance Metrics

Presented by Forte Research Systems, Inc — **Cassatt A**

Kerry Bridges, MBA, RN, CCRC
Administrator, Clinical Research Office
Indiana University Simon Cancer Center

Srini Kalluri
Founder, President, CEO and Chief Customer Officer
Forte Research System, Inc.

Carrie Nemke
Business Development
Forte Research System, Inc

6:00 pm: Welcome Reception and Cancer Center Poster Session — Artist Foyer

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 challenges and solutions implemented at their cancer centers. Everyone is invited to attend.

Friday, July 12

7:00 am: Breakfast — Warhol

7:50 am: Charge to Breakouts — Warhol

Tony Reid, MD, PhD

8:00 am: Breakout Session — 1

Trial Budgeting: *Cassatt B*

- Covering and identifying trial costs
- Start-up fees
- Pre-screening
- Identifying unexpected costs

Terri Matson, CCRP *(Breakout co-leader)*

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

IRB and Regulatory: *Cassatt A*

- Electronic document storage
- Electronic approval
- Multiple IRBs

Linda Beekman, RN, MBA *(Breakout co-leader)*
Administrative Director
Clinical Trials Office
University of Michigan Comprehensive Cancer Center

Renee Webb *(Breakout co-leader)*
Administrative Director
Clinical Research Office
Robert H. Lurie Comprehensive Cancer Center
Northwestern University

Structure and Roles at Clinical Trials Offices: *Cassatt C/D*

- Scope of CTOs
- Funding CTOs

Tony Reid, MD, PhD *(Breakout leader)*

9:00 am: Break — Artist Foyer

9:10 am: Breakout Session — 2

Medicare Coverage Analysis: *Cassatt B*

- *Responsibilities*
- *Who and how*
- *Resources for training*
- *Standard of care versus routine care*

Kelly Willenberg, MBA, BSN, CRC, CHRC *(Breakout leader)*
President, Kelly Willenberg, LLC

Data Management: *Cassatt A*

- Data management standards
- Review tools used to facilitate timely and accurate data entry
- Review how data entry errors are captured
- Review cancer center data management standards
- Review cancer center staffing models

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

Lee Doherty, EDM *(Breakout co-leader)*

Monitoring and Auditing: *Warhol*

- Auditing versus monitoring
- Risk-based approach to establishing institutional risk
- Local versus remote monitoring
- Access to electronic medical records

Joy Ostroff, RN, BSN, OCN *(Breakout co-leader)*
Administrative Director
Clinical Research, UNC Cancer Network
UNC Lineberger Comprehensive Cancer Center

Sherrie Reynolds, RN, BSN, CCRP *(Breakout co-leader)*
Quality Assurance, Clinical Trials Unit
Seidman Cancer Center at the University Hospitals Case Medical Center

10:10 am: Break — Artist Foyer

10:20 am: Breakout Session — 3

Education Programs: *Cassatt B*

- *Training/orientation*
- *Professional staff development*
- *Staff retention*

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

Alyssa K. Gateman, MPH, CCRP (Breakout co-leader)
Director, Quality Assurance Office for Clinical Trials
Dana-Farber Cancer Institute
Dana-Farber/Harvard Cancer Center

Industry Interactions: *Cassatt A*

- *Site selection*
- *Working with clinical research offices (CRO)*
- *TransCelerate BioPharma, Inc.*
- *Open studies at remote sites*
- *Principal investigator good clinical practice (GCP) training/certifications*

Elizabeth Anderson, MPH, BSN *(Breakout co-leader)*
Director, Clinical Trials Office
Knight Cancer Institute

Kerry Bridges, MBA, RN, CCRC *(Breakout co-leader)*

Changes to CCSG and Organizational Impact: *Warhol*

- *Clinical protocol data management and the protocol review monitoring systems*
- *Early phase clinical research support which replaces protocol specific research support*
- *Changes to the CCSG Data Tables 3 and 4*

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

Rhoda Arzoomanian, BSN, RN, MSM *(Breakout co-leader)*
Associate Director of Administration
UW Carbone Cancer Center

11:20 am: Breakout Session Report Back — Cassatt C/D

12:00 pm: Adjourn

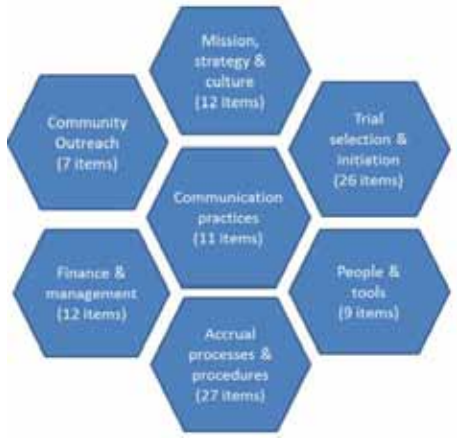
ENACCT
Education Network to Advance CANCER CLINICAL TRIALS

Expanding Access to Clinical Trials through Community Affiliations: Seven Critical Dimensions to Consider - for You and Your Community Partners

As more and more cancer centers are formalizing partnerships with community-based oncology networks, it is critical to evaluate efficiency in clinical trials accrual.

In an article published in the May/June edition of Oncology Issues, http://tinyurl.com/cojxqgk, we outline critical dimensions that should be assessed as part of any affiliation evaluation process.

In the fall of 2013, ENACCT will launch our **360° Clinical Trial Self-Assessment Tool** to help community cancer centers and networks evaluate and improve their own cancer clinical trials accrual using the critical dimensions depicted on the right. This tool is designed as a guided analysis which can be completed online, ideally by the cancer research leadership team, with data provided by staff.



Designed to focus the attention of the leadership team on qualitative and quantitative factors across the critical dimensions of an effective clinical trials process, the tool will provide benchmarks to participating sites against their peers and the ideal. ENACCT plans to provide participants with specific feedback on their strengths and weaknesses and provide additional technical assistance as needed to ameliorate barriers and capitalize on opportunities to improve accrual.

See www.ENACCT.org in September 2013!

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