AACI

Association of
American Cancer Institutes

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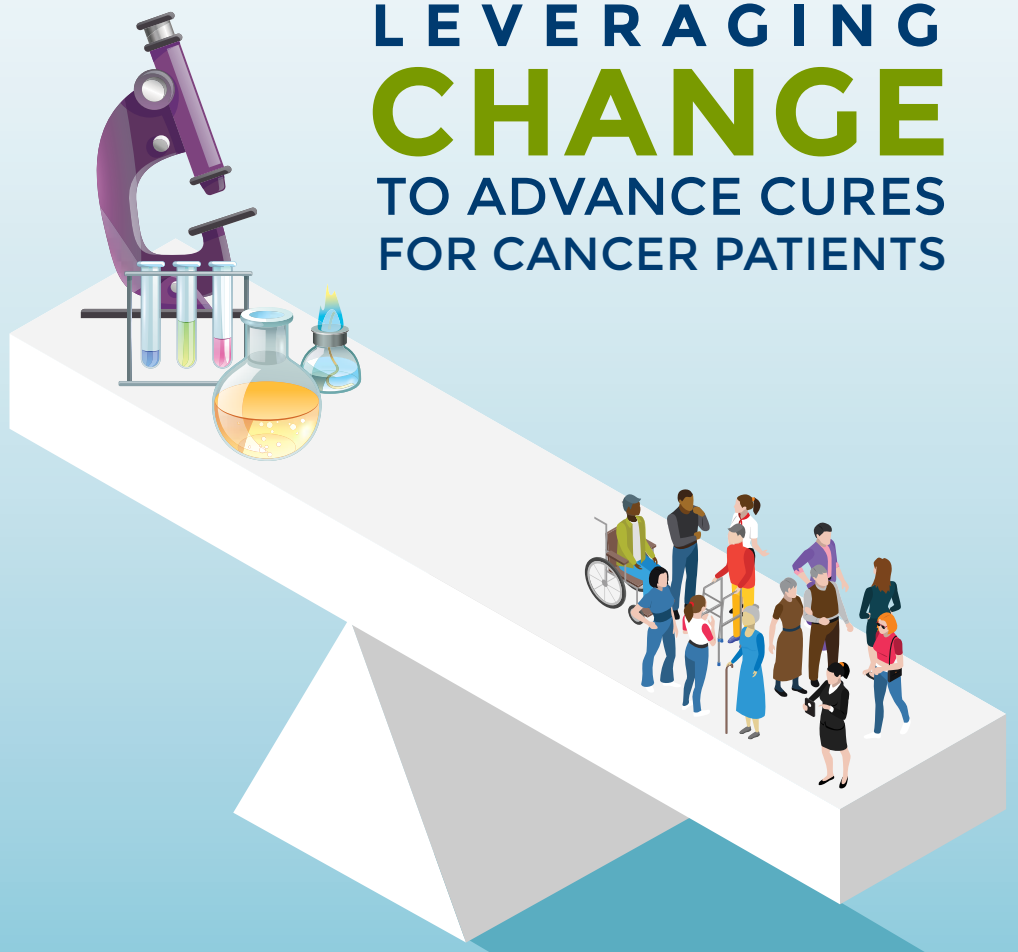
www.aaci-cancer.org

AACI CRI

Clinical Research Initiative

10TH ANNUAL MEETING

LEVERAGING CHANGE TO ADVANCE CURES FOR CANCER PATIENTS



JULY 11–12, 2018

LOEWS CHICAGO O'HARE HOTEL

AACI CRI 2018 Steering Committee

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

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

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

Stefan C. Grant, MD, JD
Wake Forest Baptist Comprehensive 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

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

Barbara Duffy Stewart, MPH
Association of American Cancer Institutes

Stephen Williamson, MD
The University of Kansas Cancer Center

Alex Zafirovski, MBA, RTT, ARRT
The Robert H. Lurie Comprehensive Cancer Center of Northwestern University

CRI Strategic Plan Goals

1. Increase AACI cancer center participation in CRI.
2. Share cancer center clinical trial best practices through the collection and dissemination of benchmarking data.
3. Integrate CRI into AACI programs/initiatives.
4. Assist the centers in increasing patient engagement and enrollment into clinical trials.
5. Develop outcomes to drive change and advance cancer center clinical research programs.
6. Develop a training curriculum for new PIs and new CTO administrative directors.
7. Provide financial support for CRI.

Wireless Internet and Presentation Information

Wireless Network: AACI CRI Wi-Fi **Password: 2018cri**

To access CRI annual meeting documents please visit
http://portal.aaci-cancer.org
Username: cri@aaci-cancer.org **Password: 2018cri**

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AACI CRI Welcome

Adapting to changing landscapes is a daily task for cancer clinical trials programs.

Stimulating the timely staging of clinical trials for optimal patient benefit requires the development of standard trial management guidelines and robust methods of evaluation. To improve clinical trials management at cancer centers, AACI's Clinical Research Initiative (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 more effective 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 goals of stimulating cancer center interactions to maximize the use of resources. CRI participants fill a variety of leadership roles and possess a comprehensive understanding of their center's entire clinical trials system.

AACI CRI Meeting Objectives

1. Address potential changes in eligibility criteria to close the gap on missed opportunities to enroll patients on clinical trials.
2. Discuss how clinical trials offices can prepare for natural disasters.
3. Describe the impact of revisions to the NCI Cancer Center Support Grant guidelines, including how they affect preparations for NCI site visits.
4. Create opportunities for peer-to-peer networking, collaboration, and ongoing communications between clinical trials office administrative and medical directors.
5. Identify lessons learned in writing and running investigator initiated trials.
6. Highlight RECIST (Response Evaluation Criteria In Solid Tumors) challenges and various implementation methods.
7. Determine how clinical research can influence clinical care.
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?

- Clinical Trials Office (CTO) Administrative Directors
- CTO Medical Directors
- Senior Cancer Center Leaders with Oversight of the Cancer Center CTO
- Deputy/Associate Directors of Clinical Research Administration
- Cancer Center Administrative Directors
- CTO Managers and Supervisors
- Administrators of the Cancer Centers Clinical Trial Management Systems
- Regulatory Agency Employees
- AACI Sustaining Members
- AACI Corporate Roundtable Members
- Representatives from Industry (e.g., drug development companies, IT technology software vendors, consultants, etc.)

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MEETING PROGRAM

10th Annual AACI Clinical Research Initiative Meeting

Wednesday, July 11 – Thursday, July 12 — Loews Chicago O'Hare Hotel

Wednesday, July 11, 2018

7:00 AM **Meeting Registration Begins** - ***Artist Foyer***

7:00 AM **Exhibits Open** - ***Artist Foyer***

7:00 AM **Breakfast** - ***Avedon Ballroom C/D***

8:00 AM **Welcome and Opening Remarks** - ***Cassatt Ballroom***

Stanton L. Gerson, MD
Case Comprehensive Cancer Center

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

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

8:30 AM **Guiding Principles of Change** - ***Cassatt Ballroom***

By most accounts, the health care industry is facing a turbulent transformation, impacted not only by the policy changes directed at the industry, but also the digital transformation that is affecting organizations across industries. The ability to successfully navigate constant change—and to help others do the same—is now a core competency for employees at all levels of organizations. What can managers do to help people weather the storm of constant change? In this address, Dr. Scott will share guiding principles of change, based on insights from research and cutting-edge practice in facilitating organizational change. Dr. Scott has more than 10 years of management and consulting experience in a variety of mid-sized, Fortune 500 companies, along with academic experience in program design and innovation. Dr. Scott has designed and taught courses on learning and performance improvement, leadership development, and change management.

Kimberly S. Scott, PhD
Northwestern University

9:30 AM **Break**

9:45 AM **Linking Value for Patients, Health Systems, and Academic Cancer Centers Across Network Practice Sites - *Cassatt Ballroom***

AACI President, Stanton L. Gerson, MD, will present an overview of the AACI Network Care Initiative. The Network Care Initiative aims to build a roadmap for providing high quality cancer care to patients in the community setting. With acquisitions, mergers, and affiliation agreements between academic cancer centers and network practice sites growing more common, the Network Care Initiative is identifying AACI cancer centers that have developed ways to provide value-added care beyond the main cancer center to patients in community settings. Dr. Gerson will share information from a comprehensive survey conducted by AACI exploring practices used to promote value-added care and clinical trials to patients.

Also in this session, panelists will discuss how they create and manage cancer clinical trials at network practice sites, select trials to open at network practice sites, support trial conduct, manage investigational drugs, discuss principal investigator oversight of trials, and address quality management to ensure trial compliance and data collection practices.

Moderator/Presenter: Stanton L. Gerson, MD
Case Comprehensive Cancer Center

Robert Ferris, MD, PhD
UPMC Hillman Cancer Center

Patricia LoRusso, DO
Yale Cancer Center
Yale School of Medicine

Jane Welter, MBA
Mayo Clinic Cancer Center

10:45 AM **Integrating Clinical Research into Clinical Care: Grasping the Low Hanging Fruit - *Cassatt Ballroom***

Cancer clinical trials are vital to providing cancer patients with promising treatments. Integrating clinical research with clinical care in today's fast-paced clinics is challenging for physicians, advance practice providers, and the clinical care teams striving for efficiency in care delivery. Recognizing that every clinic is unique, this session will suggest best practices that can ease the burden of conducting cancer clinical research studies. Session panelists will discuss trial recruitment procedures, completing trial management tasks during patient visits, documenting trials care in the electronic medical record, and managing safety while providing timely appointments and patient care.

Moderator/Presenter: Martha Mims, MD, PhD
Dan L Duncan Comprehensive Cancer Center
Baylor College of Medicine

David Marshall, MD
Hollings Cancer Center
Medical University of South Carolina

Mark Pegram, MD
Stanford Cancer Institute

11:45 AM **Lunch - *Avedon Ballroom C/D***

12:45 PM **2018 CRI Abstract Presentations - *Cassatt Ballroom***

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

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

FIRST PLACE: Building a Strong Foundation: How Leveraging Cross Collaboration Can Improve Standardization and Adoption of an eRegulatory Solution

Trisha Wise-Draper, MD, PhD[1]; Justin Osborne[1]; Benjamin Quast, MBA, CCRP[1] (presenter); Emily Werff[1]; Michael Hurley, MBA[2]
[1]University of Cincinnati Cancer Institute; [2]Complion

SECOND PLACE: It Takes a Village - Onboarding Clinical Trials Staff at an NCI-Designated Comprehensive Cancer Center

Ginnette Watkins-Keller, MSN, RN, OCN (presenter); Tracie K. Saunders, MS, RN, CCRC, OCN; Reneé Kurz, DNP, MSN, FNP-BC
Rutgers Cancer Institute of New Jersey

THIRD PLACE: Framework for Strategic Performance Management in an Academic Cancer Center's Research Administration Finance Office

Lauren Gjolaj, MBA, BSN, RN (presenter); Avantika Dang, MHA, CSSGB, PMP; Yunie Castillo, MPH; Jorge Contreras, MBA
Sylvester Comprehensive Cancer Center
University of Miami Health System

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1:45 PM Overcoming RECISTance to Providing Solid Tumor Evaluations for Cancer Clinical Trials - *Cassatt Ballroom*

In oncology clinical research, Response Evaluation Criteria in Solid Tumors (RECIST) is the standard for providing objective, accurate and reproducible tumor evaluations to measure a patient's response to cancer treatment. Since RECIST criteria are not applied to tumor evaluations outside of a clinical trial, their use can be burdensome for investigators and radiologists. Panelists will describe how cancer centers implement various methods to obtain tumor evaluations for research trials (e.g., imaging software to evaluate radiology digital content, centralized radiology reviewers for providing research patient radiology assessments, integrating a dedicated radiologist into the cancer program). Costs and reimbursement structures and the pros and cons of each method will be discussed.

Moderator: Stefan Grant, MD, JD
Wake Forest Baptist Comprehensive Cancer Center

Gina Basinsky
Dana-Farber Cancer Institute
Harvard Medical School

Reginald Munden, MD, DMD, MBA
Wake Forest Baptist Comprehensive Cancer Center

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

2:30 PM Break

2:45 PM "Note to Self": Ten Lessons for Writing and Running a Trial - *Cassatt Ballroom*

This session will examine lessons learned by an experienced investigator for developing and managing an investigator initiated trial (IIT) requiring Investigator New Drug Application (IND). Topics for discussion will include: writing a good protocol; preparing a trial budget; obtaining regulatory review approvals (e.g., feasibility, scientific, and IRB approval); and finding enough time for competing clinical responsibilities and safety monitoring for enrolled patients. Also highlighted will be best practices for developing and maintaining an FDA required IND, the pros and cons of electronic FDA submissions, and the process for reporting safety data and FDA annual progress reports.

Moderator/Presenter: Stephen Williamson, MD
The University of Kansas Cancer Center

Kaitlin Morrison, PhD
UNC Lineberger Comprehensive Cancer Center
University of North Carolina at Chapel Hill

3:30 PM Concurrent Breakout Sessions

- **Lessons Learned from Working with NCI's NCTN Program**
  Avedon Ballroom C
  The NCI's National Clinical Trials Network (NCTN) includes five US network groups and the Canadian Collaborating Clinical Trials Network. Membership in individual NCTN groups is based on criteria specific to each group, with AACI cancer centers able to participate as either a Lead Academic Participating Site or through the NCI Community Oncology Research Program. In this session, breakout leaders will facilitate discussion about lessons learned in working with NCI's NCTN.

  Jessica Moehle, CCRP
  Huntsman Cancer Institute
  University of Utah

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

  Discussant: Andrea Denicoff, MS, RN
  National Cancer Institute

- **Is Your Clinical Trials Office Prepared for a Disaster?**
  Avedon Ballroom D
  Breakout leaders will discuss how their cancer center was affected by recent disasters such as hurricanes Harvey, Irma, and Maria, and the measures that they implemented before, during, and after the disaster. This session will focus on encouraging participants to create disaster readiness plans to address issues which can halt cancer center clinical trials office operations.

  Kristie Moffett, MHA
  Moffitt Cancer Center

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

- **Operationalizing Clinical Trials at Satellite Locations**
  Warhol
  The breakout leaders will discuss the challenges of opening and managing clinical trials at satellite locations. In addition, they will discuss different staffing structures, trial feasibility, and how to gather information from satellite sites.

  Adrine Chung, MBA
  City of Hope Comprehensive Cancer Center

  Ashley Baker Lee, CCRP
  City of Hope Comprehensive Cancer Center

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- **Anticipating Financial and Therapeutic Toxicities for Patients in Complex Clinical Trials**
  Pollock
  This breakout session will address how cancer centers might effectively address financial burdens for patients enrolled in particularly expensive clinical trials. It will also discuss ways to prepare for both known and unanticipated toxicities when administering novel investigational therapies that require prolonged, direct observation of the patient and that cannot be administered in an outpatient setting. The session will also examine ways to staff and finance a trial, how to develop a trial budget to account for unexpected costs, unanticipated admission to specialized facilities, proper reporting of acute unexpected toxicities, and communicating with patients and families.

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

  Andrea Eiring, MSM, CCRA, CPHRM
  UNC Lineberger Comprehensive Cancer Center
  University of North Carolina at Chapel Hill

4:45 PM **General Sessions End**

5:00 PM **Vendor Presentation: Complion** - ***Avedon Ballroom B***
Automating Regulatory Processes to Ignite Quality & Efficiency

6:00 PM **Poster Session** - ***Artist Foyer***

6:30 PM–7:30 PM **Welcome Reception** - ***Artist Foyer*** ***Sponsored by Forte***

Thursday, July 12, 2018

7:00 AM **Meeting Registration** - ***Artist Foyer***

7:00 AM **Exhibits Open** - ***Artist Foyer***

7:00 AM **Breakfast** - ***Avedon Ballroom C/D***

8:00 AM **Welcome** - ***Cassatt Ballroom***

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

Roy A. Jensen, MD
The University of Kansas Cancer Center

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Thursday, July 12, 2018

8:15 AM **Modernizing Trial Eligibility Criteria and Closing the Gap on Missed Opportunities to Enrolling Patients to Cancer Trials** - ***Cassatt Ballroom***

Clinical trial eligibility criteria are to protect the safety of trial participants and define the trial population. However, excessive or overly restrictive eligibility criteria can slow trial accrual, jeopardize the generalizability of results, and limit understanding of the intervention's benefit-risk profile. ASCO, Friends of Cancer Research, the US Food and Drug Administration, and the NCI have examined specific eligibility criteria, (e.g. brain metastases, minimum age, HIV infection, organ dysfunction, and prior and concurrent malignancies) and made recommendations for alternate criteria to extend trials to a broader population. In this session, our panelists will discuss how recommendations based on review of clinical evidence, consideration of the patient population, and consultation with the research community were developed. The purpose of the session is to highlight these recommendations, discuss the impact on the NCI NCTN and other types of trials, address how investigators can modify current and future trials to safely enroll patients who have been previously excluded from oncology clinical trials, and operationalize the effort at your cancer center.

Moderator: Roy A. Jensen, MD
The University of Kansas Cancer Center

Edward Kim, MD
Carolinas HealthCare

Donald Harvey, PharmD, FCCP, BCOP
Winship Cancer Institute of Emory University

9:00 AM **Concurrent Breakout Sessions**

- **Lessons Learned from Working with NCI's NCTN Program**
  Avedon Ballroom C
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  Huntsman Cancer Institute
  University of Utah

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

  Discussant: Andrea Denicoff, MS, RN
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Tricia Adrales Bentz, MHA, CCRP
Hollings Cancer Center
Medical University of South Carolina

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City of Hope Comprehensive Cancer Center

Ashley Baker Lee, CCRP
City of Hope Comprehensive Cancer Center

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

Andrea Eiring, MSM, CCRA, CPHRM
UNC Lineberger Comprehensive Cancer Center
University of North Carolina at Chapel Hill

10:15 AM Break

10:30 AM Completing the NCI Cancer Center's Support Grant (CCSG): New Expectations and Implementing the Changes - *Cassatt Ballroom*

The CCSG is transitioning from weighing performance metrics to evaluating science-based work and education. This session will explore how to meet the expectations of these new CCSG parameters and determine their impact on cancer centers, particularly clinical trials operations. The session will examine particulars including: the CCSG changes as they pertain to CTO leadership; what drives higher and lower scores in relation to the clinical research program; CCSG site visits and how to demonstrate cancer center efficiency; generating the NCI CCSG Data Table 4 using the NCI's Clinical Trials Reporting Program; the CTO medical director's role in preparing the clinical research components of the CCSG for a site visit; individual experiences with preparing the CCSG, gauging the impact of disease-oriented teams on trial accrual; and defining cancer center capacity.

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

Chad Ellis, PhD
UPMC Hillman Cancer Center

Megan Kilbane, MBA
Case Comprehensive Cancer Center

Krzysztof Ptak, PhD
National Cancer Institute

Gisele Sarosy, MD
National Cancer Institute

Walter Stadler, MD
The University of Chicago Medicine Comprehensive Cancer Center

12:30 PM Lunch - *Avedon Ballroom C/D*

1:30 PM Innovations in Clinical Research Finance, Training, and Operations - *Cassatt Ballroom*

During this session, abstracts submitted to the 10th Annual AACI CRI Meeting highlighting clinical research finance, use of new technology, and investigator training will be presented. A 15-minute presentation from each author will be followed by a Q&A session.

Moderator: Alex Zafirovski, MBA
The Robert H. Lurie Comprehensive Cancer Center of Northwestern University

Development of a Principal Investigator-Specific Audit Results Dashboard
Nicole Kensinger (presenter)
Siteman Cancer Center

Logistical and Financial Challenges Involved in Opening the National Cancer Institute's Molecular Analysis for Therapy Choice (NCI-MATCH) Trial in Hawai'i's Minority/Underserved NCI Community Oncology Research Program (M/U NCORP)
Kate Bryant-Greenwood, JD, CCRP[1] (presenter); Erin Fukaya, MS[1]; Rebecca Ohta, RN[2]; Jennifer Kimbell, PhD[2]; Jeffrey Berenberg, MD[1]; Paul Morris, MD[2]; Darlena Chadwick, RN, MBA[2]
[1]University of Hawai'i Cancer Center, University of Hawai'i at Manoa; [2]The Queen's Medical Center

Implementing an EPIC Based Standardized Communication Process Specific to Clinical Trials
Jamie Littleton, RN, BSN, CCRC (presenter)
Wilmot Cancer Institute, University of Rochester Medical Center

2:30 PM Inclusion of Diverse Patient Populations in Clinical Trials - *Cassatt Ballroom*

NCI-designated cancer centers play a pivotal role in their communities and are expected to engage residents in research relevant to their catchment areas. Panelists for this session will discuss practices or partnerships with healthcare providers or organizations that support clinical trial participation for populations within their catchment area, particularly minority and underserved populations, including rural residents, the LGBTQ community, the elderly, persons of color, and those of low socioeconomic status.

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

Edith Mitchell, MD, FACP
Sidney Kimmel Cancer Center at Thomas Jefferson University

Mandi Pratt-Chapman, MA
GW Cancer Center

Tina Turner
Patient Advocate

3:30 PM Closing Remarks - *Cassatt Ballroom*

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

3:45 PM Meeting Adjourn

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AACI CRI Meeting 2018 Abstracts

1.* FIRST PLACE: Building a Strong Foundation: How Leveraging Cross Collaboration Can Improve Standardization and Adoption of an eRegulatory Solution
Trisha Wise-Draper, MD, PhD[1]; Justin Osborne[1]; Benjamin Quast, MBA, CCRP[1]; Emily Werff[1]; Michael Hurley, MBA[2]
[1]University of Cincinnati Cancer Institute; [2]Complion

2.* SECOND PLACE: It Takes a Village - Onboarding Clinical Trials Staff at an NCI-Designated Comprehensive Cancer Center
Ginnette Watkins-Keller, MSN, RN, OCN; Tracie K. Saunders, MS, RN, CCRC, OCN; Renee' Kurz, DNP, MSN, FNP-BC
Rutgers Cancer Institute of New Jersey

3.* THIRD PLACE: Framework for Strategic Performance Management in an Academic Cancer Center's Research Administration Finance Office
Lauren Gjolaj, RN, BSN, MBA; Avantika Dang, MHA, CSSGB, PMP; Yunie Castillo, MPH; Jorge Contreras, MBA
Sylvester Comprehensive Cancer Center, University of Miami Health System

Additional Abstracts (alphabetical order by AACI cancer center):

4.* Using a Team-Building Strategy to Coordinate Institutional Biosafety Practices
Sarah Bigelow, CCRP; Cathy Galasso, RN, OCN, CCRP; Kasha Krul, CCRP; Barbara Manica, PharmD; Morris Magnan, PhD, RN
Barbara Ann Karmanos Cancer Institute, Wayne State University

5.* Advancing Clinical Research Nurse Practice in a Vibrant Clinical Trial Office
Pamela S. Herena, MSN, RN, OCN; Glenna Paguio, MSN, RN, CCRP; Bernadette Pulone, BSN, RN, OCN; Brenda Williams, BSN, RN
City of Hope Comprehensive Cancer Center

6.* Precision Imaging Metrics: Changing the Way Clinical Trial Imaging Assessment is Managed
Trinity Urban, MA[1]; Erik Ziegler, PhD[1]; Bhanusupriya Somarouthu, MD[1]; Elizabeth Correa, MA[1]; Gina Basinsky[1]; Danielle Nacamuli[2]; Cheryl A. Sadow, MD[1]; Ryan O'Malley, MD[2]; Carolyn Wang, MD[2]; Annick D. Van den Abbeele, MD[1]; Gordon J. Harris, PhD[1]
[1]Dana-Farber Cancer Institute, Harvard Medical School; [2]Fred Hutchinson Cancer Research Center

7.* Diamond in the Rough: Realizing the Value of a Clinical Research Business Operations Team
Patricia D. Black, MBA
Fox Chase Cancer Center, Temple Health

8.* The Business of Investigator Sponsored Research
Jeanie Magdalena Gatewood
Fox Chase Cancer Center, Temple Health

9.* Building an Investigator-Sponsored Research Unit from Scratch
Michael C. Oldfield, JD, MBA, CCRP
Fox Chase Cancer Center, Temple Health

***Denotes Poster Present at Meeting**

2018 Abstracts

10.* Collating Data Table 4 for the Cancer Center Support Grant (CCSG) from Clinical Trials Reporting Program (CTRP) Data for Interventional Studies
Raymond Skeps, MS; Linda Mendelson; Dana Johnson Robbins; Marlisa Isom, MS; Kristi Stiffler, MPH
Fred Hutchinson Cancer Research Center

11.* Addressing Patient Barriers to Cancer Clinical Trial Enrollment
Joseph M. Unger, PhD[1]; Suanna S. Bruinooge, MPH[2]; Mark E. Fleury, PhD[3]
[1]Fred Hutchinson Cancer Research Center; [2]American Society of Clinical Oncology; [3]American Cancer Society Cancer Action Network

12.* Establishing a Research Nurse Practitioner-Led Clinic for Early Phase Clinical Trials
Edward Bentlyewski, MSN, APN, NP-C, AOCNP®; Eneil de la Peña, MSN, ANP-BC, OCN; Cirah Mira Falkenstern, MSN, RN; Fran Brogan, MSN, RN, OCN, CCRP; Moshe A. Kelsen, MBA; Richard D. Carvajal, MD; Andrew B. Lassman, MD, MS; Gary K. Schwartz, MD
Herbert Irving Comprehensive Cancer Center, Columbia University Medical Center

13.* Integrating Centralized Delegation and Training Documentation
Susie Flores; Kathryn Cooper; Leslie Segall, MPH; Makan Fofana; Katherine Lestrade, MAT; Melissa McAvoy; Suzanne Mistretta; Timothy Johnson; Dan Otap, CCRP; Moshe Kelsen, MBA
Herbert Irving Comprehensive Cancer Center, Columbia University Medical Center

14.* Dedicated Research Nursing Staff Retention and Impact on Clinical Trial Enrollment
Ruby Wu, MSN, RN, AOCNP; Alyssa Macchiaroli, MSN, RN; Frances Brogan, MSN, RN, OCN; Moshe Kelsen, MBA
Herbert Irving Comprehensive Cancer Center, Columbia University Medical Center

15.* Standardizing Selection and Prioritization of Interventional Clinical Trials at Hollings Cancer Center
Kate Anderton, MPH, CCRP; Tricia Bentz, MHA, CCRP
Hollings Cancer Center, Medical University of South Carolina

16.* Implementation of Quality Improvement Processes to Reduce Patient Wait Time for an Investigator Initiated Trial (IIT)
Vistea Crawford, CCRP
Hollings Cancer Center, Medical University of South Carolina

17.* How to Be a Principal Investigator: Developing and Implementing a Practical Training Program
Rachel Kingsford, MS, CCRP; Debbie Pitt, CCRP; Scott Low, MBA, CCRP; Lisa Weaver, CCRP; Jessica Moehle, CCRP; Adam L. Cohen, MD, MS; Theresa L. Werner, MD
Huntsman Cancer Institute, University of Utah

18.* Improving Study Activation Timelines Using a Workflow Management Approach
Erica Love, MA, MPH, CCRP[1]; Paul K. Davis, KMP[2]; Nida Cassim, MPH[1]; Stephen Vettorino[2]
[1]Laura and Isaac Perlmutter Cancer Center at NYU Langone; [2]Essex Management

19.* Trial Activation Alignment Across Three Geographic Early Phase Cancer Center Locations
Katherine Gano, MS; Jill Burton, CCRP; Andrea Kukla; Linda Sanders, MS; Andrea Tavlarides, PhD
Mayo Clinic Cancer Center

20.* Tailored Training to Accelerate Study Assessment and Start-up
Andrea Kukla
Mayo Clinic Cancer Center

21.* Huddle Up! An Interprofessional Effort to Optimize Patient Care
Katy Schroeder, BSN, RN, OCN, CCRP; Judy Ranous, BSN, RN, OCN; Theresa Rudnitzki, MS, RN, AOCNS, ACNS-BC; Rebecca Selle, CCRP
Medical College of Wisconsin Cancer Center

22.* Checking the Eligibility Checklist
Adrian Granobles; Karima Yataghene, MD; Kenasha Johnson; Saray Simo; Collette Houston
Memorial Sloan Kettering Cancer Center

23.* Developing & Implementing Institutional Workflow for Reviewing Scientific Amendments
Xhenete Lekperic; Sara Hanley, MSW; Alexia Iasonos, PhD; Krista Napolitano, MA; Ann Rodavitch, MA; Collette Houston; Michael Ayerov; Roy Cambria; Paul Chapman, MD
Memorial Sloan Kettering Cancer Center

24.* Developing a Protocol Activation Unit
Ann Rodavitch, MA; Collette Houston; Paul Sabbatini, MD; Eric Cottington, PhD; Katherine Rolla; Sara Hanley; Roy Cambria
Memorial Sloan Kettering Cancer Center

25.* MSK Cancer Alliance: Accelerating Cancer Care in the Community Setting
Mary Warren[1]; Ellen Dornelas[2]; Eric Mueller[3]; Deborah Suarez[4]; Peter Yu, MD[2]; Suresh Nair, MD[3]; Miguel Villalona, MD[4]; David Pfister, MD[1]; Paul Sabbatini, MD[1]; Jessica Kennington[1]; Collette Houston[1]
[1]Memorial Sloan Kettering Cancer Center; [2]Hartford HealthCare Cancer; [3]Lehigh Valley Health Network; [4]Miami Cancer Institute at Baptist Health South Florida

26.* Digitizing Cancer Clinical Trial Management: A Single Site Experience with Implementing 21 CFR Part 11 Compliant Digital Signatures in a Regulatory Environment
Therica Miller, MBA, CCRP; Jenny Lester, MPH, CCRP; Brett Ouimette; BJ Rimel, MD
Samuel Oschin Comprehensive Cancer Institute, Cedars-Sinai Medical Center

27. Implementing and Adapting a Protocol Acuity Rating Scale (PARS) for Evaluating Workloads and Employee Effort at an NCI-Designated Cancer Center
Meghan Wakefield, BSN, RN; Nicholas Van Kuren, MS; Daniel Vernau, MS, CCRP; Dawn Poller
Sidney Kimmel Cancer Center at Thomas Jefferson University

28.* Improving SRC Submission Quality and Reducing Time for SRC Approval
Amanda Balaban, MS, CCRP
Siteman Cancer Center

29.* An Audit Tool for the Delegation Log That Will Fix Your FDA Audit Woes
Melissa R. Haley
Siteman Cancer Center

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30. **Improving Timelines When Days Matter: Enhancements to Compassionate Use Submissions**
Melissa R. Haley; Brett Ramsey, MBA, CCRP
Siteman Cancer Center

31.* **A Policy on Policies: Why Policy Management Shouldn't End at Creation**
Emily Harms, MA, CCRP; Elizabeth Menne, RN, OCN; Brett Ramsey, MBA, CCRP
Siteman Cancer Center

32.* **Development of a Principal Investigator-Specific Audit Results Dashboard**
Nicole Kensinger
Siteman Cancer Center

33. **Developing a Multi-Institutional Program for Investigator-Initiated Trials**
Kati Kremer, CCRP; Brett Ramsey, MBA, CCRP; Erin Kelleher
Siteman Cancer Center

34.* **Real-World Research Training for Junior Investigators**
Bethany Rensink, CCRP
Siteman Cancer Center

35. **An Evaluation of Protocol Availability to Increase Minority Participation on Clinical Trials**
Jessica Thein
Siteman Cancer Center

36. **Improving FDA Audit and Monitor Visit Outcomes by Aggregating Knowledge, Experience, and Common Findings**
Sarah Uffman; Brett Ramsey, MBA, CCRP
Siteman Cancer Center

37.* **Using Rapid Cycle Improvement to Design a Scalable Appointment Scheduling System for Complex Oncology Clinical Trials at an Academic Cancer Center**
Avantika Dang, MHA, CSSGB, PMP; Lauren N. Gjolaj, MBA, BSN, RN
Sylvester Comprehensive Cancer Center, University of Miami Health System

38.* **Utilizing Voice of the Customer in Clinical Research to Drive Plan Do Study Act (PDSA) Process Improvement Projects at an Academic Cancer Center**
Avantika Dang, MHA, CSSGB, PMP; Lauren Gjolaj, MBA, BSN, RN
Sylvester Comprehensive Cancer Center, University of Miami Health System

39.* **Opportunities & Challenges in Growing an Early Phase (Phase 1) Research Infrastructure**
Yvonne Dinh, CCRP; Kristen Englund, CCRP; Jaime Merchan, MD, MMSc
Sylvester Comprehensive Cancer Center, University of Miami Health System

40.* **Implementation of a Molecular Tumor Board as a Decision Support Tool Leverages Genomic Testing to Increase Clinical Trial Accrual and Identification of Precision Oncology Therapy**
Bat-ami K. Gordon; Jared A. Cotta, MPH; Sarah Simko; Jonathan C. Trent, MD, PhD
Sylvester Comprehensive Cancer Center, University of Miami Health System

41.* **Reducing Protocol Activation Times Through Centralization of Study Start-up Tasks**
Rosa Hsieh, MS, RAC, CCRP; Andrew Nilson
Sylvester Comprehensive Cancer Center, University of Miami Health System

42. **Regulatory Document Access: Assessing Value Among Study Stakeholders**
Andrew Nilson[1]; Rosa Hsieh, MS, RAC, CCRP[1]; Helen Peck, RN, MA, OCN, CCRP[1]; Michael Hurley, MBA[2]
[1]Sylvester Comprehensive Cancer Center, University of Miami Health System; [2]Complion

43.* **Optimizing the Regulatory Department Infrastructure Within the Clinical Trials Office at an Academic Cancer Center**
Andrew Nilson; Rosa Hsieh, MS, CCRP, RAC
Sylvester Comprehensive Cancer Center, University of Miami Health System

44.* **Addressing the Unpredictable: Disaster Planning for a Large Academic Clinical Trials Office**
Helen Peck, RN, MA, OCN, CCRP
Sylvester Comprehensive Cancer Center, University of Miami Health System

45.* **Implementing a Tracking System for Clinical Research**
Rizalia Rivera-Cvijovic; Geoffrey DeGennaro; Andrew Nilson; Helen Peck, RN, MA, OCN, CCRP
Sylvester Comprehensive Cancer Center, University of Miami Health System

46.* **Implementing a CCSG Dashboard**
Rizalia Rivera-Cvijovic; Rania Saghira, MS; Geoffrey DeGennaro
Sylvester Comprehensive Cancer Center, University of Miami Health System

47.* **Implementing an Electronic Protocol Review System for the PRMC and DSMC**
Simonnette Thompson, MPH, CIP, CCRP; Geoffrey DeGennaro; Matthew Santiago; Rizalia Rivera-Cvijovic; Helen Peck, RN, MA, OCN, CCRP; Jonathan Trent, MD, PhD
Sylvester Comprehensive Cancer Center, University of Miami Health System

48. **Overcoming Regulatory Staffing Challenges**
Melissa Field, CCRP
The University of Kansas Cancer Center

49.* **Investigator Initiated Trial Steering Committee**
Christine Mackay, RN, CCRP; Stephen Williamson, MD; Scott Weir, PharmD, PhD; Andrew Godwin, PhD; Hobs Apell; Carolyn Foster, MSLIS; Kevin Schorno, MBA
The University of Kansas Cancer Center

50.* **LEARN-INFORM-RECRUIT: Increasing the Offer of Urological Cancer Trials**
Christine Mackay, RN, CCRP[1,2]; Ariel Shifter[2]; Mugur Geana, MD, PhD[1,2]; Shellie Ellis, MA, PhD[1,2]
[1]The University of Kansas Cancer Center; [2]University of Kansas Medical Center, Department of Health Policy and Management

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2018 Abstracts

51.* A Curated Cancer Clinical Outcomes Database (C3OD) for Accelerating Patient Recruitment in Cancer Clinical Trials
Dinesh Pal Mudaranthakam, MS[1]; Jeffrey Thompson[1]; Jinxiang Hu[1]; Dong Pei[1]; Shanthan Reddy Chintala[1]; Michele Park[1]; Brooke L. Fridley[2]; Byron Gajewski[1]; Devin C. Koestler[1]; Matthew S. Mayo[1]
[1]The University of Kansas Cancer Center; [2]Department of Biostatistics and Bioinformatics, Moffitt Cancer Center

52.* Accrual Prediction Program (APP): A Web Based Clinical Trials Tool for Monitoring and Predicting Accrual for Early Phase Cancer Studies
Junhao Liu, MS[1]; Jo Wick, PhD[1]; Dinesh Pal Mudaranthakam, MS[1]; Yu Jiang, PhD[2]; Matthew Mayo, PhD[1]; Byron Gajewski, PhD[1]
[1]The University of Kansas Cancer Center; [2]School of Public Health, University of Memphis

53.* Clinical Trials Office Change Management in a Diverse Network Landscape
Kate Bryant-Greenwood, JD, CCRP
University of Hawai'i Cancer Center, University of Hawai'i at Mānoa

54.* Logistical and Financial Challenges Involved in Opening the National Cancer Institute's Molecular Analysis for Therapy Choice (NCI-MATCH) Trial in Hawai'i's Minority/Underserved NCI Community Oncology Research Program (M/U NCORP)
Kate Bryant-Greenwood, JD, CCRP[1]; Erin Fukaya, MS[1]; Rebecca Ohta, RN[2]; Jennifer Kimbell, PhD[2]; Jeffrey Berenberg, MD[1]; Paul Morris, MD[2]; Darlena Chadwick, RN, MBA2
[1]University of Hawai'i Cancer Center, University of Hawai'i at Mānoa; [2]The Queen's Medical Center

55.* Factors That Impact Oncology Clinical Trial Activation Times at University of Illinois Cancer Center
Mary A. Otoo, MPH; Michelle Uriostigue Preza; Margaret Gavor, MPH; Darlene Kitterman, MBA; Oana C. Danciu, MD
University of Illinois Cancer Center

56.* Solving the Problem of Study Abandonment: Effectiveness and Analysis Outcomes of Administrative Pre-Review Committee
Jill Kessler, MS, CCRP; Jennifer Richards, MS, CCRP
University of Maryland Marlene and Stewart Greenebaum Comprehensive Cancer Center

57.* Improving Clinical Trial Activation Using Lean Six Sigma Methodology
Amelia Schmidt, MHA, CCRP; Theresa Cummings, RN, MS, CCRP; Jennifer Richards, MS, CIP, CCRP
University of Maryland Marlene and Stewart Greenebaum Comprehensive Cancer Center

58.* Using Data to Determine a Workload Model for Regulatory Staff
Daniela Bashllari, MHA; Mathew Innes, MBA, CCRP
University of Michigan Rogel Cancer Center

59.* Multi-Site IITs: Managing Stakeholder Requirements and Balancing Industry Expectations with Academic Realities
Kathleen Granlund, CCRP; Ryan Drzewicki, CCRP; Tracy Wojciechowski, CCRP
University of Michigan Rogel Cancer Center

60.* On TRACk at the Rogel Cancer Center: Centralized Trial Imaging Metrics System
Katherine E. Hersberger, PhD[1]; Rocky Fischer, MS[2]; Patricia A. Bebee, RN, MS, CCRP[2]; John F. Harju, MBA, PMP[2]; Ravi K. Kaza, MD[2,3]; Isaac R. Francis, MD[2,3]; Mishal Mendiratta-Lala, MD[2,3]; D'Andra Featherstone, CCRP[2]; Cindy Rekowski[2]; Nancy McCullough, CCRP[2]; Nabeela Iqbal, MBBS, CCRP[2]; Frank J. Manion, PhD[2]; Vaibhav Sahai, MBBS, MS[1,2]
[1]Department of Internal Medicine, University of Michigan Medical School; [2]University of Michigan Rogel Cancer Center; [3]Department of Radiology, University of Michigan Medical School

61.* Improving Start-up Times in Oncology Clinical Trials at an NCI-Designated Comprehensive Cancer Center (NCORP site): An ASCO Quality Improvement Project
Zoneddy Dayao, MD[1]; Leslie Byatt, CCRC[2]; Kaylee Deutsch, MHA, CCRP[2]
[1]University of New Mexico Comprehensive Cancer Center; [2]New Mexico Cancer Care Alliance

62.* Analysis of Barriers to Clinical Trial Accrual in an Academic Center: The Results of Identifying Clinical Trial Gaps
Jacklyn Nemunaitis, MD; Teresa Stewart, MS; Zoneddy Dayao, MD
University of New Mexico Comprehensive Cancer Center

63.* Research and Hospital Integration
Stefanie Belanger, CCRP; Stephanie Ladd, CCRP; Megan Fasold, RN, BSN, PCCN
UNC Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill

64.* Objective Data Tracking Tool, A Year In Review
Stephanie Ladd, CCRP; Stefanie Belanger, CCRP; Matthew Jansen, MS
UNC Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill

65.* Shared Investment to Build a Strong, Streamlined, and Accessible RECIST Foundation for Clinical Research
Alex Arbuckle
University of Wisconsin Carbone Cancer Center

66.* Tracking Biospecimen Collection Deviations to Improve Clinical Trial Outcomes
Jamye O'Neal; Heather Barnes; Kimberly Dahlman, PhD
Vanderbilt-Ingram Cancer Center

67.* Implementing an EPIC Based Standardized Communication Process Specific to Clinical Trials
Jamie Littleton, RN, BSN, CCRC
Wilmot Cancer Institute, University of Rochester Medical Center

68.* Effects of Profession Directed Research Order Generation on Clinical Trial Measures
Carrie Belmore, RN, BSN, OCN; Colleen Lewis, MSN, ANP-BC, AOCNP; Cathy Sharp, RN, MN, OCN, CCRP; Jennifer Schreiber, RN, BSN, OCN; Tina Williams, RN, BSN, OCN; Monica Goodman, RN, BSN, OCN
Winship Cancer Institute of Emory University

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