



Association of
American Cancer Institutes

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www.aaci-cancer.org

AACI CRI Association of American Cancer Institutes
CLINICAL RESEARCH INITIATIVE

9TH ANNUAL MEETING
**MOVING SCIENCE
FORWARD**



July 12-13, 2017 • Loews Chicago O'Hare Hotel

AACI CRI 2017 Steering Committee

Paul J. Martin, MD – Chair
Fred Hutchinson Cancer Research Center

Carrie Lee, MD, MPH – Chair-Elect
*UNC Lineberger Comprehensive Cancer Center
University of North Carolina at Chapel Hill*

Elizabeth Anderson, MPH, BSN
Stanford Cancer Institute

Theresa Cummings, RN, MS
University of Maryland Marlene and Stewart Greenebaum Comprehensive Cancer Center

Nicholas Fisher, MBA
Siteman Cancer Center

Rosemarie Gagliardi, c.EdD, MPH, CCRA
The Tisch Cancer Institute at the Mount Sinai Health System

David Gosky, MA, MBA
UK Markey Cancer Center

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

Ashley Baker Lee, CCRP
City of Hope Comprehensive Cancer Center

Jessica Moehle, CCRP
*Huntsman Cancer Institute
University of Utah*

Kristie Moffett, MHA
Moffitt Cancer Center

Barbara Duffy Stewart, MPH
Association of American Cancer Institutes

Stephen Williamson, MD
The University of Kansas Cancer Center

Wireless Internet and Presentation information

Wireless Network: AACI CRI WIFI Password: 2017cri

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 2017cri

AACI CRI Welcome

Clinical trials for cancer need good management. To offer the most benefit to patients, the trials must have standard guidelines for their management and robust methods of evaluation.

AACI's Clinical Research Initiative (CRI) aims to improve clinical trials management at cancer centers. Toward this goal, the CRI annual meeting enables those in clinical trials offices to share their best practices—through peer-to-peer networking, collaboration, and ongoing communication. All these interactions can lead to better cancer treatments.

CRI objectives include developing better methods for disseminating information across cancer centers, identifying and addressing clinical research challenges, and measuring progress. The CRI annual meeting program aligns with AACI's strategic goal of stimulating cancer center interactions to maximize the use of resources, including eliminating unproductive steps that slow down drug development. Those involved in CRI fill a variety of leadership roles and thoroughly understand their respective cancer center's clinical trials system.

This year's meeting focuses on how AACI cancer centers are adapting to manage novel and complex cancer clinical research trials that advance cancer treatment and prolong patient survival.



AACI CRI Meeting Objectives

1. Address cancer center challenges by working with novel research agents that can lead to the rapid development of new therapies.
2. Discuss how clinical trials office leaders are changing their operational structures to adapt to complex trial designs such as the NCI-MATCH Trial and basket- and umbrella-type trials.
3. Describe the impact of revisions to the NCI Cancer Center Support Grant guidelines, including how they affect preparations for NCI site visits.
4. Support peer-to-peer networking, collaboration, and ongoing communications between clinical trials office administrative and medical directors.
5. Identify policies and practices that promote staff retention, job satisfaction, diversity and stability for the clinical research workforce at cancer centers.
6. Highlight challenges in preparing for audits and site monitoring visits.
7. Create trial budgets that address research staff effort while adhering to National Trial Coverage Decision Guidelines.
8. Discuss how cancer centers are building relationships with network care sites to promote trial accrual, coordination, and monitoring to ensure study compliance and accurate research data collection that aligns with study endpoints.
9. Explore the use of information technology platforms to facilitate research data collection, electronic regulatory record management, and the capture of clinical trial finances.

Who Should Attend This Meeting?

- Administrative directors of clinical trials offices
- Clinical trials office medical directors
- Deputy/associate directors of clinical research administration
- Cancer center administrators
- Clinical trials office managers and supervisors
- Employees of research regulatory agencies
- AACI Sustaining Members
- AACI Corporate Roundtable members
- Representatives from industry, including pharmaceutical companies and clinical research organizations

MEETING PROGRAM

Association of American Cancer Institutes 9th Annual Clinical Research Initiative Meeting

Loews Chicago O'Hare Hotel - Rosemont, Illinois

Wednesday, July 12

7:00 AM Breakfast - Avedon Ballroom C/D

7:00 AM Meeting Registration Begins - Artist Foyer

7:00 AM Exhibits Open - Artist Foyer

8:00 AM Welcome - Cassatt Ballroom

Janie Hofacker, RN, BSN, MS

Association of American Cancer Institutes

Paul Martin, MD

Fred Hutchinson Cancer Research Center

Roy A. Jensen, MD

The University of Kansas Cancer Center; President-elect, AACI

8:15 AM Supporting Patients Through Clinical Trials and Beyond - Cassatt Ballroom

With experience as both a cancer survivor and a cancer physician, Dr. Beck brings a unique perspective to her research and clinical leadership at Huntsman Cancer Institute. Dr. Beck will address clinical research—especially how to encourage clinical trial enrollment—and will describe how her personal struggle with cancer has altered her views about supporting cancer patients throughout their disease trajectory. Dr. Beck's areas of research interest are end-of-life care, communication skills training, and female cancers.

Anna C. Beck, MD

Huntsman Cancer Institute

University of Utah

9:15 AM Managing Trials at Affiliate Sites - Cassatt Ballroom

In this session, panelists will identify reasons for using affiliate sites, criteria for selecting sites, and the importance of building relationships and evaluating a site's readiness for trial participation. Panelists will share ideas for establishing a budget to cover affiliate site costs for trial start-up, research staff and non-reimbursable insurance charges. The panel will also discuss the challenges faced when the lead site has minimal authority over affiliate sites to ensure regulatory compliance or to address nonconforming sites that don't accrue subjects according to established metrics. *(continued page 4)*

Moderator/Presenter: Carrie Lee, MD
UNC Lineberger Comprehensive Cancer Center
University of North Carolina at Chapel Hill

Jennie Crews, MD, MMM, FACP
Fred Hutchinson Cancer Research Center

Dennis Slamon, MD, PhD
Jonsson Comprehensive Cancer Center, UCLA

10:15 AM Break

10:30 AM Updated CCSG Guidelines - Cassatt Ballroom

Panelists will lead an open dialogue about the NCI program award, "Cancer Center Support Grants (CCSGs) for NCI-designated Cancer Centers (P30)." Topics include revisions to grant guidelines and instructions for renewing the P30 grant. Attendees will also hear some practical advice from two cancer centers that have recently completed their CCSG competing renewal using the new grant criteria.

Moderator: Dave Gosky, MA, MBA
UK Markey Cancer Center

Henry Ciolino, PhD
National Cancer Institute

Megan Kilbane, MBA
Case Comprehensive Cancer Center, Case Western Reserve University
Seidman Cancer Center at University Hospitals Cleveland Medical Center

Marcy List, PhD
The University of Chicago Medicine Comprehensive Cancer Center

David Loose
National Cancer Institute

12:00 PM Lunch - Avedon Ballroom C/D

1:15 PM 2017 CRI Abstract Presentations - Cassatt Ballroom

Abstracts received from AACI cancer center members focus on oncology research that illuminates clinical research challenges and solutions aimed at accelerating drug development for patients with cancer. The CRI Steering Committee selected three abstracts for presentation at this year's meeting. Each presentation will be 15 minutes, and a Q&A session will follow.

Moderator: Paul Martin, MD
Fred Hutchinson Cancer Research Center

Ensuring PEAK Training and Compliance in Cancer Clinical Trials

Richa Upadhyay, MD (presenter); Lediona Ardolli, MA; Rosemarie Gagliardi, c.EdD, MPH, CCRA; Donna Berizzi, RN, MSN, OCN; Matthew Galsky, MD; Ajai Chari, MD
The Tisch Cancer Institute at the Mount Sinai Health System

Improving Reproducibility of Quantitative Imaging Endpoints

Daniel C. Sullivan, MD (presenter); Michael Boss, PhD; Thomas L. Chenevert, PhD; Edward F. Jackson, PhD; Alexander Guimaraes, MD, PhD

Duke Cancer Institute, Duke University Medical Center; University of Michigan Comprehensive Cancer Center; University of Wisconsin School of Medicine & Public Health and University of Wisconsin Carbone Cancer Center; Knight Cancer Institute, Oregon Health & Sciences University

Implementing a Research Nurse Model for the Clinical Trials Office (CTO)

Helen Peck, RN, MA, OCN, CCRP (presenter); Joanne Mancini, RN, CCRP; Cathy Galasso, RN, OCN, CCRP

Sylvester Comprehensive Cancer Center, University of Miami Health System; Barbara Ann Karmanos Cancer Institute

2:15 PM Clinical Trials Coverage Analysis 101 - Cassatt Ballroom

Clinical trials coverage analysis is the initial step in developing a clinical trial budget. In this session, panelists will discuss how to prepare a trial coverage analysis to create a trial budget for contract negotiations and a billing grid for assigning charges. Panelists will also explore ways to generate documentation to support medical-necessity-of-care claims in the electronic medical record as well as billed charges and services requiring payer preauthorization. A representative from the National Cancer Institute (NCI) will discuss how they develop trial coverage analysis for National Clinical Trials Network (NCTN) phase II and phase III trials and NCI Community Oncology Research Program cancer control/prevention trials. Panelists will also address regional differences in how the Centers for Medicare & Medicaid Services determine national coverage for clinical trials.

Moderator: Paul Martin, MD
Fred Hutchinson Cancer Research Center

Andrea Denicoff, MS, RN
National Cancer Institute

Tesheia Johnson, MBA, MHS
Yale Cancer Center
Yale School of Medicine

Kelly Feehan, JD, MS
City of Hope Comprehensive Cancer Center

3:15 PM Break

3:30 PM Concurrent Breakout Sessions

- **A Deeper Dive into Managing Community and Affiliate Trials Sites - Avedon Ballroom A/B** (Wednesday Only)

Kim Keller, RN, MSN, OCN

*UNC Lineberger Comprehensive Cancer Center
University of North Carolina at Chapel Hill*

Jennie Crews, MD, MMM, FACP

Fred Hutchinson Cancer Research Center

- **Enhancing the Relationship Between Medical Directors and CTO Administrative Directors - Avedon Ballroom C**

Jessica Moehle, CCRP

*Huntsman Cancer Institute
University of Utah*

Theresa Werner, MD

*Huntsman Cancer Institute
University of Utah*

- **Operationalizing Complex Clinical Trial Designs - Pollock**

Rhoda Arzooonian, MSM, RN, BSN

*Yale Cancer Center
Yale School of Medicine*

Erin Williams, MBA

*Simmons Comprehensive Cancer Center
UT Southwestern Medical Center*

- **Research Center and Industry Staff Turnover and Its Impact on Quality Data Capture - Warhol**

Collette Houston

Memorial Sloan Kettering Cancer Center

Moshe Kelsen, MBA

*Herbert Irving Comprehensive Cancer Center
Columbia University Medical Center*

4:45 PM General Sessions End

5:30 PM Poster Session - Artist Foyer

6:00 PM Welcome Reception - Artist Foyer

Reception Sponsored by Forte Research Systems®

Thursday, July 13

7:00 AM Breakfast - Avedon Ballroom C/D

7:00 AM Vendor Presentation: Complion Going Paperless: Managing Regulatory & Clinical Trial Documents in Complion - Avedon Ballroom B

7:00 AM Exhibits Open - Artist Foyer

8:00 AM Welcome - Cassatt Ballroom

Janie Hofacker, RN, BSN, MS

Association of American Cancer Institutes

8:15 AM So You Want to Run an Investigator-Initiated Trial? Points to Consider - Cassatt Ballroom

This session will focus on developing investigator initiated trials (IIT) from concept to effective, well-designed trials that collect data to match the study's endpoints.

Panelists will identify IIT challenges such as using multiple electronic data capture systems, bridging financial gaps when pilot or donor funding is limited, navigating complex industry and clinical research organizational structures, and educating principal investigators and clinical teams about trials to ensure trial compliance (e.g., reporting trial results to ClinicalTrials.gov).

Moderator: Elizabeth Anderson, MPH, BSN

Stanford Cancer Institute

Kate Anderton, MPH, CCRP

*Hollings Cancer Center
Medical University of South Carolina*

John Musser

Moffitt Cancer Center

Steve Williamson, MD

The University of Kansas Cancer Center

9:15 AM Concurrent Breakout Sessions

- **The Burden of FDA Inspections - Avedon Ballroom B** (Thursday Only)

Nicholas Farley, MS

*Dana-Farber Cancer Institute
Harvard Medical School*

Therica Miller, MBA, CCRP

*Samuel Oschin Comprehensive Cancer Institute
Cedars-Sinai Medical Center*

Continued on page 8

● **Enhancing the Relationship Between Medical Directors and CTO Administrative Directors - Avedon Ballroom C**

Jessica Moehle, CCRP
Huntsman Cancer Institute
University of Utah

Theresa Werner, MD
Huntsman Cancer Institute
University of Utah

● **Operationalizing Complex Clinical Trial Designs - Pollock**

Rhoda Arzooonian, MSM, RN, BSN
Yale Cancer Center
Yale School of Medicine

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

● **Research Center and Industry Staff Turnover and Its Impact on Quality Data Capture - Warhol**

Collette Houston
Memorial Sloan Kettering Cancer Center

Moshe Kelsen, MBA
Herbert Irving Comprehensive Cancer Center
Columbia University Medical Center

10:30 AM Break

10:45 AM Trials and Tribulations - Cassatt Ballroom

In this session, presenters will report on the progress, or lack thereof, in solving clinical trial operations problems that were presented in abstracts submitted for the 2016 CRI Annual Meeting. Each presentation will be 15 minutes. A Q&A session will follow.

Moderator: Nicholas Fisher, MBA
Siteman Cancer Center

Pamela Degendorfer, MA, CCRP
Princess Margaret Cancer Centre
University Health Network

Moshe Kelsen, MBA
Herbert Irving Comprehensive Cancer Center
Columbia University Medical Center

Krystal Merdinger
Fox Chase Cancer Center
Temple Health

11:45 AM Lunch - Avedon Ballroom C/D

12:45 PM Breakout Sessions Report Back - Cassatt Ballroom

1:30 PM Evaluating and Streamlining Non-Value-Added Activities in Your CTO - Cassatt Ballroom

Panelists will discuss challenges associated with conducting pharmaceutical-industry-sponsored research where policies to address regulatory burdens create non-value-added work for cancer center trial sites. Examples of non-value-added activities include: use of sponsor portals; reviewing third-party serious adverse-event reports that do not meet FDA guidance for reporting; and, managing multiple site and remote monitoring visits. Panelists will share advice on how to streamline clinical research operations to eliminate non-value-added steps.

Moderator: Tess Cummings, RN, MS
University of Maryland Marlene and Stewart
Greenebaum Comprehensive Cancer Center

Hobs Apell
The University of Kansas Cancer Center

Young Kwang Chae, MD, MPH, MBA
The Robert H. Lurie Comprehensive Cancer Center
of Northwestern University

2:15 PM Practices to Promote Sustainable Staffing and Retention Models - Cassatt Ballroom

Clinical trial leaders face continual staffing challenges. Panelists will share information—collected via surveys or pilot studies and workload metrics data—about the effectiveness of various staffing models (e.g., nurse vs non-nurse) and the challenges of retaining staff, promoting employee satisfaction, ensuring balanced workloads, and addressing industry and institutional competition for high-performing staff.

Moderator/Presenter: Kristie Moffett, MHA
Moffitt Cancer Center

Pam Herena, MSN, RN, OCN
City of Hope Comprehensive Cancer Center

Carrie Lee, MD, MPH
UNC Lineberger Comprehensive Cancer Center
University of North Carolina at Chapel Hill

3:00 PM Closing Remarks - Cassatt Ballroom

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

3:15 PM Adjourn

Program Subject to Change

FIRST PLACE: Ensuring PEAK Training and Compliance in Cancer Clinical Trials

Richa Upadhyay, MD; Lediona Ardolli, MA; Rosemarie Gagliardi, c.EdD, MPH, CCRA; Donna Berizzi, RN, MSN, OCN; Matthew Galsky, MD; Ajai Chari, MD
The Tisch Cancer Institute at the Mount Sinai Health System

SECOND PLACE: Improving Reproducibility of Quantitative Imaging Endpoints

Daniel C. Sullivan, MD; Michael Boss, PhD; Thomas L. Chenevert, PhD; Edward F. Jackson, PhD; Alexander Guimaraes, MD, PhD
Duke Cancer Institute, Duke University Medical Center; University of Michigan Comprehensive Cancer Center; University of Wisconsin School of Medicine & Public Health and Carbone Cancer Center; Knight Cancer Institute, Oregon Health & Sciences University; National Institute of Standards and Technology

THIRD PLACE: Implementing a Research Nurse Model for the Clinical Trials Office (CTO)

Helen Peck, RN, MA, OCN, CCRP; Joanne Mancini, RN, CCRP; Cathy Galasso, RN, OCN, CCRP
Sylvester Comprehensive Cancer Center, University of Miami Health System; Barbara Ann Karmanos Cancer Institute

Data Reporting: A Simple Tool for Analysis and Forecasting Success

Andrea Skafel, MSc, CCRP; Wade Berry, CCRP; Mallory Kock, CCRP; Thomas Cunningham, PhD, CCRP
*Helen Diller Family Comprehensive Cancer Center
University of California San Francisco*

Adapting to Thrive: Risk-Based Monitoring of Academic Institutional Investigator-Initiated Clinical Trials

Daniel Otapp, CCRP; Fran Brogan, MSN, RN; Moshe Kelsen, MBA; Lauren Blumberg; Jennifer Wang, MS; Tiffany Negri, CCRP; Shannon Kelly; Tasha Isles Smith, MA, MPH; Stephen Emerson, MD, PhD; Andrew Lassman, MD, MS; Joseph Jurcic, MD
*Herbert Irving Comprehensive Cancer Center
Columbia University Medical Center*

“If You Build It, They Will Come”: Creation of a Dedicated Oncology Clinical Research Infusion Center

Frances Brogan, MSN, RN; Fawzia Ibrahim; Ryan Shelton; Caryn O’Mullane, RN, MSN, MBA; Moshe Kelsen, MBA; Andrew B. Lassman, MD, MS; Stephen Emerson, MD, PhD; Gary Schwartz, MD; Richard Carvajal, MD
*Herbert Irving Comprehensive Cancer Center
Columbia University Medical Center*

Development of a Streamlined Process to Collect Fresh Biopsy Specimens to Send Out for Clinical Trial Screening

Joni Harris, MS, CCRP
*Hollings Cancer Center
Medical University of South Carolina*

Converting to Electronic Regulatory Binders, and the Great Scan

Curt Hampton, MBA, MS; Jessica Moehle, CCRP; Lindsey Byrd, CCRP
*Huntsman Cancer Institute
University of Utah*

Integrating a Clinical Research Nurse Program at an Academic Cancer Hospital

Kristin Maloney, RN, BSN, OCN
*Huntsman Cancer Institute
University of Utah*

Promoting Comprehensive Site Policies and Limiting Industry Overreach

Lindsey Byrd, CCRP; Jessica Moehle, CCRP
*Huntsman Cancer Institute
University of Utah*

Using the Epic EMR for Research Documentation

Rachel Kingsford, MS, CCRP; Jessica Moehle, BS, CCRP; Leanne Lujan, BS, CCRP; Lindsay Carpenter, MSW, CCRC; Sally Fairbairn, BS, CCRP; Susan Sharry, BS, CCRP; Karthik Sonty, BS, CCRP; Theresa L. Werner, MD
*Huntsman Cancer Institute
University of Utah*

Improving Study Activation Timelines: Establishing Flow

Erica Love, MA, MPH, CCRP; Paul K. Davis, KMP; Nida Cassim, MPH
Laura and Isaac Perlmutter Cancer Center at NYU Langone; Essex Management

Development of a Complexity Assessment for Clinical Trials

Alexa Richie, DHSc; Jennifer Lineburg; Andrea Tavlarides, PhD; Dale Gamble, MHSc; Susan Rogers; Carol Griffin
Mayo Clinic Cancer Center

Improving Research Lab Sample Tracking and Cost Recovery by Implementing a Web-Based System

Wes Rood; Megan Koceja, BS; Brenda Brito; Betty Oleson, BSN, RN, CCRP; Rebecca Selle, BS, CCRP; James Thomas, MD, PhD
Medical College of Wisconsin Cancer Center

Not All Tumors Are Created Equal: Evaluating the Impact of an Interdisciplinary Molecular Tumor Board

Allison Martin, PharmD; Ben George, MD; Elizabeth Weil, PharmD, BCOP; Angela Urmanski, PharmD, BCOP; Katrina Schroeder, RN, OCN, CCRP; Kayla Mendenhall, CPhT; Mindy Waggoner, PharmD, BCOP; Carolyn Oxencis, PharmD, BCPS, BCOP
Medical College of Wisconsin Cancer Center

They Talked the Talk...But Can They Walk the Walk? Implementing a Written Test During Candidate Interviews for Clinical Research Coordinators and Assistants

Rebecca Selle, BS, CCRP; James Thomas, MD, PhD; Betty Oleson, BSN, RN, CCRP
Medical College of Wisconsin Cancer Center

Best Practices to Achieve a Successful FDA Inspection

Susan Puleio, CCRP; Veronica Tomaselli
Memorial Sloan Kettering Cancer Center

The Research Council: Developing and Implementing Institutional Policy for Clinical Research Portfolio Management

Sara Hanley, MSW; Xhenete Lekperic; David Spriggs, MD; Ann Rodavitch, MA
Memorial Sloan Kettering Cancer Center

Coordinators Asked, We Answered: The New Clinic Coordinator Education and Training Program

Emily Hawkins, CCRP; Elizabeth Menne, RN; Maria Westfall, CCRP
Siteman Cancer Center

Improving Protocol Activation Times via Automation and Centralization

Helen Peck, RN, MA, OCN, CCRP; Andrew Nilson, BHA; Simmy Thompson, MPH, CIP, CCRP; Rizalia Rivera Cvijovic; Michael A. Samuels, MD; Jonathan Trent, MD, PhD

Sylvester Comprehensive Cancer Center,
University of Miami Health System

Resource Allocation Review: Two-Year Analysis of Protocols Open to Enrollment at Least One Year

Rosemarie Gagliardi, c.EdD, MPH, CCRA; Ariel Hosey; Lediona Ardolli; Catherine Raimond; Richa Upadhyay, MD; Paula Klein, MD; Ajai Chari, MD; Matthew Galsky, MD

The Tisch Cancer Institute at the Mount Sinai Health System

Objective Data-Tracking Tool

Stefanie Belanger, BA, CCRP; Stephanie Ladd, BS, CCRP; Matthew Jansen, BA, MS

UNC Lineberger Comprehensive Cancer Center
University of North Carolina at Chapel Hill

Modeling AACI to Create a Problem-Solving Culture Within the University of Chicago Comprehensive Cancer Center

Lauren Wall, MS; Amanda Spratt, BS

The University of Chicago Medicine Comprehensive Cancer Center

Survey of Protocol Review and Monitoring Systems in U.S. Cancer Centers

Deborah H. McCollister, RN, BSN; Carrye Cost, MD; Ian Riley; Stephen Leong, MD

University of Colorado Cancer Center

First Impressions: Centralizing the CDA Process

Christine Mackay, RN, BSN, MSA, CCRP; Morgan Smotherman; Kathy Schleeter; Donna Palatas, JD; Claire Sabin Koenig, JD; Tiffany Pothapragada, PhD; Peter Griffith, JD

The University of Kansas Cancer Center

Learn-Inform-Recruit: Increasing the Offer of Urologic Cancer Trials in Community Practice

Christine Mackay, RN, BSN, MSA, CCRP; Andrew Zganjar, MD; Laurie Petty, PhD; Muger Geana, MD, PhD; Jessie Gills, MD; Tomas L. Griebing, MPH, MD; Brantley Thrasher, MD; Shellie Ellis, MA, PhD

The University of Kansas Cancer Center

Assessing Patients for Clinical Trials: An Evaluation of Radiation Oncologists at an NCI-Designated Cancer Center

Mindi TenNapel, MBA, PhD; Christine Mackay, RN, BSN, MSA, CCRP

The University of Kansas Cancer Center

Minimizing Information Redundancy Across the Institution and Improving Quality with Centralized Regulatory Document Management

Andrew Nilson; Rosa Hsieh; Cristina Ferrazzano Yaussy, MPH, CCRP; Tom Battle

Sylvester Comprehensive Cancer Center,
University of Miami Health System; Complion, Inc.

Clinical Research Office Monthly Lecture Series

Cindy Wynne-Jones, RN, CCRC; Erin Williams, MBA

Simmons Comprehensive Cancer Center
UT Southwestern Medical Center

Streamlining Research Billing with Informatics Tools and Consensus Building

Umit Topaloglu, PhD; Terra Colvin, MS; Megan Brown; Jennifer Black; Jennifer Newsome; Stacey Lewis; Kim Sweat; Jennette Cossey; Selvin Ohene; Brooke Everhart; Robin Harrelson; Meredith Hiatt; Teresa Sells; Brian Strittmatter; Garland Kitts; Lynn Kennedy; Boris Pasche, MD, PhD; Stefan Grant, MD, JD, MBA

Wake Forest Baptist Comprehensive Cancer Center

Document Management Beyond Regulatory: Breaking Down Silos and Cultivating Effective Collaboration

Amy MK Rovitelli, MS, CHRC; Tina Marie Bowdish, MS, CRCP, CHRC; Tom Battle; Cristina Ferrazzano Yaussy, MPH, CCRP

Wilmot Cancer Institute, University of Rochester Medical Center; Complion, Inc.

Mastering the Delegation-of-Authority Log: A Centralized Approach to Maintaining Site Regulatory Documents

Stephanie Speaker, CCRP; Brittany Walker, CCRP

Yale Cancer Center
Yale School of Medicine

Realizing Rapid Review: Expanding the Use of a Clinical Trials Management System to Streamline the Protocol Review and Monitoring System

LaToya Howard, CCRP; Stephanie Speaker, CCRP; Alyssa Gateman, MPH, CCRP

Yale Cancer Center
Yale School of Medicine

AACI CRI Supporters

AACI gratefully acknowledges support from the following:

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Exhibitors



AACI Corporate Roundtable Members

AACI is grateful for the support of the 2017 Corporate Roundtable Members:



ASCO Research Community Forum

The ASCO Research Community Forum serves as a go-to resource for the cancer 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 effective strategies for conducting research, and 2) develop and disseminate solution-oriented resources and tools that address challenges and facilitate clinical trial participation and accrual. The Forum is led by a Council that includes physician investigators and research administrators from a range of settings, primarily community-based research programs and academic research networks with affiliated community-based research sites.

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BRANY is the premiere resource for research support services for hospitals, academic medical centers and investigators. BRANY's services, which are designed to improve research efficiency and quality, encompass an array of services including IRB administration, accelerated study start-up, budgets, contracts, research billing and collections, IBC administration, and research compliance. Through its consulting division, the HRP Consulting Group, BRANY provides institutions human subject protection and research compliance consulting services. CITI Program, also a division of BRANY, is the leading provider of research education content. BRANY is also the developer of Protocol Builder®, an award-winning protocol writing tool for investigator-initiated research. Protocol Builder® is used by academic research institutions, medical libraries and residency programs.

Complion

Complion is a document management and workflow engine that enables cancer centers to manage all regulatory and trial documents across their office. Built by clinical researchers for clinical researchers, Complion removes walls between physicians, administrators and staff by intelligently providing secure access to the right document when they need it. Leading sites, hospitals, academic medical centers, health systems and cancer centers around the country use Complion's Part 11 platform to go paperless, improve compliance, and streamline operations.

Florence eBinders

With capabilities spanning eRegulatory, eSource, remote monitoring, eSignatures and study dashboards, eBinders helps AACI sites take on more studies with greater compliance. More centers are migrating their teams' regulatory and source processes to Florence eBinders because it's the easiest system to use. Built by a team from Microsoft, Emory Healthcare, and Medtronic, eBinders delivers compliance and software quality at scale: eBinders processes over 10,000 new trial documents a month. What's new this year? Come talk to us about eDOA and NCI dashboards, or try it yourself—get going on an investigator-initiated study for free.

Forte Research Systems, Inc.

Forte Research Systems, Inc. has been developing specialized solutions for clinical research since 2000. Forte solutions include OnCore Enterprise Research, Allegro CTMS, Forte EDC, Forte Research Evaluation System, and Forte eRegulatory Management System. Forte's subsidiary, Nimblify Inc., solves chronic problems by connecting key stakeholders, such as sponsors, CROs, and research sites. Nimblify solutions include Sponsor Ratings, Participant Payments, Clinical Operations Analytics Site Benchmarks and Research Insights, and the Nimblify Marketplace, which offers business operations solutions to help relieve administrative tasks so they expedite study activation, and focus on the research and patients. Nimblify Marketplace services include Protocol Calendars and eCRF Builds. Forte & Nimblify provide complimentary blog articles, eBooks, webinars and more to support continuous learning on industry topics. With a strong belief in community, collaboration and standards-based development, Forte also facilitates the Onsemble Community and the Allegro Community which brings clinical research professionals together twice a year at the Onsemble Conference.

Huron

Our team is composed of experienced cancer center leaders from established and aspiring cancer centers. They rely on their front-line experience and first-hand knowledge of best practices to help improve your center's performance across multiple dimensions, tailoring approaches and solutions to your center's goals, issues and organizational environment. We will help your center prepare for initial NCI designation and competitive renewal, streamline research operations, provide strategic support to cancer center leaders, fill HR needs, and create a shared vision and plan for the future.

Medicalogic.io

Medicalogic.io provides a cloud-based mobile application platform that facilitates the identification of patients for, and the enrollment of patients in, clinical trials in medicine. Our company was founded as a unique collaboration between a physician with twenty years' experience, an entrepreneur who has guided two successful technology companies, and a leader in disruptive technology who has extensive experience interfacing complex databases with mobile users. This collaboration has allowed Medicalogic.io to design an intuitive interface that delivers immediate, high-quality clinical trial information to physicians within the flow of their clinics. Our intuitive design has dramatically cut down the time it takes to identify a trial and initiate the process of patient enrollment. This new application ecosystem enables physicians to increase their enrollment of patients in clinical trials, clinical research coordinators to expedite patient onboarding, and study sponsors to receive real-time data on the performance of their clinical trials. For more information, please visit us at www.medicalogic.io.

AACI CRI Exhibitors

Patient Resource Navigator

Patient Resource's innovative, advanced patient education, navigation and reporting system provides hospitals and cancer center teams with the tools to guide and track each patient from the first appointment, throughout cancer treatment and on to survivorship. The Patient Resource Navigator has multiple components, including a survivorship record of care, distress survey modules and robust reporting features to assist centers as they apply for accreditations. Personalized one-to-one patient education guides can be ordered, which provide information specific to the diagnosis, stage and treatment plan as prescribed by a patient's doctor. The system integrates with EMRs upon request. Product video available at: <https://secure.patientresource.com/navigation>.

PFS Clinical

PFS Clinical provides flexible, on-demand solutions to solve the unique challenges inherent to clinical research. We've built a team of experts in clinical areas of research operations based on a thorough understanding of the needs and obstacles of this industry. Our clients include all types of research institutions, supported by a customizable model that allows us to match each institution's needs. PFS Clinical effectively manages the administrative components of our clients' clinical trials by enabling billing compliance, ensuring accurate and consistent documentation, improving turnaround times, and maintaining greater financial visibility. For more information, visit <https://pfsclinical.com>.



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STRATEGIC SOLUTIONS FOR CANCER CENTERS

Huron understands cancer centers.

Our team is comprised of experienced cancer center leaders from established and aspiring cancer centers. We use front-line experience and best practices to improve your center's performance across multiple dimensions, tailoring solutions based on your goals and environment.

We will help:

- Create a shared vision and plan for the future.
- Prepare for initial NCI designation and competitive renewal.
- Enhance clinical research operations.
- Streamline research administration operations.
- Provide strategic advice and support to cancer center leaders.
- Reduce backlogs or fill short-term staffing needs.
- Train new cancer center administrators and clinical research managers.

Learn more about our team by visiting:
Huronconsultinggroup.com/CancerCenters



Build a research center of excellence

Boost your clinical research operations, centralize your data and set your institution up for a successful NCI designation or CCSG renewal.



Stop by our booth or visit forteresearch.com/aaci to see what's new from Forte.



Providing on-demand services tailored for institutions seeking breakthroughs in the initiation and administration of their clinical trials.

Our flexible solutions allow institutions to:

- Enable and ensure billing compliance
- Minimize turnover and training costs
- Maintain consistent documentation
- Improve turnaround times by 50-100%



Get Started: <https://pfsclinical.com> | questions@pfsclinical.com



PREMIERE RESOURCE FOR RESEARCH SUPPORT SERVICES

- ◆ Local, Central, & Single IRB Services
- ◆ IBC Administration
- ◆ Investigator Initiated Study Monitoring
- ◆ Research Compliance Auditing
- ◆ Study Procurements
- ◆ Accelerated Study Start-Up
- ◆ Clinical Trial Agreement Negotiations
- ◆ Research Education
- ◆ Budget Development
- ◆ Medicare Coverage Analysis
- ◆ Protocol Writing Technology
- ◆ Clinical Trial Billing and Collections
- ◆ Human Subjects Protection Program Consulting

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